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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
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Enforcement Committee Report

Robert Swart, PharmD, Chair and Board Member
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The Enforcement Committee met on June 9, 2009, in Sacramento. There was not a Work Group on E-Pedigree Meeting held in conjunction with this meeting. Minutes of this meeting are provided in **Attachment A,** at the back of this tab section.

A. FOR INFORMATION: Presentation by Sharps Compliance, Inc.

Attachment 1

At this Board Meeting, Sharps Compliance, Inc., will provide information to the board about their mail back program for prescription drugs and sharps.

Over the past year, the board has been working with other state and some local agencies to develop model guidelines for the take back of unwanted prescription drugs from patients. In February, the California Integrated Waste Management Board finalized these guidelines. The guidelines were developed pursuant to SB 966 (Simitian, Statutes of 2007), and provide components for three primary types of take back programs: 1. in pharmacies or sometimes other locations, 2. at one-time or ongoing community events, and 3. return via mail back.

The board will publicize these guidelines in its July 2009 newsletter, *The Script*.

According to data collected late in 2008 by the California Integrate Waste Management Board, fewer than 100 California pharmacies report they are participating in take back programs. This is probably lower than the actual number of pharmacies in California operating such programs; however, staff is aware that many pharmacies will not participate in any take back program until the board supports the programs. (There are over 6,100 community pharmacies and over 500 hospital pharmacies in California.)

Staff from the Integrated Waste Management Board has been invited to provide a presentation to the board on the baseline survey of pharmaceutical waste returned in 2008 in California. However, state budget issues may prevent staff from making this trip.

The CIWMB guidelines are provided in **Attachment 1**.
For pharmacies, the following are some of the general parameters:

1. a secure container or bin (like a mailbox) into which patients empty contents prescription containers directly into the bin – without the assistance or intervention of pharmacy staff.
2. a two-lock system on the bin where the pharmacy has one key and the licensed integrated waste hauler who empties the bin has the other. This will provide an audit trail of security.
3. the integrated waste hauler that picks up the commingled pharmaceutical waste pulverizes the waste inside the bin or once it reaches the waste hauler's truck.
4. the pharmaceutical waste picked up is recorded by date and weight by both the pharmacy and the waste hauler. These records are kept for three years by both entities.
5. No controlled drugs or sharps are allowed to be deposited; this is posted on the container. The pharmacy, however, does not check each deposit into the bin.

B. FOR DISCUSSION AND POSSIBLE ACTION: Update on the Status of Drug and Sharps Take Back Programs in California Pharmacies

Attachment 2

This year, SB 26 (Simitian) would have required this board to develop policies and programs for pharmaceutical waste. The board would have been required to develop regulations for such programs. However, SB 26 has been stalled in the Senate Appropriations Committee due to fiscal issues. It is now a two-year bill.

The board needs to discuss how it will proceed in the future with respect to take back programs for pharmaceutical waste and sharps.

The public is demanding the creation and widespread availability of such programs, and pharmacies are one of the primary locations favored for such returns. However, safeguards are needed to protect the drug supply so that drugs are not diverted from take back channels into the primary pharmaceutical supply chain to patients.

There are also proposed amendments that were never make into SB 26 regarding regulation of reverse distributors. Reverse distributors are board-licensed wholesalers who return drugs from pharmacies to manufacturers. They are NOT authorized to handle pharmaceutical waste, which is the purview of integrated waste haulers, who are licensed by the California Department of Public Health. These amendments (**Attachment 2**) were provided to Senator Simitian's Office, but were never incorporated into SB 26.

The Department of Consumer Affairs recommends that the board develop regulations in this area, either duplicating or strengthening the regulatory parameters for drug take back programs.

C. Summary and Discussion of June 9, 2009 Enforcement Committee Meeting

1. **FOR INFORMATION: <u>Overview of the Board of Pharmacy's Complaint Investigation Processes</u>**

Attachment 3

At the June 9 Enforcement Committee Meeting, Executive Officer Herold provided an overview of the board's investigation program.

Discipline and enforcement actions are necessary to ensure public protection. The investigation process typically begins when the board receives a written complaint. Less frequently oral complaints are made to the board, but wherever possible, the board requests complaints in writing.

All complaints are screened for basic jurisdiction (e.g., cost of drugs is not within the board's regulatory jurisdiction). Receipt of all complaints is acknowledged back to the complainant within 10 working days.

Complaints are initially screened by supervising inspectors to evaluate if the scope of the complaint is within the board's jurisdiction. If seemingly within the board's jurisdiction, the complaints are then investigated by one of the board's investigation teams -- the compliance team, the drug diversion and fraud team, and the probation/Pharmacist Recovery Program (PRP) team. A board inspector, who is a pharmacist, evaluates the complaint, inspects the premises, and determines if a violation occurred or if not, recommends that the case be closed. The investigation report and documentation is reviewed by a supervising inspector, and if formal discipline will be pursued, the investigation report must be approved by the executive officer. The most severe and serious violations warrant formal discipline, and these cases are pursued with representation from the Office of the Attorney General in order to restrict or remove the license.

Lesser violations may be closed as infractions, via a citation, citation with fine or letter of admonition. These sanctions are similar to "speeding tickets."

Minor violations are noted in inspection reports as "corrections ordered," Here the goal is to ensure the problem is corrected and compliance in achieved.

Attachment 3 includes a flowchart of the complaint investigation process. **Attachment 9** provides statistics about complaints and investigation closures during 2008-09.

2. **FOR INFORMATION: <u>Discussion of the Board of Pharmacy's Citation and Fine Program Involving Medication Errors</u>**

Attachment 4

During the Enforcement Committee Meeting, Executive Officer Herold provided an overview of the citations and fines issued for medication errors in 2008 through May 2009. **Attachment 4** includes some of the examples provided of prescription error cases investigated by the board.

3. FOR INFORMATION: <u>Presentation and Discussion of the Board of Pharmacy's Pharmacists Recovery Program</u>

Attachment 5

At the June Enforcement Committee, the committee heard a presentation on the Pharmacists Recovery Program by Anne Mierles of Maximus, the program's contracted provider.

California Business and Professions Code section 4360 directs that the board seek ways to identify and rehabilitate pharmacists whose competency may be impaired due to abuse of alcohol and other drugs or due to mental illness, so that these pharmacists may be treated and returned to the practice of pharmacy in a manner that will not endanger the public health and safety. The Pharmacists Recovery Program (PRP) provides intervention and secures treatment for pharmacists and pharmacist interns who are experiencing problem with chemical dependency and/or mental illness.

Rehabilitation plans for chemically dependent pharmacists/interns typically include total abstinence from alcohol or other mood altering chemicals, inpatient or outpatient treatment, documented attendance at support groups and self-help groups such as AA and/or NA. Random body fluid testing and educational courses on chemical dependency also are required. The Pharmacy Review Committee (PRC) evaluates the pharmacists' and interns' progress and determines their ability to practice safely. The program contract will specify the type of pharmacy practice that is acceptable, and any restrictions placed on that practitioner's practice. A pharmacist, who is in a supervisory capacity or at least one management step above the PRP participant, will be identified as a work site monitor. The work site monitor must be aware of the PRP contract and provide regular assessment of the participant's work performance. As a participant continues to gain strength in recovery, the PRC, with approval of the executive officer, will gradually remove the restrictions placed on the pharmacist's practice by reviewing and modifying the treatment contract.

PRP participation is usually a two to five year commitment. The average length of time in the PRP for chemical dependency is three years. Mental Illness, depending on the severity of the diagnosis, may be longer. The mandatory length of participation must be at minimum one year. A transition phase, which may begin after at least 24 consecutive months of recovery and a minimum of 24 negative random body fluid tests, allows the participant the opportunity to be responsible for their own recovery while still in the PRP. A pharmacist/intern who meets all the criteria set by the PRC for completion and who has demonstrated that he or she is a safe recovering pharmacist/intern will be successfully completed from the PRP.

There are just under 80 participants in the board's PRP at the current time.

Attachment 5 contains a copy of a brochure on the PRP.

4. FOR INFORMATION: Discussion of the Actions of the Department of Consumer Affairs Health Care Boards to Develop Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery Programs

Attachment 6

At the June Enforcement Committee Meeting, the committee heard a presentation on SB 1441. Senate Bill1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. This committee is subject to Bagley-Keene Open Meeting Act and is comprised of executive officers and bureau chiefs from specified boards and bureaus. The Board of Pharmacy is one of these participating boards.

Given the timeline to develop these standards, the DCA created a workgroup consisting of staff from each of the healing arts boards. (The process is similar to process the board uses to promulgate a regulation.) The workgroup is responsible for developing recommended standards. The recommended standards will be vetted during a Uniform Standards Workshop, a public meeting akin to an informational hearing. The draft standards will then be presented during a public meeting to the SACC for consideration and action.

A Uniform Standards Meeting was held on May 5, 2009 to discuss standards 1 - 6. Future meetings are scheduled for:

- July 15, 2009
- September 22, 2009
- November 10, 2009

An SACC meeting was held on May 18, 2009 to consider uniform standards 1 – 6. Additional SACC meetings are scheduled for:

- July 27, 2009
- September 30, 2009
- November 16, 2009
- December 15, 2009

Attachment 6 contains a copy of the draft of standards 1-6.

5. **FOR INFORMATION: <u>Presentations and Discussions on E-Prescribing Pilot Programs Underway in California by the California HealthCare Foundation and CalPERS</u>**

During the June Enforcement Committee, the committee heard presentations about various e-prescribing efforts underway in California.

A number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing. A principal reason is that statistics indicate that 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. Other savings have been projected from redirected time currently spent by prescribers and pharmacies in verifying and switching prescription orders.

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. A current deterrent is that controlled substances cannot be e-prescribed.

During the meeting, the committee heard a presentation from the California HealthCare Foundation and CalPERS. Libby Sagara, representing the California Healthcare Foundation (CHCF), provided an overview of the statewide e-prescribing consortium efforts to secure e-prescribing in California. She stated that the CHCF e-prescribing efforts are aimed at advancing the use of e-prescribing to achieve safe and affordable health care for all Californians. Ms. Sagara indicated that the program has several objectives including a statewide e-prescribing plan through regional experience to increase provider adoption, increase payer provision of electronic eligibility, formulary and medication history, increase pharmacy connectivity, and raiser consumer and purchaser confidence and demand.

Ms. Sagara provided an overview of e-prescribing transactions, fees, and cost flow. She presented an incentive opportunity and implementation timeline for the program. Details of this presentation are provided in the meeting summary at the back of this tab section. California is not one of the highest users/adopters of e-prescribing at this time (Massachusetts is, routing 20 percent of all prescriptions this way), while California only routes 3.28 percent. However, 74 percent of California pharmacies had the connectivity needed to accept e-prescribing in 2008 (up from 72 percent in 2007).

The committee also heard from Patrick Robinson who provided an overview of the CalPERS e-prescribing pilot program. He reviewed the benefits of e-prescribing to physicians, patients, and pharmacies including safety, convenience, and efficiency. Mr. Robinson indicated that the pilot is a partnership with Anthem Blue Cross, Blue Shield of California, and Medco, and will run through 2010. He shared that the goals of the program are to determine and test a set of e-prescribing adoption strategies and best practices through collaboration with a selected set of participating physician

groups and to accelerate the adoption and use of e-prescribing in an effort to enhance patient safety and quality of care resulting from the replacement of paper prescriptions.

6. FOR INFORMATION: Discussion Regarding AB 718 (Emmerson), E-Prescribing Pilot Project

The Enforcement Committee also heard a presentation on AB 718. This year, Assemblymember Emmerson has introduced Assembly Bill 718, which would establish a pilot project in the Inland Empire until January 1, 2013 to demonstrate the value and benefits of e-prescribing. This project would be called the Inland Empire Health Plan E-Prescribing Pilot Program.

The board took no position on this bill during its April Meeting being aware that future amendments were coming. On May 27, the bill was substantially amended to specify the components of the pilot program. The board's Legislation and Regulation Committee will be discussing the bill in its current form and will provide the board and may provide the board with a recommended position.

A copy of the bill is provided under the Legislation portion of this packet.

7. FOR INFORMATION AND POSSIBLE ACTION: Demonstration of Technology Proposed for Future Pharmacy Use in California

Attachment 7

During the committee meeting, Jiwon Kim, PharmD., representing the USC University Hospital, provided an overview of "i.v.STATION," an automated, robotic-like device for compounding injectable drug. She stated that this system will enhance patient safety by preparing compounded drugs with decreased contamination, shorter wait times for patients, and increased accuracy. Dr. Kim indicated that the i.v.STATION would be implemented as a pilot program for validation testing at several universities around the country. She demonstrated the i.v.STATION dispensing process to the committee, which was impressed with the device.

Dr. Kim provided that USC is seeking permission to proceed with the testing of the i.v.STATION system. Dr. Kim was advised that the board will require a written request and that the board will likely wish to have an opportunity for the board to see the system in operation.

At this meeting, Dr. Kim will attend to provide the presentation. A written request for the authority to test this device in a hospital pharmacy is provided in **Attachment 7**.

D. FOR ACTION: <u>Strategic Plan Update for the Enforcement Committee for 2009/10 and Discussion for Future Activities of the Committee</u>

Attachment 8

At this meeting, each committee of the board will review its strategic plan and recommend a modified strategic plan for 2009-10 during every committee report.

At the June Enforcement Committee Meeting, the committee reviewed its strategic plan and recommended adoption of the proposed version provided in **Attachment 8**.

E. FOR INFORMATION: <u>Enforcement Program Statistics for 2008-09 and the Fourth Quarterly Report on Enforcement Committee Goals for 2008-09</u>

Attachment 9

Attachment 8 contains a copy of the board's enforcement statistics and the fourth quarter's status of Enforcement Committee Goals.

Attachment 1

Model Guidelines for California Pharmaceutical Drug Take Back Programs February 2009

Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB) to develop model programs for the collection from consumers and proper disposal of unused or expired home-generated pharmaceuticals[1]. In developing model programs in California, the CIWMB is also required to evaluate programs used by other state, local, and other governmental entities. The CIWMB provided a survey to those entities that have collection programs and requested that they complete and return it to the CIWMB. The purpose of the survey was to acquire information on existing home-generated pharmaceutical waste collection programs in California. From the survey results, the Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs (Procedures) were developed that would help organizations or local governments create programs through which the public may return unused or expired home-generated pharmaceutical waste (typically a prescription drug dispensed to a consumer, or a non-prescription item, such as over the counter drugs, that are no longer wanted or needed by the consumer) and meet the following minimum criteria and goals of SB 966 and of the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health (CDPH), Board of Pharmacy, Department of Toxic Substances Control, and the State Water Resources Control Board).

The minimum criteria of SB 966 and of the Pharmaceutical Working Group for home-generated pharmaceutical waste collection model programs are as follows:

1. Requires, at no additional cost to the consumer, the safe and environmentally sound take back and disposal of unused or expired home-generated pharmaceuticals;
2. Ensures protection of the public's health and safety and the environment;
3. Ensures protection of the health and safety of consumers, and employees;
4. Report to the Board the amounts of home-generated pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability, and incidents of diversion of drugs for use or sale;
5. Protects against the potential for the diversion of drug waste for unlawful use or sale;
6. Provides notices and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
7. Subjects persons or businesses to consequences for failure to comply with model programs per SB 966 and related state and federal pharmaceutical and waste management statutes at the point of transportation, deposition, and consolidation;
8. Requires that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste must be managed as medical or hazardous waste. This would include all statutory requirements for storage and handling as medical or hazardous waste, the use of registered medical or hazardous waste haulers and approved treatment technology for disposal; and
9. Requires collection locations to have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.

Additional goals of SB 966 and the Pharmaceutical Working Group include:

1. Providing for the collection of home-generated pharmaceuticals that is convenient for consumers;

1 Throughout this document, the terms "home-generated pharmaceuticals" or "home-generated pharmaceutical waste" are used. Although the term does not appear in the law establishing this program, it is the term commonly used by stakeholders to refer to unused or expired pharmaceuticals in the possession of consumers.

2. Maintaining privacy of all participants;
3. Preventing the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;
4. Ensuring that medication information is legible, so that it can be identified in case of a poisoning;
5. Developing a sustainable funding source for collection and disposal of home-generated pharmaceuticals, such as grants, utility funding, or advanced disposal fees placed on home-generated pharmaceuticals and local general funds or via extended producer responsibility funding framework.
6. Striving to develop permanent collection programs rather than one-day events, so they will be more accessible to the public;
7. Providing recommendations for implementation of a statewide program; and
8. Recommending statutory changes to, for example, the Medical Waste Management Act.

The following Procedures have been extracted from both the Pharmaceutical Collection Programs Survey collection program information on the internet, and from the Pharmaceutical Working Group and are recommended for pharmaceutical collection programs. The Procedures are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used as a model to develop a collection and disposal program for unused/expired home-generated pharmaceuticals. The Procedures are broken down by (I) Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

I. Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs

As mentioned in the previous section on goals, it is preferable that permanent home-generated pharmaceutical collection programs be developed to provide the public with consistently accessible and convenient venues to drop off unused or expired home-generated pharmaceuticals. The following procedures are basic steps to implement permanent collection programs at these types of facilities.

1. **Types of Collection Facilities** – Only the following may maintain permanent collection locations for home-generated pharmaceuticals: pharmacies with active unrestricted licenses from the California State Board of Pharmacy, police and sheriff's stations, public/environmental health agencies, physician and other licensed health care prescribers' offices, Household Hazardous Waste (HHW) facilities, and healthcare collection sites. Healthcare collection sites are physical locations licensed or operated by individuals or entities licensed by an agency within the Department of Consumer Affairs (DCA), with these locations electing to collect or take-back home-generated pharmaceutical waste and/or sharps, as applicable. Examples of healthcare collection sites include but are not limited to physicians and surgeons' offices, dentists, veterinary offices and pharmacies. If a DCA licensee has their license revoked, suspended, placed on probation or otherwise limited in any way, it shall not operate a healthcare collection site. If collection is at a police station, law enforcement must agree to and be able to collect the controlled substances and other home-generated pharmaceutical waste.

Participation by any entity is voluntary and must be done in accordance with these provisions in these procedures in order to be considered a model program. Jurisdictions such as the City of Los Angeles, San Mateo County, Ventura County, Santa Cruz County, Marin County, Santa Clara County, and nonprofit groups such as the Teleosis Institute are current examples of entities implementing permanent and ongoing programs utilizing these types of venues.

A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB by the governmental entity, organization, or business that is implementing these programs. The list of collection facilities shall include the name, address, contact, and telephone number of the facility collecting and disposing of the home-generated pharmaceutical waste.

2. **Government Agency Authorization** – Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.

3. **Medical/Hazardous Waste Hauler/Disposal Arrangements** – Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. **What Can and Cannot Be Collected**
   a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.

   b. Sharps in containers approved by the local enforcement agency may be accepted at collection sites, but shall not be placed in the same containers as the home-generated pharmaceutical waste.

   c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

   d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances.

Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines).

5. **Signage** – Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.), as well as the hours during which collection is permitted. Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. If home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility) which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to the container location. During periods of non-operation this sign may be removed and the container shall be stored in a secure storage area to prevent theft.

   Signage should include instructions on how to deposit pharmaceuticals into the secured container. Any signage should also advise consumers to remove personal information from the medicine containers but leave information as to the type of medication being deposited.

6. **How Home-Generated Pharmaceuticals Shall Be Collected** – Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies may assist consumers in placing home-generated pharmaceuticals in the bins if deemed necessary. The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler as specified in these procedures.

   a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances – Collection site staff may assist a consumer in opening a container but should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

   b. Storage – In accordance with Board of Pharmacy specifications, collection sites located in pharmacies shall not commingle pharmaceutical waste with expired, recalled or other quarantined drugs. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in containers approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in a container approved by the local enforcement agency. Employees should never touch the sharps or assist in this process.

d. Chain of Custody- When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that storage, removal and transportation of full containers and disposal are in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and registration number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. **Staffing** - The following staff are recommended at collection programs to implement the specified tasks:
   a. Pharmacist (at pharmacies) – The pharmacist has the discretion to assist any consumer who brings in home-generated pharmaceutical waste or review each consumer's deposit into the collection bin. The consumer shall deposit the items into the secured locked container. If a pharmacist chooses to assist consumers with the identification of pharmaceuticals, the pharmacist should refer customers with pharmaceuticals that have been identified as controlled substances to an appropriate collection location for those items.

   b. Law Enforcement – If a permanent home-generated pharmaceutical waste collection program decides to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances.

   c. Hazardous Waste Company Personnel (for collection at HHW facilities) - Hazardous waste personnel should provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove home-generated pharmaceutical waste, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances at a licensed hazardous waste incinerator, provide a certificate of destruction, and provide weight of materials collected. Do not allow home-generated pharmaceutical wastes that are hazardous waste (e.g. chemotherapy drugs) to be stored longer than 90 days at the facility as required for the management of hazardous waste.

   d. Medical Prescriber Staff - No physician, dentist, veterinarian or other prescriber or the staff in these offices may accept home-generated pharmaceutical waste directly from consumers. It is the consumer's responsibility to deposit the items into the secured locked container. A prescriber may assist consumers with the identification of drugs.

8. **Container Security** – It is the responsibility of the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to prevent diversion and theft opportunities and not allow staff or the entity overseeing the program from having access to the contents. Containers at permanent locations shall be locked and stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

   Bins located at pharmacies shall have a two key security system--one in the possession of the collection site's designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner: a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.

   Every collection site that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

   Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported within 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. **Essential Equipment and Supplies**
   a. Pharmacies, Physicians, Veterinarians and Other Prescribers' Offices and Police Stations – The following are examples of the types of equipment and supplies that should be provided: caged, lockable secure containers, lockable kiosks, lockable steel bins, refurbished lockable mail boxes with an internal container. These types of collection containers shall be located near a building entrance or in a lobby that allows people to drop off home-generated pharmaceuticals and not be able to retrieve them, in order to prevent theft. Other supplies include black markers to obscure personal data, signage informing the public about what can and shall not be collected.

   b. Permanent HHW Collection Facility Equipment – The following are examples of equipment and supplies typically used at permanent HHW collection facilities: four container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gallon plastic

container for mercury items), gloves, indelible markers, and sharps container and/or mail back sharps disposal kit.

10. **Budget** – In order to ensure that the program is properly run, a budget estimate should be developed so that the program is free for the public to dispose of unused and unwanted home-generated pharmaceuticals at the point of disposal. In doing so the facility will need to determine who will pay for the collection and disposal of home-generated pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected.

11. **Education and Advertising** - Collection locations operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. Educational materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceuticals. Operators shall develop and distribute materials advertising the availability of permanent collection programs. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating jurisdictions, movie theater advertisements, advertisements on buses and bus stops, print ads in recycling guides, or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

    Collection location operators shall provide instructions and information for consumers prior to bringing items to the collection location. These instructions should include:

    a. A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).

    b. Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

12. **Data Collection** - Data shall be kept on the total number of pounds collected, the number of residents utilizing the collection facility, and when possible, the types of materials collected for further study and analysis. Examples of collection forms can be accessed at www.teleosis.org/pdf/Medicine_Return_Form.pdf. Security and confidentiality measures must be taken when retaining this data.

13. **Site Visits to Collection Sites** – For programs developed and overseen by public entities, those public entities shall visit collection locations periodically to help assure that procedures are being adhered to. A collection site shall make its premises available for inspection by government agencies with jurisdiction in this area.

II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government-Sponsored One-Time or Periodic Collection Events

Although permanent collection programs are the preferred method to collect and properly manage home-generated pharmaceuticals, some jurisdictions such as Tuolumne County, Fresno County, City and County of Santa Cruz, and the City of Watsonville provide One-time or Periodic Collection Events. The following procedures are basic steps to implement One-time events:

1. **Collection Site** - Access to the location must be restricted to only consumers dropping off home-generated pharmaceuticals. The designated operator shall observe consumers dropping off home-generated pharmaceuticals and shall ensure that the home-generated pharmaceuticals wastes are stored in such a manner as to prevent theft. If any theft is observed or suspected, the operator shall contact the appropriate law enforcement agency and the Local Enforcement Agency of CDPH. The collection site should include the following:

    a. Pharmacist (if a one day event is at a facility other than a pharmacy) – It is recommended that a licensed pharmacist in good standing with the California State Board of Pharmacy be present at the event.
    b. Dedicated Collection Area - If the collection site is at an HHW facility and the home-generated pharmaceutical waste is being segregated, the facility must provide room to account for secured storage of pharmaceutical collection containers.
    c. Law Enforcement - Law enforcement may participate in a collection event to provide security for event personnel. This is optional and at the discretion of collection organizers. A law enforcement officer is only required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Per U.S. Drug Enforcement Agency (DEA) law, only a law enforcement officer may accept controlled substances from the consumer. If controlled substances will be accepted, the operator of the event shall ask the law enforcement agency that is providing the officer if the agency has any specific requirements that the event must adhere to. For example, the law enforcement agency may specify the type of packaging that the drugs must be contained in to be accepted into their evidence locker, or if the containers the collection event will provide, are adequate for the law enforcement agency purposes. For controlled substances only, law enforcement must be on site at all times and be able to see the collection and movement of the home-generated pharmaceutical wastes from the public to the collection location. Law enforcement must be able to see the transfer of home-generated pharmaceutical wastes from vehicles to the collection containers. The operator should coordinate with law enforcement to determine the appropriate position for law enforcement to be stationed.

2. **Government Agency Authorization** - Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.

3. **Medical/Hazardous Waste Hauler/Disposal Arrangements** - Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately

picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. **What Can and Cannot Be Collected**
   a. These programs provide for the collection and disposal of home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste.

   b. Sharps in containers approved by the local enforcement agency may be accepted at collection sites.

   c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

   d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to properly collect, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drug and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines).

5. **Signage** – Signage must describe what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.). Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. If home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. This sign shall be located in close proximity to the container to direct consumers to container location. During periods of non-operation this sign may be removed and the container shall be stored in a secure intermediate storage area.

   Signage should include instructions on how to deposit pharmaceuticals into the secured container. Any signage should also advise consumers to remove personal information from the medicine containers.

6. **How Home-Generated Pharmaceuticals Shall Be Collected**
   Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies may assist consumers in depositing home-generated pharmaceuticals in the bins when needed. The collection location must ensure that the medical or hazardous waste hauler or handler transports the home-generated pharmaceutical waste for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

   a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances - Collection site staff may assist a consumer in opening a container but should not otherwise assist consumers in placing

pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

   b. Storage - Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste must be removed the same day from the location in which the one-day or periodic event was held but may be stored at a secure location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

   c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in containers approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.

   d. Chain of Custody - When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that storage, removal and transportation of full containers and disposal are in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and registration number of the waste hauler taking the drugs.

   For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. **Staffing**
   Event organizers are encouraged to have the following staff at collection sites to implement the specified tasks:

   a. Greeter - direct people to the collection location and answer questions. Greeters can also screen incoming people and wastes for problems. If the event is large enough, radios are useful.

b. Law Enforcement Staff - to provide security, take possession of controlled substances if it has been determined that a controlled substance has been brought in by a consumer, transport controlled substances to evidence storage locker, document the collection of controlled substances, and arrange for and ensure U.S. DEA authorized witnessed destruction of controlled substances. Law enforcement staff can also provide crowd control and watch for problem people. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with the law enforcement agency providing an officer for the event, whether they have requirements for the type of packaging the drugs must be contained in to be accepted into their evidence locker, or if containers the collection event will provide are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel. This is optional at the discretion of collection organizers and not required for all events.

c. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled home-generated pharmaceutical waste, inventory controlled substances (if applicable), witness, and sign the inventory.

d. Hazardous Waste Personnel - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste on the same day as the event, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, provide weight of materials collected, and complete data entry.

8. **Container Security** – It is the responsibility of the entity overseeing the collection event to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to prevent diversion and theft opportunities and not allow staff or the entity overseeing the event from having access to the contents. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

   Every collection event that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

   Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported with 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. **Recommended Equipment and Supplies**
   a. Tools for counting home-generated pharmaceutical waste (pharmacist should provide this);

   b. Hazardous waste containers;
   c. Gloves (Disposable latex or non-latex);
   d. Sealable plastic bags (One-gallon and snack size, with external slide mechanism);
   e. Extension cords, grounded;
   f. Survey forms (examples can be found at http://www.teleosis.org/pdf/Medicine_Return_Form.pdf);
   g. Indelible markers;
   h. Packing tape;
   i. Containers- Check with your contracted medical or hazardous waste hauler for appropriate containers;
   j. Sharps disposal container - Provide sharps containers approved by the local enforcement agency to collect sharps if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point; and.
   k. Personal protective equipment – All staff must wear gloves (latex or non-latex) at all times when handling pharmaceutical waste. This is important as the containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) must be avoided. The use of facemasks should be considered, especially for the pharmacist who may be conducting the physical examination of the home-generated pharmaceutical waste.

10. **Budget** - An estimate of the budget should be developed and the program must be free to the public to dispose of unused and unwanted home-generated pharmaceuticals.

11. **Education and Advertising** – Collection event operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. These materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceutical waste. Event operators shall develop and distribute materials advertising for the collection event. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating cities, movie theatre advertisements, advertisements on buses and at bus stops, print ads in recycling guides or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

    Collection event operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection event:

    a. Date, Time, Location, operating hours, and contact information for the collection event.
    b. A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).
    c. Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

12. **Data Collection** - Determine amounts of home-generated pharmaceuticals collected along with the number of donators. If time allows, determine the types and amounts of home-generated pharmaceuticals collected. This information could be used for further studies and policy recommendations. Security and confidentiality measures should be taken when retaining this data.

    Each collection event must have a log specific to that collection event. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection event (b) the

address, phone number and location number where the event was located; (c) the date the collection event took place; (d) the names of at least one person from the event who witnessed the pickup by the licensed waste hauler (e) the name of the waste hauler's staff person who picked up the collected waste; (f) the weight of home-generated pharmaceutical waste removed from collection event; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals. The log should indicate the name, address and hauler number of waste hauler taking the drugs. These records shall be kept for 3 years after the life of the collection event by the host agency.

13. **Site Visits to Collection Sites** – The event organizer shall inspect the location to ensure compliance with all requirements. The CIWMB may request a report summarizing the activities of each collection location including amounts of home-generated pharmaceutical waste collected and the number of days in operation as a collection location for home-generated pharmaceuticals.

III. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs Through a Mail-Back Program

In some jurisdictions mailing back used and unused home-generated pharmaceuticals may be the only or most convenient option for the proper management of these items. An example is the State of Maine, which uses pre-paid mailing envelopes available at pharmacies, doctors' offices, and post offices to collect home-generated pharmaceuticals that may include controlled substances. In addition, some pharmaceutical companies, such as Celgene, will take back their own home-generated pharmaceuticals via mail. Celgene allows patients to return unused drugs such as thalidomide purchased from the company, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

Locations for Mail-Back Programs shall only be allowed if the following requirements are met:

1. Each entity overseeing either a Mail-Back Location or Mail-Back Program shall ensure that the home-generated pharmaceutical waste is destroyed in accordance with applicable regulations. CIWMB may request that each Mail-Back Location or Program provide information on the amounts of home-generated pharmaceuticals received and destroyed.

2. Determine locations where home-generated pharmaceuticals can be mailed for proper management and destruction. These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. In addition, these facilities must be able to provide data on the amounts of home-generated pharmaceuticals received and destroyed.

3. Operators of mail-back programs shall obtain self-sealing pre-addressed and pre-stamped envelopes that are approved by the U.S. Postal Service for containment and transportation of home-generated pharmaceutical waste. The envelopes shall also include an instruction sheet on how to package and send the home-generated pharmaceuticals.

4. Operators of mail back programs may provide postage-paid envelopes to pharmacies, one-time collection events, hospice care providers, doctors' offices, and post offices to be utilized by consumers for the mailing and destruction of unused and expired home-generated pharmaceuticals.

5. Envelopes shall be tracked to assure that all envelopes are used for their intended purposes and that all of the home-generated pharmaceuticals get to the destruction facility.

6. Operators may advertise its mail back program at pharmacies, convalescent homes, and retirement homes in order to inform potential users of the program of its availability and requirements for participation.

7. The operator shall review data on the amounts of home-generated pharmaceuticals collected to assure that the amounts are increasing and shall make changes to the program as needed to the program to assure continued growth.

Appendix I-Definitions

1. **Controlled Substance**-any substance listed in Chapter 2 (commencing with Section 11053) of Davison 10 of the CA Health & Safety Code.

2. **Event** – Include programs and one- time events for the collection of home-generated pharmaceutical waste to assure appropriate disposal of these items.

3. **Collection Programs** – include permanent collection programs, temporary collection programs, and mail back collection programs

4. **Model Program** - CIWMB a[p[proved program through which the public may return unused or expired home-generated that meets statutory criteria.

5. **Over the Counter Drug** - a non-prescription drug a defined per CA Business & Professions Code Section 4025.1 which states "non-prescription drugs" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the laws and rules of this state and the federal government.

6. **Collection Facility** - any entity CIWMB finds appropriate to implement or evaluate a model home-generated pharmaceutical waste program. The participant must agree to participate as a model program. Entities that may qualify to participate:

   a. Governmental entities (includes police and sheriff's stations, public/environmental health agencies and HHW facilities);
   b. Pharmacies with active unrestricted licenses from the California State Board of Pharmacy;
   c. Other Physician and other licensed health care prescribers' offices; and
   d. Healthcare Collection Sites that are licensed by the Department of Consumer Affairs

7. **Pharmaceutical Waste** - In this document it is considered to be a prescription drug dispensed to a consumer or a non-prescription item, no longer wanted or need by the consumer and includes home-generated pharmaceuticals in many delivery systems, such as pills, liquids, and inhalers.

8. **Prescription Drug** - is a dangerous drug as defined per California Business and Professions Code Section 4022 which means any drug unsafe for self-use in humans or animals, without the oversight of a licensed prescriber and includes the following:

   a. any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription, "Rx only", or words of similar import.
   b. any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to CA Business & Professions Code Section 4006.

Attachment 2

Senate Bill 26 (Simitian)

4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. Reverse distributors shall not accept the return of dangerous drugs that have been dispensed to patients that are later returned **by the patient or the patient's agent** to the pharmacy or another licensed entity. Instead, dangerous drugs returned by a patient **or a patient's agent** to a pharmacy, if accepted by the pharmacy, shall only be picked up or handled (if mailed) by a licensed integrated waste hauler **as defined in Health and Safety Code section (insert number here).**

For purposes of this section, "dispensed" means that the dangerous drugs have been provided to the patient or patient's agent, and taken from the pharmacy.

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(8) A licensed integrated waste hauler, as defined in Health and Safety Code section (insert section number), for the sole purpose of waste disposal of pharmaceutical waste returned to the pharmacy.

(9) Add language dealing with the return of drugs to pharmacy by consumers when Class I recall ordered by FDA. (Not sure what language we would need here; let's discuss further.)

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) Records of all drugs returned to a wholesaler or provided to a reverse distributor shall document the quantity **or weight** of **the** drugs returned, the date **the drugs were returned** and **the names of the reverse distributors or wholesalers** ~~entity~~ to **whom** the drugs were provided. Records of all drugs returned to a licensed integrated waste hauler shall list the volume in weight or measurement of the pharmaceutical waste, the date and name of the licensed **integrated** waste hauler. **For the purpose of this section, "licensed integrated waste hauler" means a person or entity as defined in Health and Safety Code section (insert number here).**

AMENDED IN SENATE APRIL 15, 2009

SENATE BILL No. 26

Introduced by Senator Simitian

December 1, 2008

An act to add Sections 4001.2, 4068.1, and 4146 to the Business and Professions Code, to amend Sections 117700, ~~117935, 117945, 117960,~~ 118000, 118040, ~~118147, and 118165~~ *and 118147* of, and to add Sections ~~117642,~~ 117669, 117748, 117904.5, 118031, and 118041 to, the Health and Safety Code, and to amend Section 47200 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 26, as amended, Simitian. Home-generated pharmaceutical waste.

The existing Pharmacy Law establishes the California State Board of Pharmacy, prescribes the licensing, regulatory, and disciplinary functions of the board, and authorizes the board to adopt rules and regulations necessary to administer laws governing the operation of pharmacies and the dispensing of drugs and devices to the public.

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Existing law, the California Integrated Waste Management Act of 1989, requires the California Integrated Waste Management Board to adopt regulations that set forth minimum standards for solid waste management and require assurance of financial ability to pay for specified injury and property damage claims resulting from the operation

of a disposal facility. The act requires the board to expend moneys from the Solid Waste Management Account in the Integrated Waste Management Fund, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, as provided.

This bill would require that local programs to help prevent the disposal of home-generated sharps waste and home-generated pharmaceutical waste at disposal sites also be included among the types of local programs that may be funded by such a grant.

Existing law, the Medical Waste Management Act, requires the State Department of Public Health to regulate the management and handling of medical waste, as defined. Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.

This bill would also exclude home-generated pharmaceutical waste, as defined, from the definition of medical waste.

Existing law regulates the methods of consolidating, storing, and transporting medical waste and home-generated sharps waste. Violation of these provisions is a crime.

This bill would regulate consolidation points for home-generated pharmaceutical waste, as defined, as well as transportation and disposal of that waste ~~by both hazardous waste haulers and common carriers, as defined~~. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4001.2 is added to the Business and
2 Professions Code, to read:
3 4001.2. To further the purposes of Section 4001.1, and to
4 protect the public from hazards caused by the improper

management and disposal of ~~waste drugs and devices~~ *pharmaceutical waste*, the California State Board of Pharmacy shall coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to properly manage pharmaceutical wastes and the disposal of these wastes.

SEC. 2. Section 4068.1 is added to the Business and Professions Code, to read:

4068.1. A pharmacy may accept the return of home-generated pharmaceutical waste, as defined in Section 117769 of the Health and Safety Code, from the public.

SEC. 3. Section 4146 is added to the Business and Professions Code, to read:

4146. A pharmacy may accept the return of home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code, from a person if the waste is contained in a sharps container.

~~SEC. 4. Section 117642 is added to the Health and Safety Code, to read:~~

~~117642. "Common carrier" means a person or company that hauls for hire goods, including, but not limited to, pharmaceutical waste or home-generated pharmaceutical waste. Home-generated pharmaceutical waste must have been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.~~

~~SEC. 5.~~

SEC. 4. Section 117669 is added to the Health and Safety Code, to read:

117669. "Home-generated pharmaceutical waste" means ~~prescribed and over-the-counter drugs~~ *pharmaceutical waste* derived from a household.

~~SEC. 6.~~

SEC. 5. Section 117700 of the Health and Safety Code is amended to read:

117700. Medical waste does not include any of the following:

(a) Waste generated in food processing or biotechnology that does not contain an infectious agent as defined in Section 117675.

(b) Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.

(c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains fluid blood, as provided in subdivision (d) of Section 117635.

(d) Waste that is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.

(e) Hazardous waste, radioactive waste, or household waste, including, but not limited to, home-generated sharps waste, as defined in Section 117671, and home-generated pharmaceutical waste, as defined in Section 117669.

(f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.

~~SEC. 7.~~

SEC. 6. Section 117748 is added to the Health and Safety Code, to read:

117748. "Pharmaceutical waste" means any pharmaceutical, prescription, or over-the-counter human or veterinary drug, including, but not limited to, a drug, as defined in Section 109925, or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(g)(1)) that meets any of the following requirements:

~~(a) The drug may no longer be sold or dispensed because it has expired.~~

~~(b)~~

(a) The drug can no longer be used for its intended purpose.

~~(c)~~

(b) The drug has been discarded.

~~(d)~~

(c) The drug has been consolidated at a location approved by the enforcement agency as a home-generated pharmaceutical waste consolidation point.

~~SEC. 8.~~

SEC. 7. Section 117904.5 is added to the Health and Safety Code, to read:

117904.5. (a) In addition to the consolidation points authorized pursuant to Section 118147, the enforcement agency may approve a location as a point of consolidation for the collection of home-generated pharmaceutical waste. These locations may include, but are not limited to, pharmacies, heath care facilities,

veterinarian offices, clinics, household hazardous waste programs, solid waste facilities, ~~senior centers~~ *nursing homes*, or government offices.

(b) A consolidation location approved pursuant to this section shall be known as a home-generated pharmaceutical waste consolidation point.

(c) A home-generated pharmaceutical waste consolidation point is not subject to the requirements of Chapter 9 (commencing with Section 118275) of Part 14 of Division ~~4~~ *104*, to the permit requirements of this part, or to any permit or registration fees, with regard to the activity of consolidating home-generated pharmaceutical waste pursuant to this section.

(d) A home-generated pharmaceutical waste consolidation point shall comply with all of the following requirements:

(1) It shall be approved by the enforcement agency for this purpose.

(2) The home-generated pharmaceutical waste collected and consolidated at the facility shall be collected and contained in a leak-resistant *and tamper-proof* container and placed in a secure area that does not allow the waste to be accessed or salvaged by unauthorized persons.

(3) Containers ready for disposal shall not be held for more than 90 days without the written approval of the enforcement agency.

(e) An operator of a home-generated pharmaceutical waste consolidation point that is approved pursuant to this section shall not be considered a generator of that waste.

(f) The end disposal facility that treats the home-generated pharmaceutical waste shall maintain the tracking documents required by Section 118040 or 118041, as applicable, and Section 118165 with regard to the pharmaceutical waste.

(g) Nothing in this section shall exempt any person from any federal or state law governing pharmaceuticals.

~~SEC. 9. Section 117935 of the Health and Safety Code is amended to read:~~

~~117935. Any small quantity generator required to register with the enforcement agency pursuant to Section 117930 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:~~

~~(a) The name of the person.~~

~~(b) The business address of the person.~~

~~(c) The type of business.~~

~~(d) The types, and the estimated average monthly quantity, of medical waste generated.~~

~~(e) The type of treatment used onsite.~~

~~(f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, the name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal, and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal.~~

~~(g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable.~~

~~(h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable.~~

~~(i) A statement certifying that the information provided is complete and accurate.~~

~~SEC. 10. Section 117945 of the Health and Safety Code is amended to read:~~

~~117945. Small quantity generators who are not required to register pursuant to this chapter shall maintain on file in their office all of following:~~

~~(a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.~~

~~(b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, and the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030, or the name of the common carrier hauling pharmaceutical~~

~~waste pursuant to Section 118031. The small quantity generator shall maintain these records for not less than two years.~~

~~SEC. 11. Section 117960 of the Health and Safety Code is amended to read:~~

~~117960. Any large quantity generator required to register with the enforcement agency pursuant to Section 117950 shall file with the enforcement agency a medical waste management plan, on forms prescribed by the enforcement agency containing, but not limited to, all of the following:~~

~~(a) The name of the person.~~

~~(b) The business address of the person.~~

~~(c) The type of business.~~

~~(d) The types, and the estimated average monthly quantity, of medical waste generated.~~

~~(e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility.~~

~~(f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable, or the name of the common carrier hauling pharmaceutical waste pursuant to Section 118031.~~

~~(g) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe, if applicable.~~

~~(h) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.~~

~~(i) An emergency action plan complying with regulations adopted by the department.~~

~~(j) A statement certifying that the information provided is complete and accurate.~~

~~SEC. 12.~~

SEC. 8. Section 118000 of the Health and Safety Code is amended to read:

118000. (a) Except as otherwise exempted pursuant to Section 118030 or 118031, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance

with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate, upon demand, to any enforcement agency personnel or authorized employee of the Department of the California Highway Patrol.

(b) Except for small quantity generators transporting medical waste pursuant to Section 118030 or small quantity generators ~~or common carriers~~ transporting home-generated pharmaceutical waste pursuant to Section 118031, medical waste shall be transported to a permitted offsite medical waste treatment facility or a permitted transfer station in leak-resistant and fully enclosed rigid secondary containers that are then loaded into an enclosed cargo body.

(c) A person shall not transport medical waste in the same vehicle with other waste unless the medical waste is separately contained in rigid containers or kept separate by barriers from other waste, or unless all of the waste is to be handled as medical waste in accordance with this part.

(d) Medical waste shall only be transported to a permitted medical waste treatment facility, or to a transfer station or another registered generator for the purpose of consolidation before treatment and disposal, pursuant to this part.

(e) Facilities for the transfer of medical waste shall be annually inspected and issued permits in accordance with the regulations adopted pursuant to this part.

(f) Any persons manually loading or unloading containers of medical waste shall be provided by their employer at the beginning of each shift with, and shall be required to wear, clean and protective gloves and coveralls, changeable lab coats, or other protective clothing. The department may require, by regulation, other protective devices appropriate to the type of medical waste being handled.

~~SEC. 13. Section 118031 is added to the Health and Safety Code, to read:~~

~~118031. Pharmaceutical waste may be shipped by a common carrier if the generator or home-generated pharmaceutical waste consolidation point meets the following requirements:~~

~~(a) The facility shall maintain documentation as required in Sections 118040 and 118041.~~

~~(b) The waste products are transported to any of the following:~~

~~(1) A medical waste facility.~~

~~(2) A hazardous waste facility.~~

~~(3) A reverse distributor, with the final destination of a medical or hazardous waste facility.~~

SEC. 9. Section 118031 is added to the Health and Safety Code, to read:

118031. (a) Except for a person who generated the home-generated pharmaceutical waste, or a family member or other designated person who is not subject to this part, no person may transport home-generated pharmaceutical waste unless the person is one of the following:

(1) A currently registered hazardous waste hauler.

(2) In possession of a limited-quantity hauling exemption granted pursuant to Section 118030, provided that the person may transport no more than five pounds of home-generated pharmaceutical waste.

(3) An operator of a home-generated pharmaceutical waste consolidation point provided that the person transports the home-generated pharmaceutical waste only from the consolidation point to a permitted treatment facility or transfer station and maintains tracking documentation, as required by Sections 118040 and 118041.

(b) Nothing in this section shall prohibit the operator of a home-generated pharmaceutical waste consolidation point from using a registered hazardous waste hauler for transporting the home-generated pharmaceutical waste to a permitted medical waste treatment or transfer station facility.

~~SEC. 14.~~

SEC. 10. Section 118040 of the Health and Safety Code is amended to read:

118040. (a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, pharmaceutical waste or home-generated pharmaceutical waste consolidated by a home-generated

pharmaceutical waste consolidation point approved pursuant to Section 117904.5, or home-generated pharmaceutical waste transported pursuant to Section 118031, a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, telephone number, and registration number of the transporter, unless transported pursuant to Section 118030.

(2) The type and quantity of medical waste transported.

(3) The name, address, and telephone number of the generator.

(4) The name, address, telephone number, permit number, and the signature of an authorized representative of the permitted facility receiving the medical waste.

(5) The date that the medical waste is collected or removed from the generator's facility, the date that the medical waste is received by the transfer station, the registered large quantity generator, or point of consolidation, if applicable, and the date that the medical waste is received by the treatment facility.

(c) Any hazardous waste transporter or generator transporting medical waste in a vehicle shall have a tracking document in his or her possession while transporting the medical waste. The tracking document shall be shown upon demand to any enforcement agency personnel or officer of the Department of the California Highway Patrol. If the medical waste is transported by rail, vessel, or air, the railroad corporation, vessel operator, or airline shall enter on the shipping papers any information

concerning the medical waste that the enforcement agency may require.

(d) A hazardous waste transporter or a generator transporting medical waste shall provide the facility receiving the medical waste with the original tracking document.

(e) Each hazardous waste transporter and each medical waste treatment facility shall provide tracking data periodically and in a format as determined by the department.

(f) Medical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the receiving state. If there is no permitted medical waste treatment facility in the receiving state or if the medical waste is crossing an international border, the medical waste shall be treated in accordance with Chapter 8 (commencing with Section 118215) prior to being transported out of the state.

~~SEC. 15.~~

SEC. 11. Section 118041 is added to the Health and Safety Code, to read:

118041. (a) A person transporting pharmaceutical waste shall maintain a completed tracking document of all pharmaceutical waste removed for treatment or disposal. A copy of the tracking document shall be included with the container holding the pharmaceutical waste.

(b) The tracking document shall include, but not be limited to, all of the following information:

(1) The name, address, and telephone number of the generator.

(2) Specific information indicating that pharmaceutical waste is being transported.

(3) The name, address, and telephone number of the person transporting the waste.

(4) The name, address, telephone number, and permit number of the permitted treatment facility or transfer station to which the pharmaceutical waste is being sent.

(5) The date that the pharmaceutical waste was collected or removed from the generator or home-generated pharmaceutical waste consolidation point.

(6) The amount of pharmaceutical waste being transported.

(c) A person ~~tracking~~ *transporting* pharmaceutical waste shall have a tracking document for the waste in his or her possession while transporting the waste. The tracking document shall be

shown, upon demand, to any enforcement agency personnel or officer of the Department of the California Highway Patrol.

(d) A medical waste treatment facility and transfer station shall *verify the amount of pharmaceutical waste being delivered,* date and sign a copy of the tracking document upon receipt, periodically provide data in a format determined by the department, and shall maintain a copy of the tracking document for three years.

(e) This section does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility for the purpose of consolidation before treatment and disposal of the pharmaceutical waste over a period of time, if the form or log is maintained in the files of the parent organization or other health care facility that receives the waste.

(f) Pharmaceutical waste transported out of state shall be consigned to a permitted medical waste treatment facility in the ~~receiving state. If there is no permitted medical waste treatment facility in the receiving state, or if the waste is crossing an international border, the home-generated pharmaceutical waste shall be treated pursuant to Section 118222 prior to being transported out of state.~~ *receiving state.*

~~SEC. 16.~~

SEC. 12. Section 118147 of the Health and Safety Code is amended to read:

118147. Notwithstanding any other provision of this chapter, a registered medical waste generator, which is a facility specified in subdivisions (a) and (b) of Section 117705, may accept home-generated sharps waste and home-generated pharmaceutical waste, to be consolidated with the facility's medical waste stream, subject to all of the following conditions:

(a) The generator of the home-generated sharps waste or home-generated pharmaceutical waste, a member of the generator's family, or a person authorized by the enforcement agency transports the sharps waste or pharmaceutical waste to the medical waste generator's facility.

(b) The home-generated sharps waste or home-generated pharmaceutical waste is accepted at a central location at the medical waste generator's facility.

(c) A reference to, and a description of, the actions taken pursuant to this section are included in the facility's medical waste management plan adopted pursuant to Section 117960.

~~SEC. 17. Section 118165 of the Health and Safety Code is amended to read:~~

~~118165. On and after April 1, 1991, all persons operating a medical waste treatment facility shall maintain individual records for a period of three years and shall report or submit to the enforcement agency upon request, all of the following information:~~

~~(a) The type of treatment facility and its capacity.~~

~~(b) All treatment facility operating records.~~

~~(c) Copies of the tracking documents for all medical waste it receives for treatment from offsite generators or from hazardous waste haulers or common carriers, pursuant to Section 118041.~~

~~SEC. 18.~~

SEC. 13. Section 47200 of the Public Resources Code is amended to read:

47200. (a) The board shall expend funds from the account, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of home-generated sharps waste, as defined in Section 117671 of the Health and Safety Code, ~~home-generated pharmaceutical waste, as defined in Section 117669 of the Health and Safety Code,~~ and hazardous wastes at disposal sites, including, but not limited to, programs to expand or initially implement household hazardous waste programs. In making grants pursuant to this section, the board shall give priority to funding programs that provide for the following:

(1) New programs for rural areas, underserved areas, and for small cities.

(2) Expansion of existing programs to provide for the collection of additional waste types, innovative or more cost-effective collection methods, or expanded public education services.

(3) Regional household hazardous waste programs.

(b) (1) The total amount of grants made by the board pursuant to this section shall not exceed, in any one fiscal year, three million dollars ($3,000,000).

(2) Notwithstanding paragraph (1), the total amount of grants made by the board pursuant to this section may exceed three

million dollars ($3,000,000) but shall not exceed six million dollars ($6,000,000), in any one fiscal year, if sufficient funds are appropriated from the Integrated Waste Management Account for this purpose.

~~SEC. 19.~~

SEC. 14. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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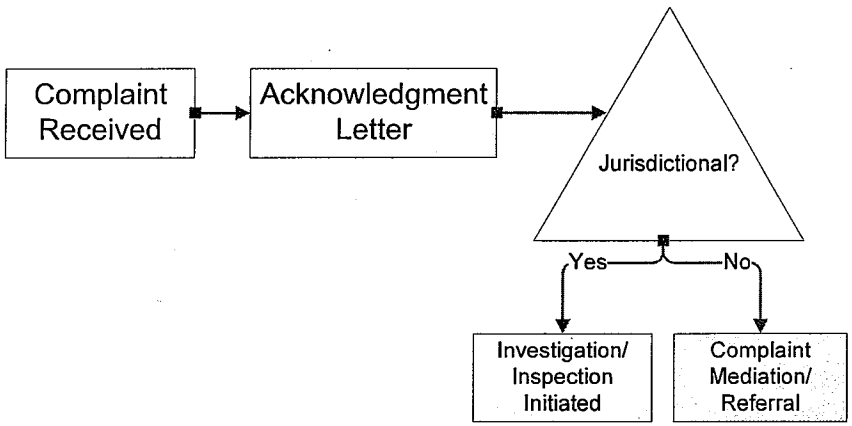
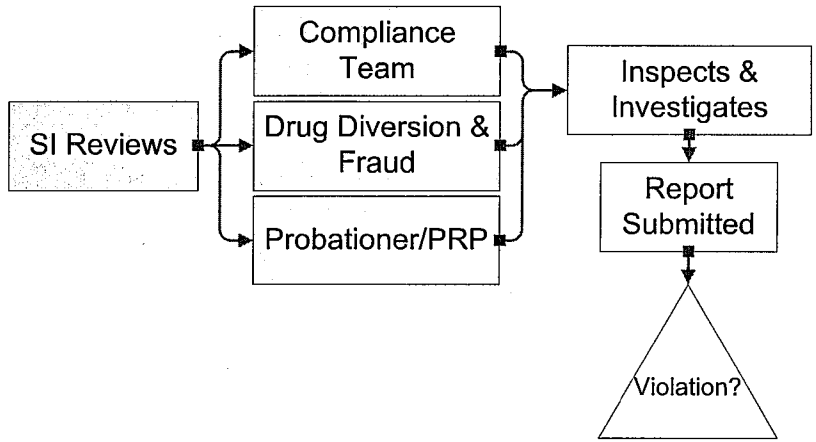
Attachment 3

Board of Pharmacy Investigational Components

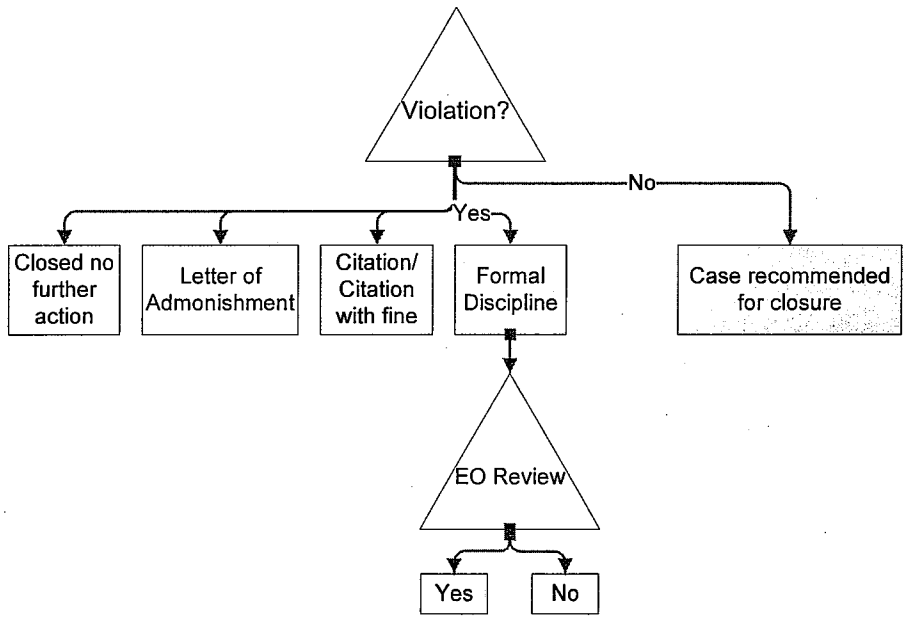
I. Complaint Intake & Investigation



II. Investigation



II. Investigation



III. Formal Discipline

- Pursued with Representation by the Office of the Attorney General
- Outcome sought: restriction or removal of license
  - License Revocation
  - License Suspension
  - License placed on probation
  - Other terms & conditions
- Use of Disciplinary Guidelines kicks in
- Formal Discipline secured by board via adoption of:
  - Stipulation
  - Proposed decision by an administration

Attachment 4

Example of Medication Errors Investigated by the Board of Pharmacy 2008-09

PRESCRIPTION ERRORS DATA

July 1, 2008 – June 1, 2009

Medication Error Category	Number	Percent of Total Citations
Wrong Drug	89	38%
Wrong Strength	38	16%
Wrong Instructions	23	10%
Wrong Patient	40	17%
Wrong Medication Quantity	3	1.5%
Other Labeling Error	11	4%
Compounding/Preparation Error	13	5.5%
Refill Errors (frequency, timeliness)	7	3%
Uncertain and ambiguous prescription	12	5%
Total # Citations for errors (may have more than one category listed)	236	

- **Case 1:** On or about January 8, 2008, a pharmacist-in-charge dispensed azithromycin 200mg/5ml to one patient when it had been prescribed for another patient.

- **Case 2:** On or about February 4, 2008, a pharmacist-in-charge dispensed ibuprofen 800mg when hydrocodone/APAP ES had been prescribed.

- **Case 3:** On or about July 17, 2007, a pharmacist-in-charge verified a prescription that was filled with Procrit 10,000U/ml, when Procrit 40,000 U/ml had been prescribed.

- **Case 4:** On or about January 22, 2008, a pharmacist dispensed Permethrin 5% Cream, when Premarin Cream had been prescribed.

- **Case 5:** On or about June 2, 2008, a pharmacist dispensed amoxicillin 400 mg/5ml oral suspension, with directions for use on the prescription label of "take 2.5 teaspoons of amoxicillin three times a day," when amoxicillin 400 mg/5ml oral suspension with directions for use of "take 2.5 ml of amoxicillin three times a day" had been prescribed.

- **Case 6:** On or about September 5, 2007, a pharmacist dispensed warfarin 5mg when Benazepril 20 mg had been prescribed.

- **Case 7:** On or about January 20, 2008, a pharmacist dispensed atenolol 100 mg when Benazepril 10 mg had been prescribed.

- **Case 8:** On or about March 19, 2008, a pharmacist-in-charge dispensed methadone 10 mg when methylin 10 mg had been prescribed.

- **Case 9:** On or about March 11, 2008, a pharmacist-in-charge dispensed piroxicam 1.5 mg when omeprazole 5 mg had been prescribed.

- **Case 10:** On or about March 10, 2007, a pharmacist dispensed Zetia 10 mg in place of Zyprexa 10 mg.

- **Case 11:** On or about December 18, 2007, a pharmacist dispensed generic augmentin ES 600 mg/ 5 ml for an eight month-old patient. The prescription was placed in a regular bag instead of a "MIX" bag, which would have signaled the prescription needed to be reconstituted prior to being dispensed. Consequently, the medicine was dispensed to the patient's agent without first being mixed with water.

- **Case 12:** On or about July 3, 2007, a staff pharmacist dispensed a prescription filled with alprazolam 0.5 mg when prednisone 5 mg had been prescribed.

- **Case 13:** On or about January 26, 2008, a pharmacist dispensed azithromycin without reconstituting the powder with water. No patient consultation was provided although it was required for this patient.

- **Case 14:** On or about August 15, 2007, a pharmacist failed to clarify a prescription that contained uncertain directions for methotrexate without contacting the prescriber for clarification as required by law. This error resulted in the prescription being dispensed with an incorrect direction of 15 mg daily instead of weekly.

- **Case 15:** On or about May 6, 2007, a pharmacist received an uncertain prescription for an irrigation solution and dispensed talc slurry order without obtaining clarification from the prescriber.

Attachment 5

Pharmacists Recovery Program Brochure

CALIFORNIA STATE BOARD OF PHARMACY
RECOVERY PROGRAM

For information or assistance,
call any time, day or night:

1.800.522.9198

A program of help.
A program of hope.
A program of voluntary participation.

MU_0003453_ENG_0903

CALIFORNIA STATE BOARD OF PHARMACY
RECOVERY PROGRAM

A confidential program for the rehabilitation of pharmacists impaired due to chemical dependency.

1-800-522-9198
24-hours a day, toll-free help

Why this Program?

Substance abuse can strike anyone. A recent study indicated that 46% of the pharmacists and 62% of the pharmacy students studied had used controlled substances at some time without a prescription. That does not mean that everyone who has used drugs improperly becomes a substance abuser, but highly educated and trained health professionals are not immune to alcoholism, other chemical dependencies or mental illness. Indeed, their greater access to abusable substances may increase potential risk. The Pharmacists Recovery Program provides a significant resource toward solving such problems for both pharmacists and registered pharmacy interns.

Problems Grow...

Problems can become more serious and more difficult to solve when not recognized quickly. If you are too close to the problem, you lose objectivity, and half-hearted or misdirected efforts often serve only to increase frustation and stress, making the problem seem unsolvable. For the pharmacist or pharmacy student, substance abuse or mental illness can impair one's professional judgement, putting at risk one's professional career, and even worse, one's life.

What is the Program?

The purpose of the Pharmacists Recovery Program is to identify and evaluate the nature and severity of the chemical dependency and/or mental illness, develop a recovery plan contract, monitor participation and provide encouragement and support. In the quickest, most confidential and least stressful manner possible, the individual receives the proper help to face the problem, deal with it and, if possible, return to the profession as a contributing member. Through the program, the chemically dependent or mentally troubled pharmacist is provided with the hope and assistance required for a successful recovery.

Who Provides the Service?

The California State Board of Pharmacy contracts with MAXIMUS, Inc. to provide confidential assessment, referral, and monitoring services for the Pharmacists Recovery Program. Founded in 1975 with the single mission of "Helping Government Serve the People™", MAXIMUS has served thousands of local, state, and federal government clients with unwavering integrity, and an unmatched commitment to quality. MAXIMUS is a team of dedicated, talented, and conscientious professionals, who through their daily efforts in the support of the government, improve the lives of individuals and families across the country.

Who Can Refer to the Program?

This recovery program accepts referrals on a voluntary basis. Any licensed pharmacist or registered intern in California who is experiencing alcohol or drug abuse or mental illness can voluntarily seek assistance by contacting a 24-hour toll-free number. All voluntary requests for information and assistance are strictly confidential; this information is not subject to discovery or subpoena. Arrangements will be made for the individual to meet with a licensed professional who will make a confidential evaluation and develop a treatment plan. Pharmacists who successfully use the program are assured that their problem and its nature will remain confidential. However, confidentiality may be compromised if the participant poses a threat to themselves or the health and safety of the public, or if the participant is terminated from the program for noncompliance or for failure to derive benefit, or if the board monitoring of the program discloses a misdiagnosis or case mismanagement.

An Alternative for the Board of Pharmacy

The Board of Pharmacy also uses the program for pharmacists who are chemically dependent or mentally impaired. Under the Pharmacists Recovery Program, the board may refer a pharmacist to the program in lieu of discipline if there has been no other significant violation of the pharmacy law. In cases that involve a serious violation, the board may refer a pharmacist to the program in addition to discipline.

How to Obtain the Services

If you have a problem or live or work with a pharmacist who does, call the Pharmacist Recovery Program toll-free at (800) 522-9198. Your call will be confidential.

1-800-522-9198

24-hours a day, toll-free help

Attachment 6

Standards for Recovery Programs for Health Care Licensees Developed Pursuant SB 1441 (Ridley-Thomas, Statutes of 2008)

SB 1441 REQUIREMENT

(1) Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

Draft Uniform Standard #1

If a board has determined that a clinical diagnostic evaluation is necessary in order to evaluate whether practice restrictions or other actions are warranted, the following minimum standards shall apply.

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:

- holds a valid, unrestricted license to do so;
- has three (3) years experience in providing evaluations of health professionals with substance abuse disorders;
- is approved by the board;

2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.

3. The clinical diagnostic evaluation report shall:

- set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem;
- set forth, in the evaluator's opinion, whether the licensee is a threat to himself/herself or others; and,
- set forth, in the evaluator's opinion, recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice.

The evaluator may not have a financial relationship, personal relationship, or business relationship with the licensee. The evaluator shall provide an objective, unbiased, and independent evaluation.

If the evaluator determines during the evaluation process that a licensee is a threat to himself/herself or others, the evaluator shall notify the board within 24 hours of such a determination.

For all evaluations, a final written report shall be provided to the board no later than 30 days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed ninety (90) days.

SB 1441 REQUIREMENT

(2) Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

Draft Uniform Standard # 2

1. The board shall determine on a case-by-case basis whether a licensee shall be temporarily removed from practice to undergo the clinical diagnostic evaluation and any treatment recommended by the evaluator. The board may utilize any statutory provisions or other authority for temporary removal of the licensee.

2. Specific requirements for the temporary removal of the licensee from practice shall be determined on a case-by-case basis by the board using the following criteria:

   - license type;
   - licensee's history;
   - documented length of sobriety/time that has elapsed since substance use;
   - scope and pattern of use;
   - treatment history;
   - licensee's medical history and current medical condition;
   - nature, duration and severity of substance abuse, and
   - threat to himself/herself or the public.

3. These same criteria shall be used by the board to determine whether to permit a licensee to return to practice on a part- or full-time basis.

SB 1441 REQUIREMENT

(3) Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status or condition.

Draft Uniform Standard #3

If the licensee has an employer, he/she shall provide the name, physical address, and telephone number of all employers and shall give specific, written consent that the licensee authorizes the board and the employers to communicate regarding the licensee's work status, performance, and monitoring.

SB 1441 REQUIREMENT

(4) Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomnicity, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

DRAFT UNIFORM STANDARD #4

The following minimum standards apply to a licensee subject to drug testing:

1. Licensees shall be tested no less then eighteen (18) times per year for the first three (3) years of continual abstinence. After the first three (3) years, licensees shall be tested no less then twelve (12) times per year.

2. The scheduling of tests shall be done on a random basis, preferably by a computer program, or as directed by the board.

3. Licensees shall be required to make daily contact to determine if testing is required.

4. Licensees shall be required to test on the date of notification as directed by the board.

5. Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.

6. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.

7. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.

8. Collection of specimens shall be observed.

9. Prior to vacation or absence, alternative testing location(s) must be approved by the board.

10. Laboratories shall be certified by the National Laboratory Certification Program or the equivalent in other countries.

11. A collection site must submit a specimen to the laboratory within one business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

SB 1441 REQUIREMENT

(5) Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

Draft Uniform Standard # 5

If the board determines a licensee must attend group meetings or support groups, the following standards shall apply:

1. When determining the frequency of required group meeting attendance, consideration shall be given to the following:

   - the licensee's history;
   - the documented length of sobriety/time that has elapsed since substance use;
   - the recommendation of the clinical evaluator;
   - the scope and pattern of use;
   - the licensee's treatment history; and,
   - the nature, duration, and severity of substance abuse.

2. The licensee shall be required to submit to the board, at least once a month, documentation of attendance at the group meeting signed or initialed by a representative of the meeting's organizer.

If the board determines a licensee must attend a group meeting facilitated by an individual who reports directly or indirectly to the board, in addition to the requirements above, the following standards shall also apply:

3. The meeting facilitator must have a minimum of three years experience in the treatment and rehabilitation of substance abuse.

4. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee.

5. The document showing attendance must be signed by the group meeting facilitator and must include the licensee's name, the group name, the date and location of the meeting, and the licensee's level of participation and progress in treatment.

6. The facilitator shall report any unexcused absence within two (2) business days.

SB 1441 REQUIREMENT

(6) Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

Draft Uniform Standard #6

In determining whether inpatient, outpatient, or other type of treatment is necessary, the Board shall consider the following criteria:

- recommendation of the clinical diagnostic evaluation pursuant to Uniform Standard #1;
- license type;
- licensee's history;
- documented length of sobriety/time that has elapsed since substance abuse;
- scope and pattern of substance use;
- licensee's treatment history;
- licensee's medical history and current medical condition;
- nature, duration, and severity of substance abuse, and
- threat to himself/herself or the public.

Attachment 7

USC's Request to Test i.v.Station in a Hospital Pharmacy

USC
UNIVERSITY
HOSPITAL

July 7, 2009

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd, Suite N219
Sacramento, CA 95834

RE: Request for permission to implement ivSTATION™ beta testing at USC University Hospital

Dear Ms Herold:

I am writing to request permission from the California State Board of Pharmacy to implement ivSTATION™ beta testing at USC University Hospital. ivSTATION™ is an automated intravenous drug compounding robotic device, which enhances patient safety by decreasing contamination and shortening the time the patient waits for the drugs. This device meets all United States Pharmacopeia 727 requirements.

I thank you for providing us with the opportunity at the June 9th Enforcement Committee Meeting to present the implementation plan for the market validation testing at USC University Hospital. As our research pharmacist Jiwon Kim Pharm.D. described this pilot program, ivSTATION™ will be interfaced with current pharmacy computer system and patient-specific intravenous drugs will be prepared and dispensed directly to the nurses by ivSTATION™. To ensure accuracy of the compounded drug, ivSTATION™ weighs the final product and provides complete logs and photos of each preparation for full traceability. Safety data are available from the manufacturer but to further ensure safety of the device, USC University Hospital will conduct 1-month run-in period, during which time the accuracy of all compounded products will be verified and the implementation of validation testing will proceed only with 100% accuracy.

I look forward to the Board's comments regarding this project and I thank you again for your interest in this pilot program.

Sincerely,

Melanie D. Joe, Pharm.D., FCSHP
Director of Pharmacy
USC University Hospital
USC Norris Cancer Hospital

1500 San Pablo Street
Los Angeles,
California 90033
(323) 442-8500

Attachment 8

Proposed Strategic Plan for 2009-10

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1 Measure:	Achieve 100 percent closure or referral on all cases within 6 months by June 30, 2011: Percentage of cases closed or referred within 6 months
Tasks:	1. Mediate all consumer complaints within 90 days. 2. Investigate all other cases within 120 days. 3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.
Objective 1.2 Measure:	Manage enforcement activities for achievement of performance expectations Percentage compliance with program requirements
Tasks:	1. Administer the Pharmacists Recovery Program. 2. Administer the probation monitoring program. 3. Issue citations and fines within 30 days 4. Issue letters of admonition within 30 days 5. Obtain immediate public protection sanctions for egregious violations. 6. Pursue petitions to revoke probation within 90 days for noncompliance with probationary conditions.
Objective 1.3 Measure:	Achieve 100 percent closure on all administrative cases within one year by June 30, 2011. Percentage closure of administrative cases within 1 year
Objective 1.4 Measure:	Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011. Percentage of licensed facilities inspected once every 3 years
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. 2. Inspect sterile compounding pharmacies annually before renewal or before initial licensure. 3. Initiate investigations based upon violations discovered during routine inspections.

Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011
Measure:	The number of issues
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products 3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances. 4. Evaluate establishment of an ethics course as an enforcement option. 5. Participate in emerging issues of the national level affecting the health of Californians regarding their prescription medicine. 6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing. 7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions. 8. Liaison with other state and federal agencies to achieve consumer protection. 9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public. 10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas. 11. Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards. 12. Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.

Attachment 9

Enforcement Statistics 2008-09
and
Fourth Quarterly Strategic Plan Update 2008-09

Board of Pharmacy Enforcement Statistics
Fiscal Year 2008/2009

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 08/09
Complaints/Investigations					
Initiated	638	514	479	884	2515
Closed	696	310	502	638	2146
Pending (at the end of quarter)	2162	1831	2343	2742	2742
Cases Assigned & Pending (by Team)					
Compliance Team	224	270	151	89	89
Drug Diversion/Fraud	160	182	112	76	76
Probation/PRP	12	125	53	75	75
Mediation/Enforcement	145	170	65	17	17
Criminal Conviction	497	508	1512	1410	1410
Application Investigations					
Initiated	81	120	97	53	351
Closed					
Approved	46	32	56	38	172
Denied	10	11	26	6	53
Total*	70	64	100	54	288
Pending (at the end of quarter)	257	323	328	338	338
Citation & Fine					
Issued	424	87	210	244	965
Citations Closed	258	178	389	239	1064
Total Fines Collected	$418,500.00	$240,975.00	$238,312.50	$277,687.50	$1,175,475.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2008/2009

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 08/09
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	37	32	67	60	136
Pleadings Filed	29	28	15	47	72
Pending					
Pre-accusation	73	76	125	137	137
Post Accusation	76	84	74	99	99
Total	153	160	205	267	267
Closed**					
Revocation					
Pharmacist	0	1	2	3	3
Pharmacy	1	2	0	1	3
Other	3	5	11	3	19
Revocation,stayed; suspension/probation					
Pharmacist	3	3	2	2	8
Pharmacy	0	0	0	0	0
Other	0	0	0	0	0
Revocation,stayed; probation					
Pharmacist	0	2	3	5	5
Pharmacy	0	0	0	0	0
Other	1	2	0	0	3
Suspension, stayed; probation					
Pharmacist	0	0	0	0	0
Pharmacy	0	0	0	0	0
Other	0	0	0	0	0
Surrender/Voluntary Surrender					
Pharmacist	2	0	0	0	2
Pharmacy	0	0	0	1	0
Other	1	2	2	3	5
Public Reproval/Reprimand					
Pharmacist	0	0	0	0	0
Pharmacy	0	0	0	0	0
Other	0	0	0	0	0
Cost Recovery Requested	$46,643.50	$62,140.50	$38,241.00	$94,910.75	$147,025.00
Cost Recovery Collected	$25,856.54	$45,622.15	$24,226.65	$32,525.30	$128,230.64

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2008/2009

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 08/09
Probation Statistics					
Licenses on Probation					
Pharmacist	96	95	106	110	110
Pharmacy	2	4	3	4	4
Other	13	16	14	12	12
Probation Office Conferences	10	8	15	15	48
Probation Site Inspections	41	26	50	36	153
Probationers Referred to AG for non-compliance	3	0	1	1	5

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 6/30/09)

Program Statistics					
In lieu of discipline	1	2	0	0	3
In addition to probation	3	2	1	3	9
Closed, successful	5	7	2	1	15
Closed, non-compliant	0	1	0	1	2
Closed, other	1	1	2	2	6
Total Board mandated Participants	59	59	58	58	58
Total Self-Referred Participants*	20	20	20	21	21
Treatment Contracts Reviewed	56	51	52	47	206

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of June 30, 2009

California State Board of Pharmacy Citation and Fine Statistics July 1, 2008 – June 30, 2009

965 Citations were issued this fiscal year

Total dollar amount of fines issued this fiscal year
$ 65,658,675.00

Total dollar amount of fines collected
$1,175,475.00*

*This amount also reflects payment of citations issued prior to July 1, 2008.

The average number of days from date case is opened until a citation is issued is 214

Average number of days from date case is routed to Citation Unit to date citation is issued 19.61

612 citations are closed. The average number of days from date citation is issued to date citation is closed is 126

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
965	160	8	192	102	259	20	48	2

Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.*	Unlicensed Premises	Unlicensed person
16	13	4	7	19	79	10	23	3

*Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1: Achieve 100 percent closure on all cases within 6 months.

Measure: Percentage of cases closed.

Tasks:

1. Mediate all complaints within 90 days (for cases closed during quarter).

	N	< 90 days	< 120 days	< 180 days	Longer	Average Days
Qtr 1	197	173	6	2	16	47
		88%	3%	1%	8%	
Qtr 2	56	50	1	2	3	40
		89%	2%	4%	5%	
Qtr 3	133	97	9	8	19	74
		73%	7%	6%	14%	
Qtr 4	321	223	38	40	20	85
		70%	12%	12%	6%	

2. Investigate all cases within 120 days (for cases closed during quarter).

	N	< 120 days	< 180 days	< 270 days	Longer	Average Days
Qtr 1	499	378	79	28	14	63
		76%	16%	6%	3%	
Qtr 2	223	171	25	17	10	93
		77%	11%	8%	4%	
Qtr 3	368	268	19	40	41	116
		73%	5%	11%	11%	
Qtr 4	370	169	102	83	16	136
		46%	28%	22%	4%	

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	N	< 180	< 270	< 365	> 365
Closed, no additional action	186	170	10	5	1
Cite and/or fine letter of admonishment	476	447	18	3	8
Attorney General's Office	34	21	6	4	3
Qtr 2	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed, no additional action	143	136	2	2	3
Cite and/or fine letter of admonishment	105	94	8	2	1
Attorney General's Office	31	19	7	3	2
Qtr 3	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed, no additional action	198	157	20	10	11
Cite and/or fine letter of admonishment	230	203	15	7	5
Attorney General's Office	73	41	13	10	9
Qtr 4	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed, no additional action	357	291	14	35	16
Cite and/or fine letter of admonishment	271	209	30	17	15
Attorney General's Office	64	33	22	5	5

Objective 1.2	Manage enforcement activities for achievement of performance expectations.
Measure:	Percentage compliance with program requirements.

Tasks:

1. Administer the Pharmacists Recovery Program.

	Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program
Qtr 1	20	3	0	5
Qtr 2	20	59	1	7
Qtr 3	20	58	0	2
Qtr 4	21	58	1	1

2. Administer the Probation Monitoring Program.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Individuals	108	117	119	110
Sites	3	6	4	5
Tolled	18	14	20	15
Inspections Conducted	41	26	50	36
Successfully Completed	9	1	1	0
Petitions to Revoke Filed	1	0	0	0

3. Issue all citations and fines within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	423	389	29	3	2	15
		92%	7%	1%	.5%	
Qtr 2	85	50	31	5	0	29
		59%	36%	5%	0%	
Qtr 3	212	107	37	37	31	24
		50%	18%	18%	14%	
Qtr 4	240	190	42	5	3	24
		79%	17%	2%	2%	

4. Issue letters of admonishment within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	31	22	6	3	0	24
		71%	19%	10%	0%	
Qtr 2	15	6	9	0	0	29
		40%	60%	0%	0%	
Qtr 3	20	6	10	4	2	30
		30%	50%	20%	10%	
Qtr 4	35	29	5	1	0	21
		85%	14%	1%	0%	

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	0	0	2
Qtr 2	0	0	2
Qtr 3	0	0	1
Qtr 4	0	0	1

6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.

	30 days	60 days	> 60 days	N
Qtr 1	0	0	3	3
Qtr 2	0	0	0	0
Qtr 3	1	0	0	1
Qtr 4	0	0	0	0

Objective 1.3

Achieve 100 percent closure on all administrative cases within 1 year.

Measure:

Percentage of administrative cases closed within 1 year.

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	13	4	2	5	0	2	553
		30%	15%	38%	0%	15%	
Qtr 2	16	2	8	2	3	1	680
		13%	50%	13%	19%	6%	
Qtr 3	27	14	10	2	1	0	390
		52%	37%	7%	4%	0%	
Qtr 4	21	7	5	5	1	3	582
		33%	24%	24%	5%	14%	

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.

Tasks:

1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.

	Number of Inspections	Aggregate Inspections This Cycle	Percent Complete
Qtr 1	345	4271	59%
Qtr 2	373	4530	56%*
Qtr 3	295	4299	60%
Qtr 4	389	4067	59%

* Decrease due to new licenses issued for CVS/Long's buyout.

2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.

	Number of Inspections	Number Inspected Late
Qtr 1	59	0
Qtr 2	67	0
Qtr 3	37	0
Qtr 4	40	0

3. Initiate investigations based upon violations discovered during routine inspections.

	Number of Inspections	Number of Investigations Opened	Percent Opened
Qtr 1	345	70	20%
Qtr 2	373	13	4%
Qtr 3	295	11	4%
Qtr 4	389	4	1%

Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California. *Sept. 28, 2006:* *Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.* *Sept. 30, 2006:* *Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.* *Oct. 6, 2006:* *FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 & 8 Meeting.* *Dec. 2006:* *Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.* *Jan. 2007:* *EPCglobal finalizes electronic messaging standards for electronic pedigrees.* *Feb. 2007:* *EPCglobal convenes regional meeting with hospitals to discuss implementation issues of e-pedigree in these facilities. Hospitals are encouraged to join the board's Workgroup on Implementation of E-Pedigree Meetings.* *March 2007:* *Two board members and executive staff meet with nine EPCglobal representatives to walk through EPCglobal's messaging standards and business scenarios. The standard complies with California's e-pedigree requirements although some questions remain about situation-specific criteria.* *Board convenes fifth Workgroup on Implementation of E-pedigree Meeting. Presentations are made by EPCglobal, AmerisourceBergen and SupplyScape.* *May 2007:* *Board presents information at the National Association of Boards of Pharmacy annual meeting on California's electronic pedigree requirements in both a poster session and a full presentation to the full assembly.* *June 2007:* *Board convenes sixth Workgroup on E-Pedigree Meeting, with the largest attendance of any prior meeting. Presentations were made by EPCglobal, Pfizer, Walgreens and PhRMA. Hospital pharmacies were specifically invited to attend this meeting.* *July 2007:* *Board hears presentations on EPCglobal standards.* *Sept. 2007:* *Enforcement Meeting has large audience (200 people).* *Presentations by PhRMA, GSK, Bracco, CPhA, EPCglobal, Walgreens, Rite Aid, CVS, rfXcel, and HDMA.* *Federal legislation enacted for the FDA supports California requirements.* *Major presentations made on California's standards to LogiPharma (Philadelphia) and HDMA Subcommittee of board meets with EPCglobal representatives on standards.* *Oct. 2007:* *Major presentations at EPCglobal Conference in Chicago.* *At Board Meeting, presentations made by IBM/Amerisource Bergen, Alien Technology and EPCglobal on readiness of technology.*

Dec. 2007: *Enforcement Committee Meeting solely dedicated to Workgroup on E-Pedigree (an eight-hour meeting). Largest meeting to date involving over 400 individuals representing all members in the pharmaceutical supply chain. Board encourages discussion of grandfathering and inference, and seeks information via a template. Industry seeks delay. Many request board to specify technology. Board releases template for readiness assessment.*

Jan. 2008: *Board reviews requests for delay until 2011 from members of the pharmaceutical supply chain.*

Feb. 2008: *Questions and Answers released. Specialized area of the board's website is created to consolidate e-pedigree information.*

March 2008: *Board delays implementation date for e-pedigree requirements from January 1, 2009 until January 1, 2011.*

April 2008: *Board sponsors legislation that will enhance some of the pedigree requirements, allowing for staggered implementation, as well as provisions for regulations on inference and grandfathering.*

June 2008: *Board meets as a public meeting rather than an Enforcement Committee Meeting to hear discussions and presentations on the status of e-pedigree implementation and to discuss and review the amendments to its e-pedigree legislation, SB 1307.*

Sept. 2008: *Governor signs SB 1307, which delays implementation until 2015-2017, and makes other modifications.*

Oct. 2008: *Board convenes workgroup on e-pedigree meeting.*

March 2009: *Board convenes workgroup on e-pedigree as part of the Enforcement Committee. Presentation made by FDA, Congressman Buyer's office, GS1 and Oracle.*

April 2009: *Board submits comments to the FDA regarding nomenclature for the unique identifier.*

2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.

Sept. 2006: *Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.*

Oct. 2006: *Board adds Consumer friendly materials regarding sales of these drugs to its website.*

3. Monitor the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.

Sept. 2006: *Drug Enforcement Administration releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.*

Oct. 2006: *Board considers proposed rule.*

Nov. 2006: *Board submits letter supporting change in Drug Enforcement Administration policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.*

2nd Qtr 07/08: *Drug Enforcement Administration agrees to allow a 90-day supply of Schedule II drugs to be prescribed at one time in serial prescriptions.*

June 2008: *Drug Enforcement Administration published proposed regulations that would provide physicians and other authorized prescribers with the option of issuing electronic prescriptions for controlled substances.*

July 2008: *Board to discuss Federal Drug Enforcement Administration's proposed rule to allow e-prescribing for controlled substances at its July board meeting.*

Sept. 2008: *Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.*

4. Evaluate establishment of an ethics course as an enforcement option.

June 2007 *Subcommittee meets with ethicist trainer for Dental Board.*

Aug. 2007: *Subcommittee meets with Medical Boards Ethics course provider (Institute for Medical Quality).*

Oct. 2007: *Institute for Medical Quality provides information to board about program; recommendation of committee is to move forward with the specialized program. Board approves development of program at board meeting.*

Jan. 2008: *Staff compile resource materials and begin steps to develop framework for program. Board agrees to establish program.*

April 2008: *Legislation/Regulation Committee to develop draft language for a regulatory proposal. Draft language for a new regulation to be presented and reviewed at July 2008 Board Meeting.*

July 2008: *Board moves ethics regulation for 45 day notice and plans action at the October Board Meeting.*

Oct. 2008: *Board holds regulation hearing on proposed requirements for the ethics class.*

Dec. 2008: *Board releases regulation for 15 day comment.*

Jan. 2009: *Board adopts regulation.*

April 2009: *Rulemaking file compiled and submitted to the Department of Consumer Affairs for review.*

5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.

May 2007: *Board staff provides presentation at National Association of Boards of Pharmacy annual meeting on California's pedigree requirements.*

June 2007: *Board works with Center for Medicare and Medicaid Services on security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.*

Nov. 2007: *Staff meets with FDA officials to discuss California's e-pedigree requirements and new federal law for FDA's action involving pharmaceutical chain security.*

May 2008: *The Executive Officer gives a poster presentation on the board's e-pedigree requirements at the annual National Associations of Boards of Pharmacy (NABP) meeting.*

May 2008: *The Executive Officer attends a drug tracking conference of manufacturers and wholesalers and presents status of California's e-pedigree efforts.*

June 2008: *Executive staff and supervising inspector provide a presentation via videoconference at the Fourth Global Forum on Pharmaceutical AntiCounterfeiting.*

Nov. 2008: *Executive Officer Herold provides information about SB 1307 to a conference of drug manufacturers and wholesalers.*

Dec. 2008: *Executive Officer Herold provides information about SB 1307 to a conference of drug manufacturers and wholesalers and at a conference on drug distribution chain security.*

Executive Officer Herold participates on a National Association of Boards of Pharmacy Task Force on designing patient-centered labels.

Board President Schell participates on a National Association of Boards of Pharmacy Task Force on drug take-back programs.

	6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing. *Sept. 2007:* *Provided comments on proposed statutory requirements.* *Dec. 2007:* *Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.* *Provided comments on proposed e-prescribing initiatives.* *Oct. 2008:* *Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.* *Nov. 2008:* *Board hosts conference on e-prescribing as part of department's Professionals Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.* *Jan. 2009:* *Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.* *March 2009:* *Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.* 7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions. June - *Oct. 2007:* *Board works with the Department of Health Care Services to implement security forms until subsequent federal legislation delays implementation until April 2008.* *Dec. 2007:* *Meeting with Department of Health Care Services on issues involving security forms for MediCal prescriptions.* *April 1, 2008:* *Requirements that all written prescriptions for MediCal prescriptions be written on security forms containing at least one specified security component takes effect.* *April 2008:* *Subscriber alert released with information for contact resources from the California Department of Health Care Services about security forms for MediCal prescriptions.* *Oct. 2008:* *Requirements for security forms in place.*

	8. Liaison with other state and federal agencies to achieve consumer protection. *1st Qtr 07/08:* *Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.* *2nd Qtr 07/08:* *Bimonthly meeting with the Department of Health Care Services continue.* *Board inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services.* *Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.* *3rd Qtr 07/08:* *Bimonthly meetings with the Department of Health Care Services continue.* *Board works with the Drug Enforcement Administration on joint investigations and receives specialized training.* *4th Qtr 07/08:* *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.* *3rd Qtr 08/09:* *Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.* *4th Qtr 08/09:* *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.* *Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.* *The federal Drug Enforcement Administration provides training to board staff on new requirements for online pharmacies selling controlled substances.*

9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public.

March 2008: *Second meeting with state agency stakeholders on developing components for model programs that conform with diverse state agency security and safety requirements.*

June 2008: *Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take-back programs.*

Aug. 2008: *Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.*

Oct. 2008: *Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps.*
Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.

Nov. 2008: *Executive Officer provides written and verbal testimony at California Integrated Waste Management Board hearing on the model guidelines.*

Dec. 2008: *Executive Officer participates in public hearing at the California Integrated Waste Management Board on possible changes to the model guidelines adopted by the California Integrated Waste Management Board in November.*

Feb. 2009: *California Integrated Waste Management Board amends model guidelines to include provisions advanced by the board.*

Jul. 2009: *Board publishes guidelines in The Script.*
Mail return processes reviewed by the board.

10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas.

4th Qtr 07/08: *Board initiates inspections of 40 California hospitals looking for counterfeit heparin and unlicensed sales but discovers recalled heparin still in 40 percent of hospitals inspected. Board notifies the Food and Drug Administration and California Department of Public Health and initiates inspections of 533 hospitals during April-June.*
Recalled heparin is found in 94 of these facilities. Data reported to board during June Board Meeting.

1st Qtr 08/09: *The Script highlights problems found in heparin inspections. Citations and fines issued to facilities with recalled heparin. Work with hospitals begins to strengthen drug control within facilities.*

2nd Qtr 08/09: *Hospitals and Pharmacists-in-Charge fined where recalled heparin was discovered by the board.*

3rd Qtr 08/09: *First stakeholder meeting scheduled to discuss drug distribution within hospitals.*

March 2009: *First stakeholder meeting convened.*

June 2009: *Second stake holder meeting convened. Development of model guidelines for recalls underway.*

11. Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards.

4th Qtr 08/09: *Draft proposals for required components 1-6 developed.*

12. Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.

4th Qtr 08/09: *Provisions for Request for Proposal developed: Request for Proposal released.*

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	27 %	1716 - Variation from prescription	18 %	4301(j)/111295/351- Adulterated Heparin Held at Pharmacy	23 %
4231(a)/1732.5- Requirements for renewal of pharmacist license/ Accreditation agencies	4%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	7%	1716 - Variation from prescription	8%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	4%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	4%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	7%
1707.2(b)(1)(A)- In addition to the obligation to consult...a pharmacist shall provide oral consultation patients... whenever the prescription drug has not previously been dispensed to a patient...	3%	4104-Procedures individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity to take action when licensed	3%	4104-Procedures to take action when licensed individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity	3%
1761(a)- No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	3%	4115(e)-Pharmacy technician license required	3%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	2%
1732.5 - Renewal requirements for pharmacist	2%	1707.2(b)(1)(A)- In addition to the obligation to consult...a pharmacist shall provide oral consultation to patients...whenever the prescription drug has not previously been dispensed to a patient...	2%	1707.2(b)(1)(A)- In addition to the obligation to consult...a pharmacist shall provide oral consultation to patients...whenever the prescription drug has not previously been dispensed to a patient...	2%
1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	2%	1761(a)- No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	2%	4342-Actions by board to prevent sale of preparations or drugs lacking quality or strength; penalties for knowing or willful violation of regulations governing those sales	2%
4301(j)/111295/351- Adulterated Heparin Held at Pharmacy	2%	4063-Refill of prescription for dangerous drug or device; prescriber authorization	2%	1715-Self-assessment of a pharmacy by the pharmacist in charge	2%
1711(d)-Quality assurance program finding shall be used to develop systems to prevent medication errors...	1%	4342-Actions by board to prevent sale of preparations or drugs lacking quality or strength; penalties for knowing or willful violation of regulations governing those sales	2%	1304.11-Inventory requirements	1%
111666-Time limit for filling schedule II prescription	1%	4301(j)/111295/351- Adulterated Heparin Held at Pharmacy	2%	1711(d)- Quality assurance program finding shall be used to develop systems to prevent medication errors...	1%

Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were twenty-six office conferences held this fiscal year

Number of requests	450

Number scheduled	450

Number appeared	324

Number Postponed	98**

**Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	29
Failed to appear	11

Total number of citations affirmed	176

Decision	Total citations	Total dollar amount reduced
Modified	53	$23,550.00
Dismissed	48	$50,000.00
Reduced to Letter of Admonishment	2	$200.00

Please note eight cases are pending decisions due to additional investigation being required.

Attachment A

Minutes of the June 9, 2009 Meeting of the Enforcement Committee

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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE MEETING
MINUTES

DATE: June 9, 2009

LOCATION: Department of Consumer Affairs
Hearing Room, Suite S-102
1625 N. Market Boulevard
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Robert Swart, PharmD, Chair
Ramón Castellblanch, Public Member
Randy Kajioka, PharmD
Greg Lippe, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joan Coyne, Supervising Inspector
Janice Dang, Supervising Inspector
Judi Nurse, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Schieldge, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Rob Buckner, Enforcement Manager
Tessa Fraga, Staff Analyst

Call to Order

Chair Swart called the meeting to order at 9:43 a.m.

1. Overview of the Board of Pharmacy's Complaint Investigation Processes

Executive Officer Virginia Herold provided an overview of the board's complaint investigation process. She explained that discipline and enforcement actions are necessary to ensure public protection. Ms. Herold stated that the process begins with a

written complaint. All complaints are screened and acknowledged within 10 working days. Complaints deemed jurisdictional are then investigated by one of the investigation teams including the compliance team, the drug diversion and fraud team, and the probation/pharmacist recovery program (PRP) team. The assigned investigation team evaluates the complaint and determines if a violation occurred or recommends that the case be closed. Severe violations warrant formal discipline and are pursued with representation by the Office of the Attorney General in order to restrict or remove the license.

Joshua Room, Deputy Attorney General, provided that cases forwarded to the Attorney General's Office may also be subject to prosecutorial discretion.

Public Comment

Steve Gray, representing Kaiser Permanente, questioned if any additional notification is provided after the initial acknowledgement of a complaint.

Ms. Herold responded that the consumer is notified when a case has been closed or referred to the Attorney General's Office.

Dr. Gray asked if the investigation process includes an interview with the consumer who made the complaint.

Ms. Herold responded that preliminary interviews are conducted. She advised that the majority of the complaints received are medication errors, which are easily identified by the public.

Mr. Room emphasized the difference between violations that are referred to the attorney general's office for formal discipline and other violations that do not warrant license discipline including citations and fines.

Pierre DelPrato, representing the California Pharmacists Association, sought clarification on citations for failure to provide patient consultation.

Ms. Herold provided that the board is a major proponent of patient consultation. She indicated that the board receives a small number of complaints for failure to consult, many of which usually arise in the course of medication errors.

Ms. Herold reviewed the following enforcement statistics for 2007-2008:

COMPLAINTS RECEIVED BY SOURCE 2007-08

Public	770
Government/Law Enforcement	90
Licensed Professional Groups	187
Internal (Board or Committee Staff) *	902

Other or Anonymous **	438
Total Received	2,387

* Includes complaints opened as a result of a subsequent arrest rap sheet.
** Includes application investigations.

COMPLAINTS REFERRED TO NON SWORN INVESTIGATORS FOR FORMAL INVESTIGATION

Investigations Opened	1,382
Criminal Charges/Conviction of a Crime	11
Fraud	14
Personal Conduct/Substance Abuse/Mental Physical Impairment	15
Negligence/Incompetence	562
Sexual Misconduct	0
Unprofessional Conduct	260
Discipline by Another State	0
Unlicensed Unregistered Activity	139
Unsafe/Unsanitary Conditions	0
Non Jurisdictional	16
Other *	361
Total Closed	1,378
Total Pending *	715
Referred to AG	74

FORMAL ACTIONS FILED

Accusations / Petitions to Revoke Probation Filed	77
Statements of Issues Filed	7
Criminal Actions Filed	0
Civil Actions Filed	1
Restraining Orders / Interim Suspension Orders Issued	2

CITATIONS AND FINES

Total Citations Issued	1003
Citations Issued Without a Fine	836
Citations Withdrawn	20
Citations Dismissed	3
Fines Assessed	$1,746,850
Fines Reduced	$32,350
Fines Collected	$812,795

ADMINISTRATIVE OUTCOMES AGAINST LICENSES AND PERMITS

Revocation	32
Surrender of License	17
Probation With Suspension	14
Suspension Only	0
Probation Only	9
Public Reprimand	0
License or Applicant Denied	48
Other Decisions	4
Withdrawn/Dismissed	3

INSPECTION DATA

Total Number of Inspections	2,089
Notices of Violation Issued *	863

* The Board does not currently have the authority to issue a notice of violation; however, Board inspectors found 863 sites inspected were not in compliance with State and Federal laws and regulations. These sites were either formally warned or educated, or an investigation was opened to pursue formal action.

DIVERSION PROGRAM

Total Referrals to Program	88
Voluntary Self-Referrals	28
Board Referrals	60
Cases Closed	18
Successful Completions	10
Non-Compliance	3
Withdrawals	3
Not Eligible / Not Interested	2

COST RECOVERY TO CONSUMER AFFAIRS

Amount of Cost Recovery Ordered	$258,182
Total Amount Collected	$123,543

TIMELINE FOR DISPOSITION OF COMPLAINTS

Investigations Closed	**1,378**
Up to 90 Days	73
91 to 180 Days	366
181 to 1 Year	773
1 to 2 Years	160
2 to 3 Years	6
Over 3 Years	0
AG Cases Closed	**76**
Up to 1 Year	32
1 to 2 Years	29
2 to 3 Years	13
3 to 4 Years	2
Over 4 Years	0
Total AG Cases Pending	129

Chair Swart sought clarification on cost recovery and the difference between the amounts for fines issued and the fines collected.

Ms. Herold provided that the board is not always able to collect all of the fines issued. She advised that the board is entering into a pilot project with the department to use collection agencies to collect fines.

There was no additional committee or public comment.

2. Discussion of the Board of Pharmacy's Citation and Fine Program Involving Medication Errors

Ms. Herold provided an overview of the citations and fines issued for medication errors in 2008 through 2009. She shared data for prescription errors and provided examples of prescription error cases.

Public Comment

Lee Worth, representing the Department of Health Care Services, asked whether or not medication errors that result in patient harm are being tracked and if a threshold for this fine has been instituted.

Ms. Herold provided that these citations are being tracked. She advised that the medication errors that could result in patient harm are usually corrected by the pharmacist and the board is never notified. Ms. Herold indicated that patient harm is independent of the amount of the fine; however, fines involving patient harm are generally higher.

Mr. Room provided that patient harm is not a requirement for either citation and fine or formal discipline action.

Mr. Worth sought clarification regarding levels of responsibility and citations.

Ms. Herold provided that the examples provided indicate that in some instances, the pharmacist-in-charge (PIC) dispensed the medication error. She advised that the pharmacy involved was also issued a citation without a fine.

John Grupps, representing the UC Davis Medical Center, commended the board for its efforts and interest in medication errors and improving medication safety. He asked whether or not fining for medication errors is consistent with the blame free environment and the ultimate goal to increase the reporting of errors. Mr. Grupps questioned if this approach would encourage a pharmacist to self report when facing a fine.

Ms. Herold provided that the quality assurance requirement requires all medication errors to be evaluated and corrected. She advised that this requirement supports the blame free environment and allows for the error to be remedied.

Discussion continued regarding medication errors and self reporting.

Steve Gray, representing the California Pharmacists Association, questioned if the board has researched how other healing arts boards use the citation and fine program.

Ms. Herold provided that the board has not researched other board's programs. She explained that each board has many differences and has implemented the citation and fine program at different levels.

There was no additional committee or public comment.

3. Presentation and Discussion of the Board of Pharmacy's Pharmacists Recovery Program

Joan Coyne, Supervising Inspector, provided an overview of the Pharmacist Recovery Program (PRP). She stated that the PRP was created by legislation to identify and rehabilitate pharmacists whose competency may by impaired due to abuse of alcohol or other drugs or due to mental illness, so they may be treated and returned to the safe practice of pharmacy and will not endanger public health and safety. Ms. Coyne indicated that as required by statute, the PRP has two distinct functions including providing a diversion program for licensees referred by the board either in lieu of or in addition to disciplinary action and to provide a confidential source of treatment for pharmacists who enter voluntarily without the knowledge of the board. She provided that PRP currently has 72 board referred participants and 15 self-referral participants.

Anne Mireles, clinical case manager for the PRP, provided an overview of substance abuse, addiction, and the PRP. She detailed the intake process, progression through the program, and program completion.

No committee or public comment was provided.

4. Discussion of the Actions of the Department of Consumer Affairs Healing Arts Boards to Develop Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery Programs

Assistant Executive Officer Anne Sodergren provided an overview of SB 1441 (Chapter 548, Statutes of 2008). She stated that the bill has two primary goals including auditing the existing diversion program and to establish in the Department of Consumer Affairs the Substance Abuse Coordination Committee, which would be comprised of the executive officers of the department's healing arts licensing boards and a designee of the State Department of Alcohol Drug Programs.

Ms. Sodergren provided that the bill would require the committee, by January 1, 2010, to formulate uniform and specific standards in specified areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. She advised that the department has comprised a workgroup consisting of staff from each of the healing arts boards that is responsible for developing recommended standards.

Ms. Sodergren provided that the workgroup has completed drafts standards for the first six standards.

Ms. Sodergren provided that the one of the greatest challenges with this bill is accommodating each board and their individual statutory authority. She advised that the workgroup is drafting minimum standards to allow for the flexibility required.

Committee Discussion

Ramón Castellblanch sought clarification regarding how the diversion programs are financed.

Ms. Sodergren responded that funding varies depending on the program. She stated that the board subsidizes a portion of the PRP participant fees. Ms. Sodergren indicated that the participant is responsible for the additional costs including the drug testing fees.

Ms. Coyne provided that insurance plans may also cover these fees.

Ms. Herold clarified that the minimum requirements are already maintained by the PRP.

Ms. Mireles provided that health support group facilitators are willing to work with the participants to address any financial hardships and their ability to pay participation costs.

There was no additional committee discussion. No public comment was provided.

5. Presentations and Discussions on E-Prescribing Pilot Programs Underway in California by the California HealthCare Foundation and CalPERS

Presentation

Libby Sagara, representing the California Healthcare Foundation (CHCF), provided an overview of the statewide e-prescribing consortium efforts to secure e-prescribing in California. She stated that the CHCF e-prescribing program is aimed at advancing the use of e-prescribing to achieve safe and affordable health care for all Californians. Ms. Sagara indicated that the program has several objectives including a statewide e-prescribing plan through regional experience to increase provider adoption, increase payer provision of electronic eligibility, formulary and medication history, increase pharmacy connectivity, and raiser consumer and purchaser confidence and demand.

Ms. Sagara provided an overview of e-prescribing transactions, fees, and cost flow. She presented an incentive opportunity and implementation timeline for the program.

Ms. Sagara recommended that the board continue its involvement and support of e-prescribing efforts. She encouraged the board to provide recommendations to the statewide e-prescribing consortium.

Committee Discussion

Greg Lippe questioned if safeguards are in place to protect patient privacy and to prevent hacker threats.

Ms. Sagara provided that CHCF is working with the state to determine the best processes for obtaining consent. She advised that consent forms are frequently distributed. Ms. Sagara stated that the e-prescribing applications are username and password protected.

Patrick Robinson, R. Ph., MBA, representing California Public Employees' Retirement System (CalPERS), provided that unlike internet applications, this system has security that is maintained at a variety of levels to maintain information from a secure line process.

Mr. Castellblanch sought clarification regarding data security and the businesses that collect this data.

Ms. Sagara provided that agreements are signed between providers and vendors to ensure the security of data protection.

Discussion continued regarding the security of data and the transferring of information.

Chair Swart provided that incentives for pharmacies are available including time and labor savings and error prevention.

Randy Kajioka sought clarification regarding the transfer of information from the prescriber to the pharmacy and notification when a prescription has been filled.

Ms. Sagara provided that this is a vendor by vendor functionality component.

Mr. Robinson provided that e-prescribing is comprised of a variety of transactions. He advised that these transactions will include notifications for when a prescription has been filled and when a prescription has been picked up by the consumer.

Mr. Lippe sought clarification on how the process would impact independent pharmacies.

Ms. Sagara provided that transaction fees for independent pharmacies do pose a challenge. She advised that these programs can be funded by foundations or join a partnership with a provider.

Ms Herold sought clarification regarding the status of e-prescribing technology and software.

Ms. Sagara provided that older e-prescribing programs are functional; but, do have varying levels of functionality.

There was no additional committee discussion. No public comment was provided.

Presentation

Mr. Robinson provided an overview of the CalPERS e-prescribing pilot program. He reviewed the benefits of e-prescribing to physicians, patients, and pharmacies including safety, convenience, and efficiency. Mr. Robinson indicated that the pilot is a partnership with Anthem Blue Cross, Blue Shield of California, and Medco and will run through 2010. He shared that the goals of the program are to determine and test a set of e-prescribing adoption strategies and best practices through collaboration with a selected set of participating physician groups and to accelerate the adoption and use of e-prescribing in an effort to enhance patient safety and quality of care resulting from the replacement of paper prescriptions.

Committee Discussion

Mr. Castellblanch sought clarification regarding the collection of patient drug history.

Mr. Robinson provided that health plans collect this information.

Ms. Herold sought clarification regarding the e-prescribing applications used by the five volunteer physician groups involved in the pilot.

Mr. Robinson provided that the applications are used to send prescriptions to identified pharmacies.

There was no additional committee discussion. No public comment was provided.

6. Discussion Regarding AB 718 (Emmerson), E-Prescribing Pilot Project

Theresa Jennings, representing Reed Elsevier Company, provided an introduction to the Inland Empire Health Plan E-Prescribing Pilot Program.

Teresa Trujillo, representing Assemblymember Emmerson, provided an overview on AB 718. She stated that the bill would establish a pilot in the Inland Empire until January 1, 2013 to demonstrate the value and benefits of e-prescribing.

There was no committee or public comment.

Presentation

Greg Shulman, representing Informed Decisions, LLC, provided a company overview of Informed Decisions and the EMPOWERx program. He stated that EMPOWERx is a technological solution that provides drug related decision support and e-prescribing to physicians. Mr. Schulman demonstrated the EMPOWERx product and its functionality.

Committee Discussion

Mr. Room sought clarification regarding the EMPOWERx product and the Drug Enforcement Administration (DEA) requirements for controlled substance prescribing.

Mr. Shulman provided that all providers undergo a credential screen to verify their license through the DEA.

Ms. Jennings provided that the EMPOWERx product will notify the prescriber if their patient is receiving prescriptions from other providers.

Mr. Room questioned if the prescriber maintains any control over the prescription after they have completed their portion of the transaction.

Mr. Shulman responded that the prescriber can discontinue the prescription and rewrite the prescription with any necessary changes.

Mr. Room asked if the purpose for the medication can be inputted.

Mr. Shulman responded that the purpose and any other additional information can be entered in the "free text" field.

Mr. Lippe questioned if any plans have been made to provide this product internationally.

Mr. Shulman responded that international plans have not been made at this time.

There was no addition committee discussion. No public comment was provided.

7. Demonstration of Technology Proposed for Future Pharmacy Use in California

Presentation

Jiwon Kim, PharmD., representing the USC University Hospital, provided an overview on i.v.STATION, an automated injectable drug compounding system. She stated that this system will enhance patient safety by dispensing drugs with decreased contamination, shorter wait times for patients, and increased accuracy. Dr. Kim indicated that the i.v.STATION will be implemented as a pilot program for validation testing at several universities around the country. She demonstrated the i.v.STATION dispensing process to the committee.

Committee Discussion

Chair Swart sought clarification regarding the stocking process.

Dr. Kim provided that the product will be stocked by a pharmacist with select, low-incidence IV medications and solutions. She advised that the system includes a camera that verifies that all medications stocked are accurate.

Dr. Kajioka sought clarification regarding how the system will be cleaned.

Dr. Kim provided that the system and all products are checked for sterility and accuracy on a regular basis.

Ms. Herold sought clarification regarding the intent for Dr. Kim's presentation.

Dr. Kim provided that USC is seeking permission to proceed with the testing of the i.v.STATION system.

Ms. Herold provided that it will need to be determined if this system is in conflict with current pharmacy law. She advised that if the system is implemented, the pharmacist will be held responsible for any errors or patient harm. Ms. Herold stated that the board does not have the ability to waive statutory law; but, does have the ability to waive regulations under the auspices of a pilot program.

Robert Ratcliff, Supervising Inspector, sought clarification regarding the dosage capabilities of the system.

Dr. Kim provided that there are plans to expand the dosage capabilities after the system has been successfully implemented.

Mr. Ratcliff questioned if the system will account for the lot number.

Dr. Kim provided that the system will provide a complete log and photos for each preparation for full traceability. She indicated that the lot number will be included.

Kristy Schieldge, DCA Staff Counsel, recommended that all requests to the committee be submitted in writing.

Chair Swart encouraged Dr. Kim to provide both a written request and an opportunity for the board to see the system in operation.

There was no additional committee discussion. No public comment was provided.

8. Request by Asteres Inc. for Flexibility Regarding 16 California Code of Regulation Section 1713 from Automated Delivery Devices

Chair Swart provided that a representative from Asteres was unable to attend.

9. Update of the Committee's Strategic Plan Objectives for 2009-10

Chair Swart referenced the Enforcement Committee's strategic plan contained within the committee packet provided.

The committee reviewed the plan and will submit it to the full board for review and approval.

10. Public Comment for Items Not on the Agenda

Steve Gray, representing Kaiser Permanente, recommended that the board consider and review the criteria used to approve systems for e-prescribing. He suggested that this could be added as an agenda item for a future meeting.

The meeting was adjourned at 1:29 p.m.