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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Report

Randy Kajioka, PharmD, Chair
Greg Lippe, Public Board Member
Ramón Castellblanch, PhD, Public Board Member
Shirley Wheat, Public Board Member

ENFORCEMENT COMMITTEE REPORT AND ACTION

Report of the Meeting held on June 16, 2010.

a. **FOR DISCUSSION: Review of the Federal Drug Enforcement Administration's Proposed Requirements for the E-Prescribing of Controlled Substances**

Attachment 1

Background

The federal Drug Enforcement Administration (DEA) released on March 22 proposed requirements to enable e-prescribing of controlled drugs. Until June 1, 2010, federal law did not allow the electronic prescribing of written prescriptions for controlled drugs. The comment period on the proposed interim final rule ended on May 31, 2010.

At the April Board Meeting, the board was led in a discussion of the proposed, highly technical requirements by Deputy Attorney General Joshua Room. After a short discussion, the board agreed to send a request to the DEA to extend the comment period another 120 days so that the board and others could carefully read and consider the more than 330 pages of requirements and policy statements released by the DEA. A copy of the board's letter is provided in **Attachment 1**.

E-prescribing of controlled substances is an important and significant change for prescribers, for pharmacy and for patients. The volume of material released by the DEA for this regulation is extensive – 334 pages, and fortunately, not all these pages are text of the requirements. However, the regulation is very technical and is difficult to readily digest.

Committee Discussion/Action

The committee was advised that the DEA has not responded to our request for an extension to the comment period and has not trained staff in field agents. The committee voted to establish an ad hoc committee to review and provide guidelines on the DEA proposed rules.

b. **FOR INFORMATION: Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding the Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area**

Attachment 2

Background:

In 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. This was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Basically, a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. The machine was to be located near -- specifically adjacent -- to the physical area of the pharmacy.

A number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive.

This regulation was promulgated cautiously. Throughout 2006, the board modified and adopted the regulation now in effect as section 1713. In January 2007, the regulation actually took effect. A copy of this regulation section is in **Attachment 2**.

Request

During the January 2010 Board Meeting, Phil Burgess representing Asteres made a presentation to board seeking a waiver from 1713(d) to allow automated dispensing machines to be located in areas other than the requirements of this section that restrict the automated dispensing machine to be adjacent to the secure pharmacy area. At that time the board asked Mr. Burgess to refine his request and return to the board so the board would more fully understand the proposal. A copy of Mr. Burgess' original request is provided in **Attachment 2** as well as a summary of the discussion from the January 2010 Board Meeting.

During the June Enforcement Committee Meeting, Mr. Burgess requested that the board waive regulation section 1713(d)(6) regarding the placement of automated medication dispensing machines in hospitals to allow for the installation of the ScriptCenter "pickup" system in a hospital environment whereby the unit is not directly attached to the pharmacy. He made a second request for a special waiver to allow for a pilot of this system to demonstrate that improved access will increase medication adherence. Mr. Burgess indicated that he would like the waiver for a five year period.

Committee Discussion/Action

The committee discussed the proposals and sought clarification on the potential impact of the request. In response Mr. Burgess specified that use of this machine would be limited to hospital employees that elect to use this system and detailed the security measures.

Mr. Burgess was advised that his request to allow for a pilot of this system must be done in a research project in conjunction with a school of pharmacy as provided for in CCR 1706.5. The committee did not take action on this item.

Post Meeting Update

Since the last committee meeting, the executive officer has had several conversations with Asteres staff. Asteres is unsure if it wishes to request the board to make a regulation change or go establish a research project through a school a pharmacy to evaluate whether use of these machines for hospital staff will increase medication adherence by the staff.

During this Meeting

At the time of this writing, no additional information from Asteres is available. A representative from Asteres will need to present either request the board consideration at this or a future meeting. Counsel will be available to discuss any legal issues surrounding these requests.

c. **FOR INFORMATION: Discussion of a Drug Distribution Model Proposed by Medco Health Solutions, Using Two Pharmacies, Each with Specialized Functions.**

Attachment 3

Background

Title 16, CCR section 1707.4 authorizes a licensed pharmacy to process a refill request received by another pharmacy. A copy of this section is in **Attachment 3**.

Proposal

Under this proposal, a patient comes into a community pharmacy and receives medication adjudicated by Medco. The prescription is then either filled by the community pharmacy, or filled by Medco and shipped to the community pharmacy for dispensing. A copy of the proposal is provided in **Attachment 3**.

Committee Discussion/Action

The committee was provided with a presentation from Medco highlighting a drug distribution model that is currently being pilot tested in several states. The committee discussed the model process. It was clarified that in instances where the medication is not picked up by the patient, the pharmacy will destroy the medication through a reverse distributor. All documentation and records will be available for the board for inspection. The committee did not take action on this item. Medco was advised that the model appears consistent with pharmacy law. Medco indicated that they would provide both pharmacies' names and address on the prescription label.

During this Meeting

A representative from Medco will be available to answer questions. No action is required by the board on this item.

d. **FOR DISCUSSION AND POSSIBLE ACTION: Update and Possible Action to Initiate a Rulemaking on the Board's Efforts to Implement Components of the Department of Consumer Affairs' Consumer Protection Enforcement Initiative**

Attachment 4

Since July 2009, the Department of Consumer Affairs has been working with the health care boards to upgrade their capabilities to investigate and discipline errant licensees to protect

the public. The proposed changes include three areas: 1) additional resources, 2) a new computer system and 3) legislative changes. The goal is to ensure the average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months. Formal discipline means those cases which are the most serious, and for which license removal or restriction is being sought.

Many of the legislative changes were incorporated into SB 1111 (Negrete-McLeod). During the April 2010 Board Meeting, the board was advised that SB 1111 failed passage in a policy committee, so the board did not discuss SB 1111 in any detail during that meeting.

Following this, the department identified provisions contained in the bill that could be implemented through regulations, and directed that all healing arts boards develop language and initiate the rulemaking process.

During the June 2010 Board Meeting, the board reviewed draft regulation language for some changes. The identified sections were:

- Amendment to Section 1760 – Disciplinary Guidelines. The proposed amendment would specify that any proposed decision that includes findings of fact that include that a licensee engaged in sexual contact with a patient, client or customer, or a licensee convicted of a sexual offense shall contain an order of revocation. The proposed change provided an exception to this and also defined sexual contact. The board took no action on this proposal.
- Amendment to Section 1762 – Unprofessional Conduct. The proposed amendment to this section would specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide requests as requested by the board; failure to comply with a court order or subpoena for records; and failure to notify the board an arrest, indictment, conviction or discipline as specified. The section also specified that the board is authorized to revoke a license or deny an application for an act requiring an individual to register as a sex offender. It was the consensus of the board to bring this issue back to a future meeting for discussion.
- Amendment to Section 1769 – Application Review and Criteria for Rehabilitation. The proposed amendment would allow the board to request that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice. The board voted to require that once it has been determined that an applicant is to be evaluated; the evaluation shall be completed within 60 days. Within 60 days of the evaluation, the report shall be received from the evaluator.
- Amendment to Section 1770 – Substantial Relationship Criteria. The proposed amendment would specify that a crime or act that resulted in a licensee being required to register as a sex offender would be considered substantially related to the functions and qualification of the license. The board did not take action on this proposal.

Attachment 4 contains a copy of the regulation language that was discussed during the June 2010 Board Meeting. Additional items for consideration will be discussed at the next enforcement committee and will be brought to the board for consideration in October.

Committee Discussion/Action

The committee did not discuss the proposed regulations changes at its June 16 meeting since they had been discussed during the board meeting held six days earlier. However the

committee was advised that board staff has evaluated the board's enforcement processes for improvements, and identified 8 improvements that could be implemented to improve board efficiency and reduce investigation time, without compromising enforcement activities. Below is a summary of these changes initiated to date as well as the status.

1. Complete case assignments on line.
Status: Completing testing of the new process. Staff is working to finalize written procedures.
2. Complete review of draft accusations on line
Status: Accusations are now reviewed on line by field staff. Staff will finalize written procedures.
3. Prescreen complaints at assignment with an AGPA (associate analyst) – the AGPA would follow up to ensure that complaints are assigned. Screen out non-jurisdictional and close or refer as appropriate.
Status: Training is complete and this provision is implemented. As indicated in previous months, this is a temporary solution, and full implementation cannot be achieved without additional staff resources.
4. AGPA to complete license history instead of board inspector including past complaint investigation assignments, violations and outcomes of investigations, also previous inspections, date and who performed the inspection.
Status: A draft template has been developed; however, policies and procedures are not yet in place. Initiated a pilot with limited investigator staff to assess value to inspectors.
5. Develop a method to automatically populate information on the investigation report instead of using expensive inspector time.
Status: A draft template has been developed, however policies and procedures are not yet in place. Initiated pilot with limited investigator staff.
6. Train non-attorney staff to prepare default decisions to speed investigation closures.
Status: Training completed. Board staff preparing some default decisions in-house.
7. Secure automated fingerprint background checks and criminal record information from the Department of Justice.
Status: Implemented and staff trained.
8. Begin drafting some Petitions to Revoke Probation in house.
Status: Internal staff completed first PTR. Draft is currently undergoing review.

A report is submitted monthly to the department on the board's continued efforts. Board staff has identified additional changes; however implementation of many of these items cannot begin until additional resources are available.

e. **FOR DISCUSSION: Update on the California Drug "Take Back Programs from Patients.**

Attachment 5

Background

Senate Bill 966 required CalRecycle to work with agencies including the Department of Toxic Substances Control, the State Water Resources Control Board, and the California State Board of Pharmacy to develop criteria and procedures for model pharmaceutical waste collection programs by December 2008. SB 966 also required CalRecycle to analyze model programs for

effectiveness, cost, accessibility, and safety. These findings must be included with recommendations in a report to the Legislature by December 2010.

Since 2007 the board has been discussing drug “take back” programs. Such programs are growing in popularity as consumers look for a safe, convenient and environmentally friendly way to dispose of unused medicine. Further, environmentalists continue to advocate for such programs to reduce the amount of such medicine that ends up in our water supply and landfills.

The board has heard presentations from vendors making collection containers for pharmacies, heard concerns from the Department of Public Health, and has worked with the California Integrated Waste Management Board (now Cal Recycle) to establish parameters for these programs.

In the February 2010 *The Script*, the board promoted the take-back guidelines developed by the California Integrated Waste Management Board pursuant to SB 966 (Simitian, Chapter 542, Statutes of 2007).

Since April, board inspectors have been directed to take pictures of drug take back programs in place in pharmacies, and to encourage compliance with the state’s guidelines.

The Drug Enforcement Administration continues to be concerned about these programs nationally, and is working with counties that are establishing principally short-term take back programs for controlled drugs. In some communities, law enforcement is working under the DEA’s preference to accept take back controlled drugs at law enforcement facilities.

Committee Discussion/Action

During its meeting, the committee was advised that the Cal Recycle Program was holding a workshop on home-generated pharmaceutical waste collection and disposal on July 20, 2010. No action was taken on this item.

Post Meeting Update

Board staff attended the July meeting with the committee chair. This meeting was convened to discuss a draft report assessing implementation of the proposed guidelines developed in late 2008 for California by the CIWMB/Cal Recycle. A copy of this draft 2010 report to the Legislature on drug take back programs operating under the model guidelines, as required by SB 977, is provided in **Attachment 5**.

There are four proposals arising from the report:

1. Continue Current Practices
2. Improve Guidelines, Enforcement and Establish Clear State Agency Roles and Responsibilities
3. Implement Product Stewardship
4. Create a Statewide Collection Program Using an Advanced Disposal Fee and State Oversight.

These appear on pages 33-38 of the report.

During this Meeting

The Board may wish to discuss the Model Guidelines developed for drug take back (provided in **Attachment 5**). As these guidelines have no effect of law, the board may want to encourage that the elements of them be incorporated into legislation so they can be enforced. If the board so chooses, comments must be provided to Cal Recycle by August 17, 2010.

f. **FOR DISCUSSION: Question and Answer Session on the Board's Implementation of the Compounding Regulations.**

Background

Beginning in 2004, the board facilitated meetings with industry to established regulations for pharmacies that compound. As a result, the board developed regulations to define the parameters under which a pharmacy can compound. These regulations took effect on July 6, 2010.

Committee Discussion/Action

During the meeting, Supervising Inspector Bob Ratcliff responded to questions submitted in advance of the meeting, as well as questions from attendees. These questions and answers appear in the minutes of this June 16 meeting.

Post Meeting Update

Board staff will develop a fact sheet based on the questions and answers, and this fact sheet will be posted on the board's Web site. Board staff will continue to take questions and will update the Q&A's. The board or committee may wish to designate additional time for another Q&A session at a future meeting.

g. **FOR DISCUSSION: Pharmacies Dispensing Prescriptions for Internet Web Site Operators.**

Attachment 6

Background

California Business and Professions Code section 4067 prohibits a person from dispensing a drug on the internet without a prescription issued pursuant to a good faith medical examination. (A copy of this section is provided in **Attachment 6**.)

At the December Enforcement Committee, the committee was advised that the board's inspectors have investigated a number of cases where California pharmacies are filling prescriptions from Internet Web sites in situations where patients are in a number of states, a prescriber is writing prescriptions for the patients from a single state, and the California pharmacy is filling the prescription.

Many times these prescriptions are not valid because an appropriate exam by a prescriber has not occurred. California law allows the board to issue citations at \$25,000 per invalid prescription delivered to patients in California. Often these drugs are controlled drugs or other non-controlled drugs of abuse (e.g., Soma, Tramadol).

Over the last 18 months, the board has issued multiple million dollar fines to California pharmacies for filling such false prescriptions. The Drug Enforcement Administration is also involved in some of these Web site investigations and has fined California pharmacies for their participation.

Pharmacies are facilitating the illegal distribution of prescription drugs from the Internet. From discussion with the owners of several of these pharmacies investigated by the board, the pharmacies receive an offer via a faxed notice offering amounts as low as between \$3 and \$6 per prescription plus drug costs to fill these orders. However the economics greatly benefit the Web site operator. The patient may pay \$100 to \$200 purchase a prescription from the Internet – the pharmacy may get \$6 or \$10 from such a sale.

Committee Discussion/Action

The committee discussed the issue and was provided with a listing of significant fines issued in the last year to California pharmacies aiding internet providers in the distribution of prescription drugs with a valid prescription. It was suggested that additional legislation may be need that that the Enforcement Committee could identify solutions and refer them to the Legislation and Regulation Committee. No action was taken on this item.

h. FOR INFORMATION: Post Implementation Review of the Board's Criminal Conviction Unit

Background

Included as part of last year's budget, was a staff augmentation for the board to establish the Criminal Conviction Unit within the board. This specialized unit was created to address the significant increase in the number of subsequent arrest notifications that the board receives, in part because of an increase in our licensing population, but mainly because of the transition the Department of Justice made to an automated system.

Committee Discussion/Action

The committee was advised on the significant progress of the unit after one year.

On of July 1, 2009, there were 1708 investigations pending. As of June 1, 2010, that number was reduced 629 investigations pending. Additionally over 1900 cases have been completed. Below is a snapshot of the final disposition of those cases.

Referred for Formal Discipline	190
Citation and Fine Issued	112
Letter of Admonishment Issued	152
B&PC 4301 Letter Issued	633
Closed No Further Action	785
Closed Referred to PRP	2
Closed Other	30
Closed No Violation	1
	<hr/>
	1,905

This unit was envisioned to be a "beginning to end" unit, meaning that the staff would not only complete the investigation, but also complete the final processing as well, e.g., issue the citation and fine, refer the matter to the Office of the Attorney General, etc. (This workload is

currently being processed by other staff but is impacting other workload priorities.) The committee was advised that as we continue to reduce the number of pending investigations, staff will begin training in these other functions to ensure the final resolution is achieved timely, consistent with our consumer protection mandate. No action was taken on this item.

i. FOR DISCUSSION: Update of the Committee's Strategic Plan 2010-11.

Attachment 7

Background

Each fiscal year, the board updates its strategic plan. The current plan was developed in 2006-07 with the assistance of a consultant. Since then, each year the board has reviewed and as necessary revised its strategic plan. These are typically minor adjustments and additions.

As part of the Organizational Development Committee Report scheduled for tomorrow, the board will be voting on the strategic plan in its entirety for 2010/11.

Committee Discussion/Action

The committee was provided with suggested additions to the strategic plan for consideration and discussion.

The committee voted to approve the 15 tasks identified in Objective 1.5 in the Enforcement Committee's Strategic Plan and add the following additional tasks:

16. Complete review of pharmacies dispensing prescriptions for Internet web site operators
17. Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB)

A copy of the committee's Strategic Plan for 2010/11 is provided in **Attachment 7**.

j. Minutes of the Meeting Held June 16, 2010.

Attachment 8

A summary of the meeting held on June 16, 2010 is provided in **Attachment 8**.

OTHER ENFORCEMENT ITEMS

k. Changes to Current Regulations and Statutory Requirements to Implement the Uniform Standards Recommended by DCA's Substance Abuse Coordination Committee (per SB 1441) Ridley-Thomas, Chapter 548, Statutes of 2008)

Attachment 9

Background

In 2008, SB 1441 was enacted to direct health care boards with so called "diversion programs" for health care licensees to establish department-wide minimum standards for participation. (Technically, a diversion program stops discipline in favor of rehabilitating a licensee with a

substance abuse problem, so long as he/she remains abstinent.) These mandatory standards would apply to those in a diversion program as well as those licensees who are on probation for substance abuse violations.

The board has its Pharmacists Recovery Program, which serves the board's public protection mandate by closely monitoring program those with substance abuse or other specified conditions. However, the PRP is not a diversion program. Instead, the board encourages a licensee under investigation for a substance abuse program to enter the program in advance of the board's formal discipline. Thus the licensee enters a strict monitoring program while the investigation and enforcement processes continue.

There are 16 of these standards under development by a committee comprised of board executive officers. The standards are not yet finalized, but are nearing completion. A copy of the standards is provided in **Attachment 9**.

At the request of the department, each health care board was to review and begin necessary actions to implement these standards. Board Counsel Schieldge identified whether each standard needs statutory and/or regulation modifications. In addition the standards were reviewed for compliance with the board's contract with the vendor that administers the PRP.

Recent Action

Recently the department requested that each affected board submit a report documenting their efforts to implement these standards. **Attachment 9** is a copy of the report that was provided to the Deputy Director of Enforcement in July.

I. FOR INFORMATION: Enforcement Statistics 2009/10

ATTACHMENT 10

Attachment 10 includes the enforcement statistics for 2009/10. Also provided are 5 year comparison charts detailing the growth the board's enforcement activities.

m. FOR INFORMATION: Fourth Quarterly Report of the Committee's Goals for 2009/10

ATTACHMENT 11

Attachment 11 contains a fourth quarter's status of Enforcement Committee Goals.

ATTACHMENT 1



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

May 7, 2010

Drug Enforcement Administration
Attn: DEA Federal Register Representative/ODL
8701 Morrisette Drive
Springfield, VA 22152

RE: COMMENTS OF THE CALIFORNIA STATE BOARD OF PHARMACY
Request for 120-day Extension of the Comment Period, to October 1, 2010
Docket No. DEA—218I: *Electronic Prescriptions for Controlled Substances*

To Whom It May Concern:

I write on behalf of the California State Board of Pharmacy (Board). We are pleased to respond to Docket No. DEA—218I, an Interim Final Rule (IFR) and Request for Comment titled *Electronic Prescriptions for Controlled Substances*. As we remarked in our September 15, 2008 comments on the initial Notice of Proposed Rulemaking (NPRM), we are encouraged that the Drug Enforcement Administration (DEA) is actively moving to permit electronic prescribing (e-prescribing) for controlled substances. We believe that widespread adoption of e-prescribing has significant potential to reduce medication errors and associated outcomes, and that the ability to use e-prescribing for controlled substances is necessary to encourage widespread adoption. In our prior comments, we urged you to consider the value of widespread adoption, and to balance that interest against our shared interest in maintaining a secure drug delivery system. We thank you for the effort you have put into reviewing and responding to all of the comments received.

We have so far conducted only a preliminary review of the IFR, and have not yet had the opportunity to either engage in extensive analysis or receive and review analyses of the IFR from the affected industries, the public, or other stakeholders. Our comments on the NPRM benefited from the input of affected and interested parties. We would like any comments we might submit on the IFR to have that same benefit. However, the present deadline for response (June 1, 2010) does not provide us with enough time to review any such input in aid of meaningful comments. In particular, it may take some time for industry members and/or third-party vendors to assess or assimilate the technical requirements imposed by the IFR, and for us to understand based on their input and our own analysis the magnitude and necessity of any burden(s) imposed thereby.

To ensure that both we and other persons that might wish to submit comments on the IFR have an adequate opportunity to do so, we are requesting that you extend your own deadline¹ for submission of comments by 120 days, to October 1, 2010. This will provide a total of 180 days in which to submit comments. We believe that is a more appropriate comment period.

¹ We understand that this deadline may also be separately extended by congressional review.

Again, we applaud your efforts in proposing the draft regulations, and emphasize that we view ourselves as joined with you in this task of ensuring a safe and secure prescription delivery system for controlled substances. We are greatly encouraged that the DEA has taken the step of defining an appropriate system for e-prescribing controlled substances. The document you have produced is impressive in its scope and its complexity. We would like to be of assistance in this project, and request additional time to be sure that any further input we provide is well-informed.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together, on this and on other matters. Please feel free to contact the Board at any time if we can be of assistance to you. The best route for contact is via Executive Officer Virginia Herold, at (916) 574-7911, or Virginia_Herold@dca.ca.gov.

Sincerely,

A handwritten signature in cursive script that reads "Kenneth H. Schell".

KENNETH H. SCHELL
President, California State Board of Pharmacy

ATTACHMENT 2

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be to or from Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Ms. Herold:

On behalf of Asteres, we hereby request an appearance before the California Board of Pharmacy at the January 20/21 meeting in Sacramento.

The purpose of our appearance will be to seek approval for the installation of an automated prescription "pick up" system in a hospital environment whereby the unit is not directly attached to the pharmacy.

Upon review of Section 1713, we feel that the Board has regulatory authority to grant this request based upon Paragraph 1713 (b) which states in part:

"In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause. Subdivision (a) contains the language prohibiting the picking up of prescriptions from "any place not licensed as a retail pharmacy". We will be prepared to justify this action by the Board demonstrating how that the unit will be in a high-traffic, secure area on the hospital campus and that a telephone installation immediately adjacent to the unit will allow readily available access by the patient to a pharmacist for counseling.

Failing this argument, then we would request a specific waiver from Section 1713 (d) (6) requiring that "the device is located adjacent to the secure pharmacy area". We are prepared to have representatives appear from California hospitals to represent to the Board that by allowing flexibility in the placement of these "pick-up" devices on their campuses, that the net result will be to improve patient compliance and thereby improve patient care. Asteres will present past history to show to the Board that these devices can be installed in an area not adjacent to the pharmacy, yet in a secure manner..as well as in a manner where counseling by a pharmacist to the patient will be equally if not more readily available than in a standard retail environment.

Thank you for your consideration.

Phil

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Excerpt of the Minutes of January 22, 2010 Board Meeting:

Presentation - Phil Burgess and Mike de Bruin, Asteres

Phil Burgess, representing Asteres, provided an overview of ScriptCenter, a 24/7 automated pharmacy prescription pick-up machine including the registration and authorization process. He reviewed patient safety and security benefits and added that ScriptCenter has successfully delivered over 450,000 prescriptions without one delivery error.

Mr. Burgess requested that the board waive regulation Section 1713(d)(6) regarding the placement of automated medication dispensing machines in hospitals.

Board Discussion

Mr. Brooks sought clarification regarding how a pharmacy obtains a ScriptCenter machine.

Mike de Bruin provided that there are multiple methods of acquisition strategies.

Burgess provided that each machine will have a phone located adjacent to the machine to allow the patient to immediately contact the pharmacist.

Mr. Lippe asked if the patient will be charged a transaction fee.

Mr. Burgess provided that no transaction fee is charged.

Mr. de Bruin provided that the machine will collect the patient's insurance co-pay.

Ms. Herold sought clarification regarding if it is intended for the machine to be made available to both hospital staff and patients.

Mr. Burgess indicated that Asteres would like the machine to be available to both hospital staff and patients. He provided that only refill prescriptions would be filled and the machine would only be located on the hospital campus in a secure environment, not necessarily in a hospital.

Mr. Room asked if any machines have been installed outside of a hospital campus.

Mr. de Bruin provided that machines have been installed in other areas in other states.

Mr. Room provided that this request may not be granted under a Section 1713 waiver.

Discussion continued regarding the ScriptCenter system and its applicability to pharmacy law and Section 1713. Advantages and disadvantages of the system were evaluated. Concern was expressed that this process may depersonalize the pharmacist and prescription service. It was clarified that in the event a waiver is granted, the waiver would be granted to the licensed facility and not to Asteres.

Public Comment

Dr. Allan Schaad, representing Catholic Healthcare West (CHW), provided that CHW would like to provide ScriptCenter as a service to their employees.

Dr. Castellblanch sought clarification regarding why the waiver is also being requested for patients.

Mr. Burgess provided that the machine can benefit the spouses of employees and children of employees.

Discussion continued regarding the request and the placement of the machine in a secure area on the hospital campus. Concern was expressed that the request does not specify placement of the machine.

Dr. Steve Gray, representing Kaiser Permanente, offered support for the ScriptsCenter concept. He encouraged the board to grant a waiver under Section 1713 (b) for employees and to consider further discussion of a waiver for other patients.

Mr. Weisser sought clarification regarding mail order prescriptions and patient requests for phone consultations with a pharmacist.

Dr. Gray provided that in the rare event that a patient does have a question, they can often get their questioned answered faster by calling a pharmacist than if they were to wait in line at a pharmacy.

Mr. Burgess provided that the ScriptsCenter machine allows for a pharmacist to be available to the patient when the adjacent pharmacy is closed during off hours.

Ms. Herold provided that pharmacies using such a device are required to provide immediate access to a telephone for patients to contact a 24-hour pharmacy in the event their pharmacy is closed.

Ms. Herold indicated that board staff will provide some guidelines to assist Asteres with providing the required clarification regarding their request.

There was no additional board discussion or public comment.

ATTACHMENT 3

California Code of Regulations

1707.4. Procedures for Refill Pharmacies.

(a) A pharmacy licensed by the board may process a request for refill of a prescription received by a pharmacy within this state, provided:

(1) The pharmacy that is to refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.

(2) The prescription container:

(A) is clearly labeled with all information required by Section 4076 of the Business and Professions Code; and

(B) clearly shows the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient.

(3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.

(4) Both pharmacies maintain complete and accurate records of the refill, including:

(A) the name of the pharmacist who refilled the prescription;

(B) the name of the pharmacy refilling the prescription; and

(C) the name of the pharmacy that received the refill request.

(5) The pharmacy which refills the prescription and the pharmacy to which the refilled prescription is provided for dispensing to the patient shall each be responsible for ensuring the order has been properly filled.

(6) The originating pharmacy is responsible for compliance with the requirements set forth in Section 1707.1, 1707.2 and 1707.3 of the California Code of Regulations.

(b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.

Authority cited: Section 4005, Business & Professions Code. Reference: Sections 4063, 4076, 4081 and 4333, Business & Professions Code.

Overview: Medco intends to participate in agreements whereby it provides services to community pharmacies in a Central Fill/Central Processing arrangement. These services will generally be the filling of the prescription; however, when circumstances warrant may include, but not limited to prescriber and patient contact, Drug Utilization Review, data entry and dispensing.

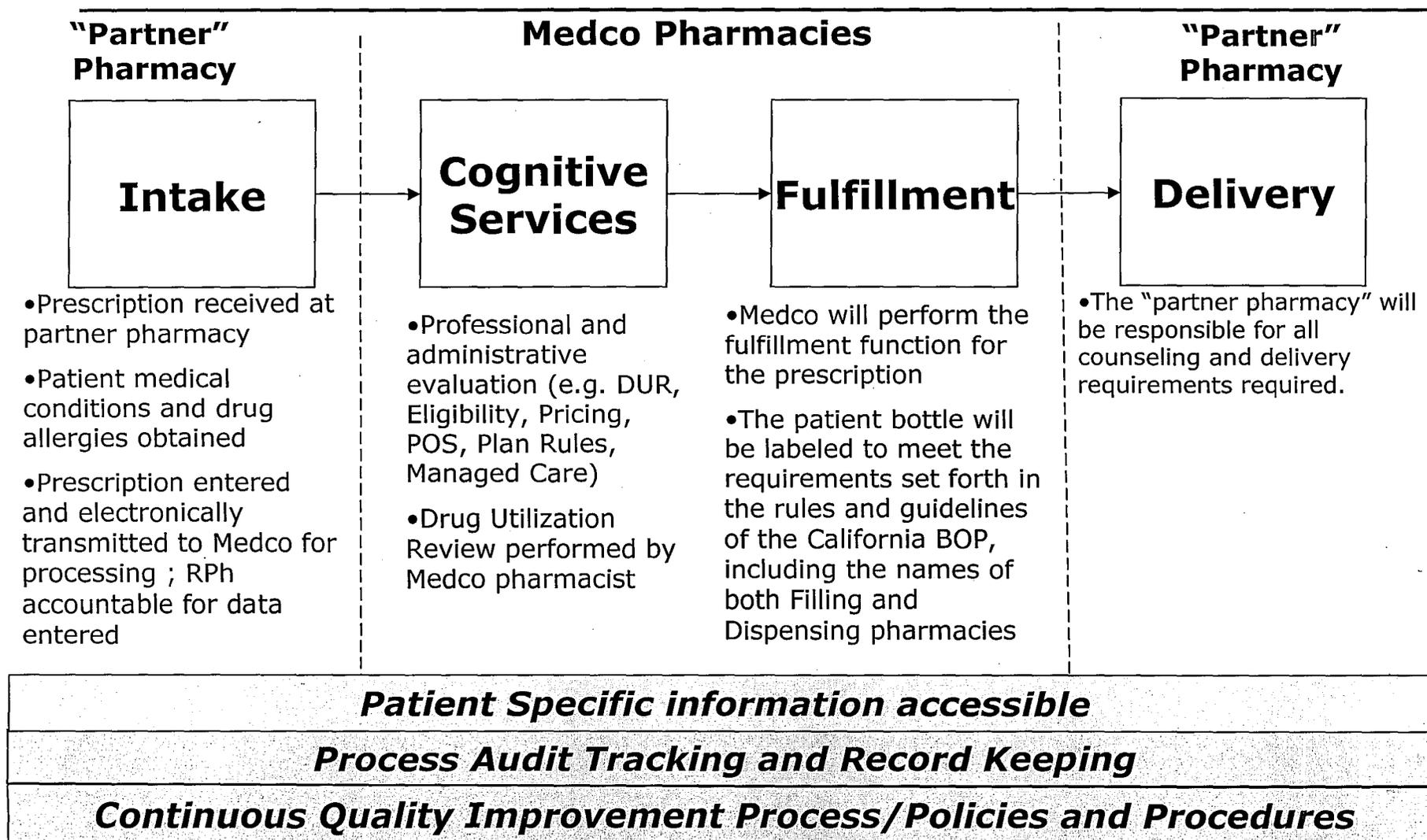
California Resident Community Pharmacies: Medco intends to enter into Central Fill/Central Processing arrangements with community pharmacies resident in the state of California and licensed by the Board. The prescriptions will be filled at Medco pharmacies in states other than California and returned back to the California community pharmacy for delivery. It is understood that as the delivery pharmacy will be located in California, the rules of the California Board of Pharmacy will prevail.

The following describes specific situations:

1. In those instances where the medication is not picked up by the patient, the pharmacy will destroy the medication through a reverse distributor. All documentation will be available for the Board for inspection.
2. The community pharmacy will have access to the patient's medication history dating back one year. The active prescriptions (those dispensed in the last six months) will be available through an active process. The remaining six months will be available to the pharmacist through a retrieval process.
3. Medco will perform DUR prior to dispensing the prescription. The results of the DUR and any interventions will be communicated to the community pharmacy.
4. The community pharmacy will provide the necessary patient counseling consistent with California rules upon delivering the prescription to the patient.

Since, it is Medco's desire to enter into this arrangement with multiple partners in the state, Medco will utilize a Medco assigned number on the prescription bottle so as to eliminate the possibility of duplicate prescription numbers. As part of a participation agreement the community pharmacy will have a system in place that will cross reference this unique number to the original prescription number and this functionality can be demonstrated to the Board. Such a system will prevent the assignment of duplicate prescription numbers, which could result in errors when prescription refills are requested.

California Community Pharmacy Centralized Prescription Processing Workflow



ATTACHMENT 4

Proposed amendments to section 1760 of Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled “Disciplinary Guidelines” (Rev. ~~10/2007~~ 6/2010), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

(a) Notwithstanding the disciplinary guidelines, any proposed decision issued by an Administrative Law Judge in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code that contains any findings of fact that: (1) the licensee engaged in any act of sexual contact with a patient, client or customer; or, (2) the licensee has been convicted of or committed a sex offense, shall contain an order revoking the license. The proposed decision shall not contain an order staying the revocation of the license or placing the licensee on probation.

(b) Subdivision (a) shall not apply to sexual contact between a pharmacist and his or her spouse or person in an equivalent domestic relationship when that pharmacist provides services as a licensed pharmacist to his or her spouse or person in an equivalent domestic relationship.

(c) For the purposes of this section, “sexual contact” has the same meaning as defined in subdivision (c) of Section 729 of the Business and Professions Code and “sex offense” has the same meaning as defined in Section 44010 of the Education Code.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

Proposed addition of Section 1762. to Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1762. Unprofessional Conduct Defined

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later, unless the licensee is unable to provide the documents within this time period for good cause. For the purposes of this section, "good cause" includes physical inability to access the records in the time allowed due to illness or travel.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Failure to report to the board, within 30 days, any of the following:

(1) The bringing of an indictment or information charging a felony against the licensee.

(2) The arrest of the licensee.

(3) The conviction of the licensee, including any verdict of guilty, or pleas of guilty or no contest, of any felony or misdemeanor.

(4) Any disciplinary action taken by another licensing entity or authority of this state or of another state or an agency of the federal government or the United States military.

(e) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority cited: 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301 Business and Professions Code.

Proposed amendments to Section 1769. of Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1769. Application Review and Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The report of the examiners shall be made available to the applicant. The board shall pay the full cost of such examination. If after receiving the report of evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 480, 482, 820, 4030, 4200 and 4400, Business and Professions Code.

Proposed amendments to Section 1770. of Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1770. Substantial Relationship Criteria.

(a) For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

(b) An applicant's, licensee's or registrant's crime or act shall be considered to be substantially related to the qualifications, functions or duties of the license or registration if such crime or act resulted in the licensee or registrant being required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law.

Authority cited: Sections 481, 4005, Business and Professions Code. Reference: Sections 475, 480, 481, 4200, 4300, 4309 and 4301, Business and Professions Code.

ATTACHMENT 5

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 pharmaceuticals¹. 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 pharmaceutical 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 donors. 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 Division 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 approved 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 as 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.

Evaluation of Home-Generated Pharmaceutical Programs in California

CalRecycle Background Paper
for July 20, 2010 Workshop

Issued July 12, 2010

Contents

I. Introduction	4
1. Senate Bill 966 (SB 966)	4
2. Purpose of Background Paper	4
II. Program Surveys and Results	7
1. Program Surveys	7
2. Number of Model Programs by Type	9
3. Program Evaluations for Safety, Accessibility, Cost Effectiveness and Efficacy	10
• Safety (Security)	11
• Statewide Accessibility (Accessibility)	14
• Cost Effectiveness	16
• Efficacy (Collection Rate)	19
• Summary Ranking for all four factors by collection program type	22
III. Challenges and Barriers	24
1. Safe Collection of Pharmaceuticals is Expensive.	24
• Collection of Controlled Substances	24
• Registered Waste Haulers & Disposal Facility Options	25
• Two Key Locking Collection Bins	25
• Use of Secure Containers at HHW Sites	25
• Record Keeping and Data Collection	26
2. Lack of Public Awareness and Participation	26
3. Lack of Sustainable Funding	26
4. Lack of Goals	26
5. Unclear Requirements, Policies & Authority	27
• U.S. Drug Enforcement Administration (DEA)	27
• California Board of Pharmacy	27
• Department of Toxic Substances Control (DTSC)	27
• California Department of Public Health (CDPH)	28
IV. Overview of Programs Outside of California	28
1. International Guidelines and Programs	28
• World Health Organization (WHO)	28
• European Union	28
• Canada	29

2. National Programs.....	30
• Federal Legislation and Regulations	30
• Proposed Federal Legislation	31
• Nation-wide efforts.....	31
3. State Programs	31
• Proposed State-Level Legislation	33
V. Potential Options for Further State Action.....	33
Option 1. Continue Current Practices	34
Option 2. Improve Guidelines, Enforcement, and Establish Clear State Agency Roles and Responsibilities	35
Option 3. Implement Product Stewardship.....	36
Option 4. Create a Statewide Collection Program Using an Advanced Disposal Fee and State Oversight	37
Parting Comments.....	39
VI. Source Reference Notes.....	40

I. Introduction

1. Senate Bill 966 (SB 966)

Enacted in 2007, Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) addresses improper disposal of pharmaceutical waste into sewer systems that results in pharmaceuticals entering waterways and drinking water. The goal of SB 966 is to establish a program through which the public may conveniently return drugs for safe and environmentally sound disposal.

SB 966 directed the California Integrated Waste Management Board, which is now the California Department of Resources Recycling and Recovery (CalRecycle), to:

1. Establish final criteria and procedures for model collection programs by December 2008.

CalRecycle worked closely with numerous agencies, including the California Department of Public Health (CDPH), the Department of Toxic Substances Control, the State Water Resources Control Board, and the California State Board of Pharmacy, and considered stakeholder input to develop criteria and procedures for model pharmaceutical waste collection programs. CalRecycle adopted *Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs*¹ (Guidelines) in November 2008, with a subsequent revision in February 2009. Programs are not required to follow these *Guidelines* but they must be consistent with them in order to be a model program under SB 966.

2. Evaluate model collection programs in California

CalRecycle sent surveys to all known programs that collect home-generated pharmaceuticals in California. This paper presents the results of these surveys.

3. Report to the Legislature by December 2010.

As required by SB 966, CalRecycle will include the following components:

- An evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness;
- Consideration of the incidence of diversion of drugs for unlawful sale and use, if any; and
- Recommendations for the potential implementation of a statewide program and statutory changes.

2. Purpose of Background Paper

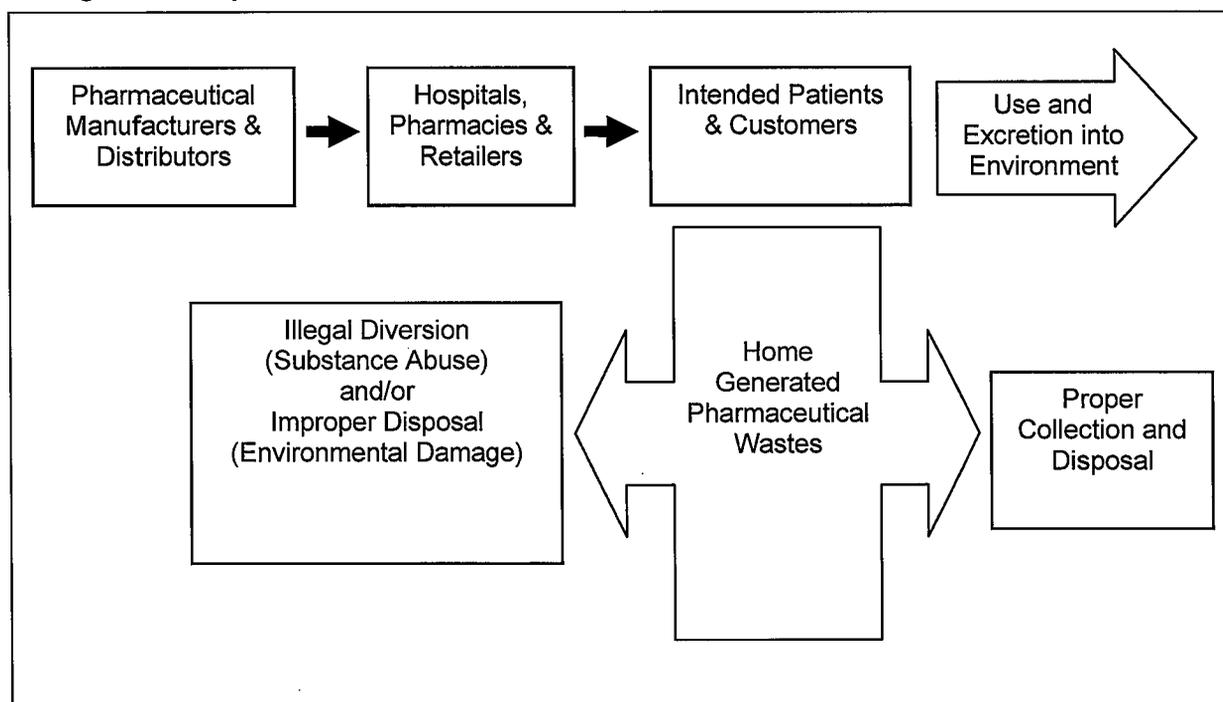
This paper will serve as a basis for discussion at the July 20, 2010, "California's Model Drug Collection Program Workshop" and it will serve as foundational material as CalRecycle prepares the required report to the Legislature. This material is intended to stimulate discussion and input from stakeholders and affected parties.

This paper includes:

- **Program Surveys and Results (Section II):** The types and number of home-generated pharmaceutical waste collection programs in California, the number that meet the Guidelines for model programs within each type, and an evaluation of programs based on the four factors in SB 966 (safety, statewide accessibility, cost effectiveness and efficacy);
- **Challenges and Barriers (Section III):** Some of the challenges to program implementation;
- **Overview of Programs Outside of California (Section IV):** National and international programs; and,
- **Potential Options for Further State Action (Section V):** Preliminary analysis of potential options for state action.

Figure 1 shows a simplified view of the flow of pharmaceuticals, including both prescription medications and non-prescription (over-the-counter) medications. This paper only deals with one aspect of the life cycle of pharmaceuticals, specifically the post consumer fate of unused pharmaceuticals that become home-generated pharmaceutical waste. This paper discusses current efforts and future options to properly collect and dispose of this home-generated pharmaceutical waste in ways that minimize illegal diversion (potentially leading to substance abuse) and improper disposal (potentially leading to environmental damage).

Figure 1. Simplified Flow of Pharmaceuticals



Based on information available to CalRecycle, collection programs in California collect approximately 200,000 pounds of home-generated pharmaceutical waste per year. However, this is likely a small percentage of all home-generated pharmaceutical waste. There is not a definitive estimate of the amount of home-generated pharmaceutical waste in California. However, several sources suggest that a very large amount is sold and that a significant percentage subsequently becomes waste in California:

- In California pharmacies, the total retail sales for filled prescription drugs in 2009 (not including over-the-counter drugs or mail order prescriptions) reached nearly \$19 billion for more than 300 million prescriptions.²
- The Associated Press estimated that Americans generate at least 250 million pounds of pharmaceuticals and contaminated packaging in medical facilities each year.³ Relative to California population, that would be approximately 30 million pounds in California hospitals alone.
- Some estimates suggest that 10% to 33% of all pharmaceuticals go unused.⁴ There is not universal agreement on these percentages, with some studies reporting as little as 3% unused while others report that 50% or more are unused.⁵
- In addition, the number of prescriptions per 100 people has increased between 1995 and 2008 from 0.8 to 1.2 nationwide.⁶ Considering our aging population, this trend is likely to continue.

Several topics that are not within the direct scope of this analysis but which are related to the topic are listed below. The paper does not discuss some further, while others are discussed when necessary as they relate to the collection programs:

- Excretion. While human excretion is a major pathway for pharmaceuticals to reach the environment, it occurs before pharmaceuticals become home-generated wastes. The latter issue, home-generated wastes, is the focus of this background paper.
- Drug Distribution Solutions. While fewer prescriptions, reduced sales of pharmaceuticals, or changes resulting in more complete usage of medications could result in a lower amount of home-generated pharmaceuticals, these actions would occur before pharmaceuticals become home-generated wastes.
- Controlled Substances. SB 966 specifically states that it does not apply to controlled substances; however, they are mentioned in this report because their special requirements impact collection programs for other home-generated pharmaceutical wastes.
- Reverse Distributors. Reverse distributors collect unused and expired medication from hospitals and pharmacies and in return provide monetary credit or disposal of that waste. This activity occurs before pharmaceuticals become home-generated wastes. In addition, several concerns exist regarding applying this concept to home-generated wastes.*

* Once dispensed, medications may be tampered with, kept in inappropriate conditions, and become unfit for redistribution. According to the California Board of Pharmacy, a reverse distributor may not accept previously dispensed medicine & may not have sufficient safety standards to prevent illegal drug diversion.

II. Program Surveys and Results

1. Program Surveys

During April and May 2010, CalRecycle sent surveys to 67 program managers that represented all known home-generated pharmaceutical collection programs.[†] This paper includes results based on the surveys submitted by June 10, 2010.

Many program managers represented more than one program and often more than one type of program. There were three one-page surveys, each covering one of the three major program types (continuous collection programs, events, or mail-back programs, which are described below). As a result, a program manager may have filled out numerous surveys (one for each program) using the appropriate survey forms.

The survey forms (available under “Documents” at <http://www.calrecycle.ca.gov/Actions/PublicNoticeDetail.aspx?id=217&aiid=217>) varied by program type and included up to 25 questions that requested information on operations, funding, costs, collection amounts and security practices that related to the standards in the Guidelines. Not all of the surveys were complete and some appeared to contain contradictory, unsupported or unexplained responses. This is not unexpected when dealing with complex topics and self-directed survey instruments.

Three main types of programs collect home-generated pharmaceuticals in California: continuous collection programs, events, or mail-back programs.

For this paper:

- Continuous collection programs are defined as drop-off locations that have scheduled collection hours at least weekly throughout the year.[‡]
- Collection events are defined as programs that provide:
 - Periodic drop-off opportunities at different locations.
 - Infrequent drop-off opportunities at a single location, in comparison to continuous collection programs (e.g., an average of one or two days each month or less at the same location).
- Mail-back collection programs are defined as programs that transport drug waste through the U.S. Postal Service to an appropriate disposal location.

[†] CalRecycle became aware of these programs through workshops, discussions and other communications. Other programs may exist.

[‡] CalRecycle acknowledges that there is a spectrum of collection frequencies and approaches. The line between continuous collection programs and collection events is not black and white. For the purposes of this analysis, CalRecycle chose weekly collection as the threshold to distinguish between the two.

Overall, CalRecycle identified 297 collection programs and program managers returned surveys for 256 programs (86% of total). The return rate varied by collection program as shown in Figure 2. The percentage of responses in each program type adequately represents current collection efforts in California.

Figure 2. Number of Programs and Number of Survey Responses by Program Type

	Number of Known Individual Programs	Total Number of Individual Programs Represented in Survey	Percentage of Programs with Survey Responses (%)
Continuous Collection - Pharmacies	112	102	91%
Continuous Collection - Law Enforcement	65	63	97%
Continuous Collection – Household Hazardous Waste Facilities	26	18	69%
Continuous Collection - All Other	38	24	63%
Collection Events	53	46 [§]	87%
Mail-back	3 ^{**}	3	100%
Total	297	256	86%

Based on the survey responses, the primary locations for continuous collection programs are pharmacies (102), law enforcement sites (63), and Household Hazardous Waste (HHW) collection sites (18). Ten other location types^{††} contribute another 24 continuous collection sites, but the low numbers and differences between them make it difficult to draw conclusions regarding these locations.

The remainder of this paper will focus on the top three continuous collection location types (pharmacies, law enforcement, and HHW), as well as collection events and mail-back programs.

[§] Program managers returned surveys for 50 of the known collection events. However, four surveys contained information from prior to 2009. CalRecycle became aware of two other programs after this analysis was completed. Finally, the “No Drugs Down the Drain” campaign consisted of more than 200 local one-day and ongoing pharmaceutical collection options during the week of October 4 – 11, 2008. This campaign was not included because it predated the survey period. As a result, this paper reflects 46 survey respondents.

^{**} Some pharmacies use tamper-resistant cardboard “mail-back” boxes (which hold 10- or 20-gallons). Pharmacies keep these containers on site until they are full. Individual consumers do not use these boxes, so this practice is included as part of the continuous collection programs operated at pharmacies.

^{††} Other locations include: clinics (6), hospitals (4), city halls (3), senior centers (3), dentists (2), door-to-door pickup (2), water districts (1), wastewater treatment plants (1), offices (1), and fire stations (1).

The responding collection events range from regular mobile collection events to limited hours at permanent household hazardous waste sites (e.g., first Saturday of each month) to highly coordinated events at multiple sites in a one-week period. Typical collection events are located in parking lots, vacant lots, pharmacies, senior centers, police substations, and household hazardous waste facilities.

The three mail-back programs all began in the Bay Area in 2009: the City of San Francisco, Teleosis (a non-profit organization in the Bay Area), and Santa Cruz County. While only a few mail-back programs currently operate in California, other states and countries utilize mail-back collection programs (as discussed below in Section IV. Overview of Programs Outside of California).

The number of surveys used in different analyses within this paper may vary because not all surveys included all the necessary information to do the necessary calculations or determinations.

The analyses in the remainder of this paper are based on the respondents not on the “known universe,” because the responses are considered “confirmed” programs and have data associated with them.

2. Number of Model Programs by Type

Based on the survey responses on the 256 programs, CalRecycle determined that 89 (35%) met all the standards in the Guidelines and were model programs and 167 did not meet at least one criterion. Some of the criteria in the Guidelines, some of the questions on the survey and some of the responses to the survey contained some ambiguity, so these model program determinations contain some subjective considerations. As shown in Figures 3 and 4, there are more model programs and higher percentages of model programs in some collection program types than other program types.

Figure 3. Numbers of Model and Non-Model Programs by Type

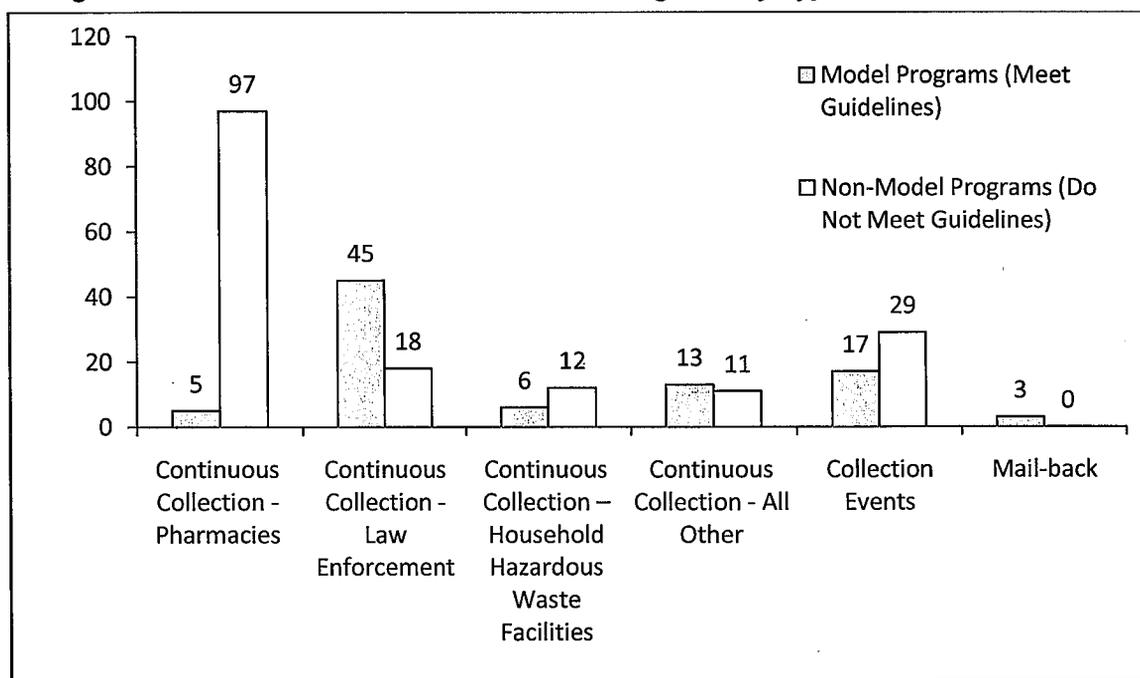


Figure 4. Numbers and Percentages of Model Programs

	Number of Model Programs (Meet Guidelines)	Number of Non-Model Programs (Do Not Meet Guidelines)	Percentage of Model Programs Within Program Type
Continuous Collection - Pharmacies	5	97	5%
Continuous Collection - Law Enforcement	45	18	71%
Continuous Collection – Household Hazardous Waste Facilities	6	12	33%
Continuous Collection - All Other	13	11	54%
Collection Events	17	29	37%
Mail-back	3	0	100%
Total	89	167	35%

Of the 207 continuous collection programs, 69 adequately met the Guidelines and are model programs. Five pharmacy collection programs are models (5%), 45 law enforcement collection programs are models (71%), and 6 HHW collection programs are models (33%). Of the 46 collection events, 37% (17) adequately met the Guidelines and are model programs. Of the three mail-back collection programs, 100% (3) adequately met the Guidelines and are model programs. The Guidelines emphasize the secure management of home-generated pharmaceutical wastes. To be a model, a program must meet each of the criteria in the Guidelines. The performance of programs in this area varies tremendously as discussed under “Safety (Security)” in the next section.

3. Program Evaluations for Safety, Accessibility, Cost Effectiveness and Efficacy

This section evaluates the four factors in SB 966: safety, accessibility, cost effectiveness, and efficacy. While SB 966 only calls for an evaluation of “model programs”, for completeness this paper analyzes all programs that responded to the surveys. For each factor, the sections below contain:

- **Definition.** A working definition of the factor.^{††}
- **Limitations.** The major limitations identified by CalRecycle regarding application, interpretation, and/or comparison.
- **Numerical Results.** The data in tabular and/or chart form. The tables below contain simplified survey questions. For the complete survey questions, refer to the blank survey documents.
- **Relative Rankings.** Relative rankings of each program type for the individual factor considered.

^{††} CalRecycle acknowledges that each of these factors could be defined in different ways, using different metrics.

SAFETY (SECURITY)

DEFINITION

For this paper, safety pertains to the security of pharmaceutical waste collection to prevent illegal diversion. The Guidelines contain many criteria designed to prevent or deter the public and/or program employees from taking pharmaceuticals out of the collection system for abuse or sale. CalRecycle attempted to capture these criteria in the survey questions. “Safer” collection programs meet more of the criteria and the “safest” qualify as model programs.

LIMITATIONS

As mentioned above, some of the criteria and some of the questions on the survey contained some ambiguity, so model program determinations contained some subjective elements. Incomplete surveys could also result in the failure to meet the Guidelines, regardless of what the answer might have been had the response been provided.

NUMERICAL RESULTS

As shown in Figure 5 through Figure 8 below, different program types had different levels of success in meeting the criteria in the Guidelines. One unmet criterion disqualifies a program from being a model. Within each program type, different programs failed to meet different combinations of criteria so the percentages are not additive.

Continuous Collection Pharmacy Programs:

While 60% of the 102 continuous collection pharmacy programs responded that they were consistent with the Guidelines, CalRecycle determined that only 5% actually qualified as model programs.

Each line in Figure 5 shows the number and percentage of pharmacy programs that would not meet the Guidelines based on a single criterion alone. Pharmacy programs had issues with nine safety-related criteria. Issues related to collection bin access and handling were responsible for most pharmacy program disqualifications: two-key bins (93%), locking full bins (84%), and public access to bins (65%).

Figure 5. Safety – Continuous Collection Pharmacy Programs & Guideline Criteria

Simplified Survey Questions Representing Guideline Criteria	Number of Pharmacies Not Matching Individual Criterion	Percent that would not be Models based on each Criterion
Only police collect controlled substances?	2	2%
Secure drug waste container?	33	32%
Two-key collection bin?	95	93%
Lock bin when full?	86	84%
Bin is not publicly accessible?	66	65%
Permission to store longer than 90 days?	26	25%
Maintaining a log?	52	51%
Log accompanies controlled subs?	2	2%
CDPH-registered hauler?	11	11%

Continuous Collection Law Enforcement Programs:

While 100% of the 63 continuous collection law enforcement programs responded that they were consistent with the Guidelines, CalRecycle determined that only 71% actually qualified as model programs.

Each line in Figure 6 shows the number and percentage of law enforcement programs that would not meet the Guidelines based on a single criterion alone. Law enforcement programs had issues with five safety-related criteria. Issues related to controlled substances (29%), storage times (22%) and hauler registration (29%) were responsible for most law enforcement program disqualifications.

Figure 6. Safety – Continuous Collection Law Enforcement Programs & Guideline Criteria

Simplified Survey Questions representing Guideline Criteria	Number of Law Enforcement Not Matching Individual Criterion	Percent that would not be Models based on each Criterion
Only police collect controlled substances?	18	29%
Secure drug waste container?	1	2%
Permission to store longer than 90 days?	14	22%
Maintaining a log?	3	5%
CDPH-registered hauler?	18	29%

Continuous Collection HHW Programs:

While 78% of the 18 continuous collection HHW programs responded that they were consistent with the Guidelines, CalRecycle determined that only 33% actually qualified as model programs.

Each line in Figure 7 shows the number and percentage of HHW programs that would not meet the Guidelines based on a single criterion alone. HHW programs had issues with three safety-related criteria. Issues related to documentation (50%) and storage times (44%) were responsible for most HHW program disqualifications.

Figure 7. Safety – Continuous Collection HHW Programs & Guideline Criteria

Simplified Survey Questions representing Guideline Criteria	Number of HHW Not Matching Individual Criterion	Percent that would not be Models based on each Criterion
Permission to store longer than 90 days?	8	44%
Maintaining a log?	9	50%
CDPH-registered hauler?	2	11%

Collection Events:

While 76% of the 46 collection events responded that they were consistent with the Guidelines, CalRecycle determined that only 37% actually qualified as model programs.

Each line in Figure 8 shows the number and percentage of collection events that would not meet the Guidelines based on a single criterion alone. Issues related to documentation (46%) were responsible for most collection event disqualifications.

Figure 8. Safety – Collection Event Programs & Guideline Criteria

Simplified Survey Questions representing Guideline Criteria	Number of Collection Events Not Matching Individual Criterion	Percent that would not be Models based on each Criterion
Participants access to drugs?	7	15%
Maintaining a log?	21	46%
CDPH-registered hauler?	4	9%

Mail-back Programs:

All three mail-back programs responded that they were consistent with the Guidelines, CalRecycle determined that they all qualified as model programs. Mail-back programs had no issues with safety-related criteria.

RELATIVE RANKING

As shown in Figure 9, relative safety performance can be determined based on the number of model programs, the number of areas in which a program type fails, and/or the percentage of the programs not meeting the safety criteria.

Figure 9. Safety – Relative Performance

	Number of Model Programs (Meet Guidelines)	Number of Criteria causing Disqualifications	Percentage of Programs not meeting Safety Criteria
Continuous Collection - Pharmacies	5	9	95%
Continuous Collection - Law Enforcement	45	5	29%
Continuous Collection – Household Hazardous Waste Facilities	6	3	67%
Collection Events	17	3	63%
Mail-back	3	0	0%
Total	76		

Pharmacies operate the most collection programs (102), but 95% of them fail to meet safety criteria in nine different criteria areas. As a result, there are only five model pharmacy programs in California.

Law enforcement operates the second highest number of collection programs (63) in the state and has the highest number of model programs (45). However, 29% of law enforcement programs fail to meet safety criteria in five different criteria areas.

Collection events account for the third highest number of programs (46) in the state. Of that number, 63% of them fail to meet safety criteria in three different criteria areas. As a result, there are only 17 model collection events in California.

Continuous collection at HHW sites account for the fourth highest number of programs (18) in the state, and 67% of them fail to meet safety criteria in three different criteria areas. As a result, there are only six HHW model programs in California.

Mail-back programs have the smallest number of programs (3) and the highest success rate (100%) at meeting the safety criteria with three model programs in California.

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

DEFINITION

For this paper, public accessibility pertains to the ability of the public to utilize a collection program. Two factors that correlate to accessibility are the overall number of collection sites and their access hours. A tally of the returned surveys provides the number of sites for each program type, while the survey included questions regarding hours of operation per week.

LIMITATIONS

Number of sites:

An increase in the number of collection sites in the state may not correlate to a more even geographic distribution throughout the state. Some people may not consider all types of sites equally accessible (e.g., anecdotal reports suggest some people are afraid of going to law enforcement sites), so the raw number may be misleading. Additionally, events may not be the most numerous programs, but in rural areas, targeted local collection events could provide the easiest access compared to longer travel distances to continuous collection programs.

Hours of operation:

Hours of operation varied significantly within program type as well as between program types; use caution when comparing averages when this type of variability exists. For example, among continuous collection programs, hours of operation may be a meaningful comparison. However, comparing these programs to mail-back programs is difficult; e.g., should the measure of accessibility for mail-back be picking up the envelope (limited hours) or putting it in the mail (unlimited hours)? In addition, the total number of hours may be less important than the "effective hours" in which people are likely to use a program; e.g., 24-hour access may not result in 3 times the effective access or triple the collection amounts compared to access during the "right" 8 hours per day. Finally, because of their infrequent nature, collection events are not comparable regarding hours of operation but if tailored correctly to the population served could nonetheless be accessible.

NUMERICAL RESULTS

Figure 10 shows accessibility as expressed by the number of programs in California.

Figure 10. Accessibility - Number of Programs

	Total Number of Individual Programs Represented in Survey	Percentage of Respondents (%)
Continuous Collection - Pharmacies	102	40%
Continuous Collection - Law Enforcement	63	25%
Continuous Collection – Household Hazardous Waste Facilities	18	7%
Collection Events	46	18%
Mail-back	3	1%

Figure 11 shows accessibility as expressed by the number of hours per day.

Figure 11. Accessibility - Number of Access Hours per Day

	Range of Responses (hours per day)		Average (hours per day)
	Min	Max	
Continuous Collection - Pharmacies	5	12	9
Continuous Collection - Law Enforcement	3	24	19
Continuous Collection – Household Hazardous Waste Facilities	1	9	3
Collection Events (on Event Days)	3	12	7
Mail-back (to pickup mailers)	6	10	8

RELATIVE RANKING

In terms of the number of programs, pharmacies are more accessible with 102 programs represented in the survey, followed by law enforcement (63), collection events (46), HHW (18) and mail-back (3). These relative rankings reflect the total number of pharmacies in California as a whole compared to law enforcement stations (thousands compared to hundreds).

In terms of average hours of operation per site per day, law enforcement programs had the longest average operational hours (19), more than double the average hours of pharmacies (9). HHW programs followed with an average of 3 hours per day. Collection events are not directly comparable, but were available for an average of 7 hours on event days. Mail-back programs allow the public to send packages at anytime at any mailbox, but the public could obtain mail-back envelopes an average of 8 hours per day.

Accessibility is a very subjective measure. If tailored correctly to a target population, any or all of these program types could result in reasonable access for the public. Because accessibility is dependent on consumer behavior, consumer preferences will drive the actual use of collection programs. Based on a recent study of consumers in Washington and Oregon, 64% of those surveyed would be somewhat or very likely to take their home-generated pharmaceutical waste to a "convenient" drop-off location while 55% of those surveyed would be somewhat or very likely to use a mail-back program for their home-generated pharmaceutical waste.⁷

COST EFFECTIVENESS

DEFINITION

For this paper, cost effectiveness pertains to the amount of pharmaceuticals collected in comparison to the cost of the program used to collect them. There were survey questions on both quantities collected and on costs incurred. For this analysis, this metric is the average cost per pound for each program type.

LIMITATIONS

Responses that did not include both costs and pounds of pharmaceutical waste collected were not included in the cost effectiveness analysis. Errors or misreporting in either overall cost or amount collected will impact the reliability of the cost per pound calculation.

Program costs may include: 1) advertising costs; 2) a medical or hazardous waste hauler's collection, transportation, disposal, and processing fees (hauler fees); or 3) administrative/staff time. Survey respondents could choose to provide costs for any or all of these categories. This analysis uses whatever cost data was provided. For instance, many programs did not provide advertising costs because their program was mature enough that advertising was not needed, or funds were so limited that it was not an option. Also, in many cases, staff time was not tracked and was not provided. Because all costs were not included, this may be a low estimate.

The cost data varied significantly within program type as well as between program types; when this type of variability exists, use caution when comparing averages.

Most HHW programs do not track pharmaceutical weights separately from poisons they collect. Most reported estimated weights. One was excluded from the analysis as it reported a combined weight.

Many programs represented in the survey results did not encourage removing pills from pill bottles and placing them in a plastic baggie before depositing them at the collection point. In some cases, the amount collected included packaging and in some cases it did not. For more comparable numbers for cost effectiveness, the amounts were all standardized to remove the weight of packaging. The correction assumed that in mixtures of pharmaceuticals and packaging, 54% of the weight is due to the pharmaceuticals and 46% is due to the packaging (based on an average of estimates in four other reports).⁸ The correction significantly impacts the cost results, as shown in Figures 12, 13 and 14.

NUMERICAL RESULTS

Figure 12 shows the cost effectiveness as expressed by the cost in dollars per pound collected without any correction for the weight of packaging.

Figure 12. Cost Effectiveness – Cost per Pound (as reported)

	Range of Responses		Number Included in Average	Average Cost per Pound
	Min	Max		
Continuous Collection - Pharmacies	\$1.00	\$16.67	75	\$5.60
Continuous Collection - Law Enforcement	\$0.38	\$13.89	63	\$4.56
Continuous Collection – Household Hazardous Waste Facilities	\$0.13	\$6.38	15	\$2.86
Collection Events	\$0.87	\$16.67	36	\$6.06
Mail-back	\$6.39	\$50.40	3	\$33.05

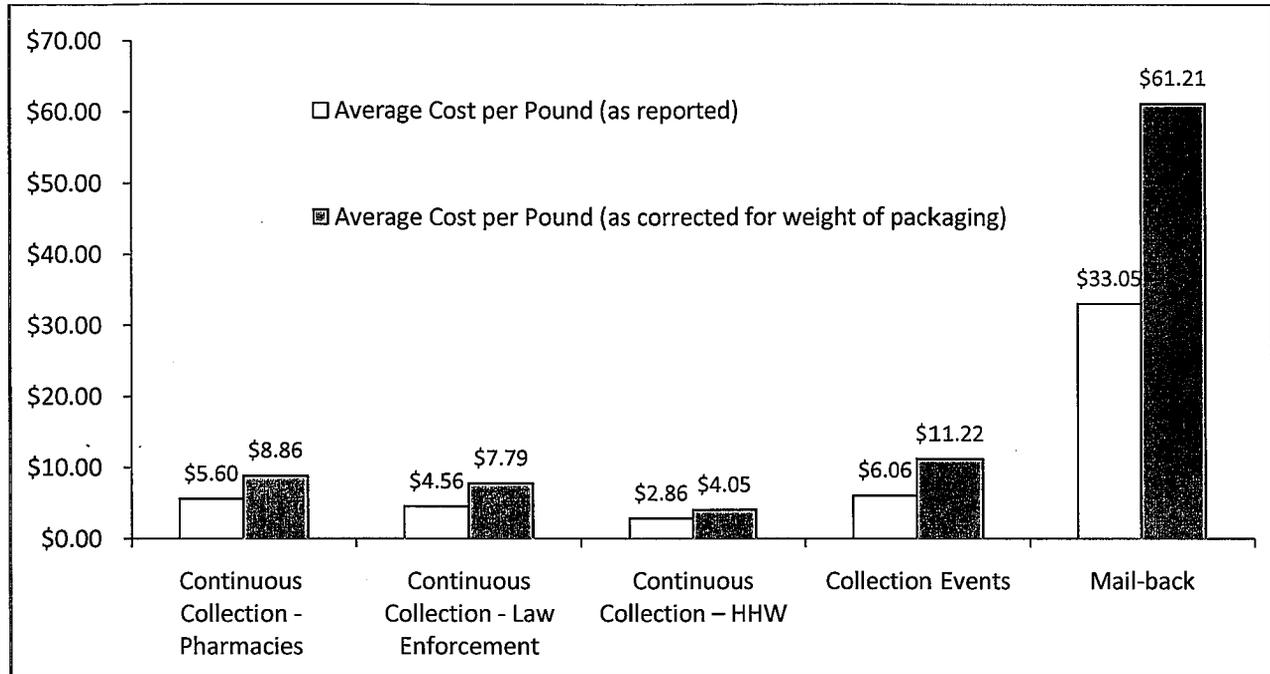
Figure 13 shows the cost effectiveness as expressed by the cost in dollars per pound collected after correction for the weight of packaging.

Figure 13. Cost Effectiveness – Cost per Pound (corrected to remove packaging)

	Range of Responses		Number Included in Average	Average Cost per Pound
	Min	Max		
Continuous Collection - Pharmacies	\$1.00	\$30.87	75	\$8.86
Continuous Collection - Law Enforcement	\$0.69	\$25.72	63	\$7.79
Continuous Collection – Household Hazardous Waste Facilities	\$0.24	\$11.82	15	\$4.05
Collection Events	\$1.60	\$30.87	36	\$11.22
Mail-back	\$11.83	\$93.33	3	\$61.21

Figure 14 compares the costs as reported with the costs after correction for the weight of packaging.

Figure 14. Cost Effectiveness – Costs as Reported and as Corrected



RELATIVE RANKING

In terms of cost per pound after correcting for packaging, HHW programs spent the least amount per pound (\$4.05), followed by law enforcement (\$7.79), pharmacies (\$8.86), and events (\$11.22). Mail-back programs have the highest cost per pound (\$61.21).

The cost per pound shown above for mail-back programs is higher because it includes the upfront cost of all the mailers purchased, not just those incinerated at the time of the survey. The percentages incinerated by the three programs at the time of the survey were 18%, 33%, and 38%. The cost per pound will go down as more envelopes are distributed and returned because the weight of home-generated pharmaceuticals collected will go up but the costs will remain the same. Additionally, the mail-back programs require that medications remain in their packaging, so correcting for removal of packaging may not be as useful. Finally, mail-back cost effectiveness can be significantly affected by the amount of pharmaceuticals included in each mailer; increasing the weight of each envelope lowers the cost per pound in cases of flat rate shipping arrangements.

Cost per pound may not be the only indicator for cost effectiveness. Collection events are often found in jurisdictions with limited resources. In situations in which the cost to open and/or operate a continuous collection program is prohibitive, collection events may allow a jurisdiction to reach all citizens with some level of collection service. Collection events appear to be more commonly utilized in areas with large dense populations such as the City of Los Angeles or the Bay Area, and also in rural jurisdictions where they provide at least some level of service to a diffuse population.

EFFICACY (COLLECTION RATE)

DEFINITION

For this paper, efficacy is measured in three ways:

- The total amount of pharmaceutical waste collected by a program divided by the number of operating days (pounds per operating day),
- The total amount collected by program type in California (total pounds per program type), and
- The average amount collected by each program type (average pounds per program).

LIMITATIONS

A common criterion is pounds collected per capita; however, this metric does not work for this analysis because the population served by a collection program (e.g., one pharmacy) is unknown.

As discussed above, both cost effectiveness and collection rate rely on weight data for collected pharmaceuticals. For this analysis, as discussed earlier, the pounds of pharmaceutical waste collected were adjusted by a 54% factor for those programs reporting they did not encourage removing pharmaceutical waste from its packaging. While these calculations were done for general comparison purposes on mail-back programs, this does not provide a direct comparison to mail-back programs since mailer instructions state that pharmaceuticals must be in their original containers.

For continuous collection programs, amount collected per day of operation equates to the amount collected at an individual site divided by the entire eight-month period. For a one-day collection event, the amount collected is divided by one day to yield the pounds collected per day of operation. As a result, comparisons between continuous collection program types may be feasible. However, comparing these programs to collection events can be problematic because the boundaries of the program are less clear (e.g. a single event, a single envelope, the entire series of events, or all envelopes).

NUMERICAL RESULTS

Figure 15 shows the efficacy as expressed by the pounds collected per day of operation without any correction for the weight of packaging.

Figure 15. Efficacy – Pounds Collected per Day of Operation (as reported)

	Range of Responses		Number Included in Average	Average Pounds per Day of Operation
	Min	Max		
Continuous Collection - Pharmacies	0.3	12.3	75	2.0
Continuous Collection - Law Enforcement	0.1	34.7	63	7.1
Continuous Collection – Household Hazardous Waste Facilities	0.4	10.3	16	2.0
Collection Events (on event days)	2.5	482.0	36	163.1
Mail-back	0.1	6.5	3	2.3

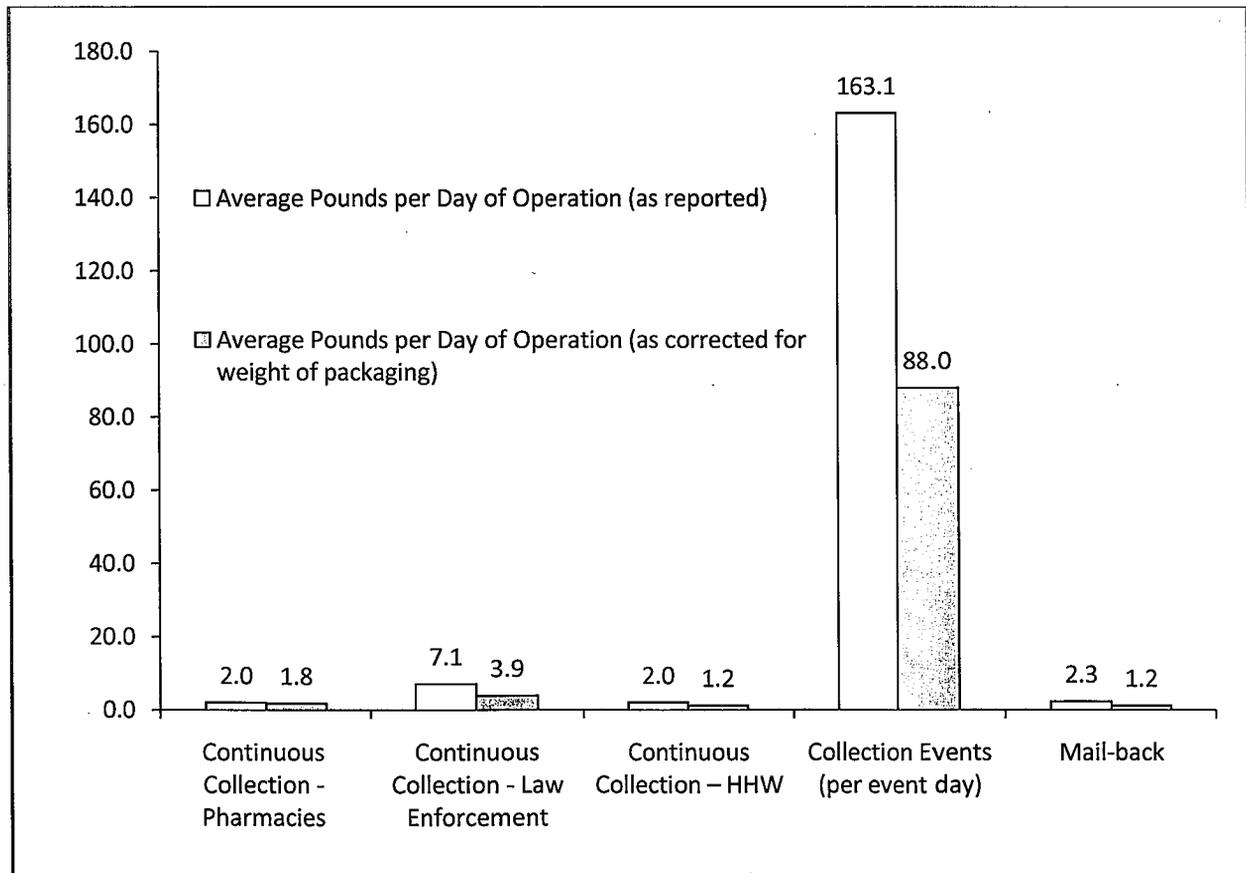
Figure 16 shows the efficacy as expressed by the pounds collected per day of operation after correction for the weight of packaging.

Figure 16. Efficacy – Pounds Collected per Day of Operation (as corrected, without packaging)

	Range of Responses		Number Included in Average	Average Pounds per Day of Operation
	Min	Max		
Continuous Collection - Pharmacies	0.2	12.3	75	1.8
Continuous Collection - Law Enforcement	<0.1	18.7	63	3.9
Continuous Collection – Household Hazardous Waste Facilities	0.2	5.6	16	1.2
Collection Events (on Event Days)	1.4	260.0	36	88.0
Mail-back	<0.1	3.5	3	1.2

Figure 17 compares the efficacy as reported with the efficacy after correction for the weight of packaging.

Figure 17. Pounds Collected per Site by Program Type



Efficacy can also be demonstrated by the total amounts collected by each program type in California, and the average amounts collected by programs in each program type, as shown in Figure 18. Even though pharmacy programs outnumber law enforcement programs, the overall collection amount for law enforcement programs is considerably higher, as is the average pounds collected per law enforcement program.

Figure 18. Efficacy – Total Pounds & Average Pounds Collected by Program Type

	Pounds Collected per Program Type (as reported with packaging)	Average Pounds Collected per Program (as reported)	Pounds Collected per Program Type (as corrected for packaging)	Average Pounds Collected per Program (as corrected)
Continuous Collection - Pharmacies	18,120	178	17,543	172
Continuous Collection - Law Enforcement	194,522	3,088	105,088	1668
Continuous Collection – Household Hazardous Waste Facilities	9,349	519	5,361	298
Collection Events	5,040	110	2,722	59
Mail-back	1,678	559	906	302

RELATIVE RANKING

When efficacy is measured as the average pounds collected per day of operation (after correcting for packaging), collection events collected the most per day (88.0 pounds per event). Among the continuous collection programs, law enforcement collected the most (3.9 pounds per day of operation), followed by pharmacies (1.8 pounds per day of operation) and HHW programs (1.2 pounds per day of operation). Mail-back programs also collected an average of 1.2 pounds per day of operation.

When efficacy is measured as the total amount collected by program (after correcting for weight of packaging), law enforcement programs collected the most (105,088 pounds), followed by pharmacies (17,543 pounds), HHW (5,361 pounds), collection events (2,722 pounds) and mail-back programs (906 pounds).

When efficacy is measured as the average amount collected by each program within each program type (after correcting for weight of packaging), law enforcement programs collected the most (1668 pounds per program), followed by mail-back (302 pound per program), HHW (298 pounds per program), pharmacies (172 pounds per program) and collection events (59 pounds per program).

SUMMARY RANKING FOR ALL FOUR FACTORS BY COLLECTION PROGRAM TYPE

The relative rankings shown in this section should be used for general comparison purposes only. The rankings are merely numbers one through five (from best to worst) in each measurement. The ranking scale just shows numeric order and does not reflect the relative sizes or any linear relationship between the programs. The limitations that applied to each of the individual metrics still exist when the results are shown in rank order.

Figure 19 shows the relative summary rankings for the safety and accessibility metrics presented above.

Figure 19. Summary Rankings – Safety & Accessibility

	Safety Rankings			Accessibility Rankings		
	Number of Model Programs	Number of Problem Criteria	Percent of Programs not meeting Safety Criteria	Number of Programs	Percent of Programs in State	Average number of access hours per day
Continuous Collection - Pharmacies	4	5	5	1	1	2
Continuous Collection - Law Enforcement	1	4	2	2	2	1
Continuous Collection – Household Hazardous Waste Facilities	3	2	4	4	4	5
Collection Events	2	2	3	3	3	4
Mail-back	5	1	1	5	5	3

Figure 20 shows the relative summary rankings for the cost effectiveness and efficacy metrics presented above.

Figure 20. Summary Rankings – Cost Effectiveness & Efficacy

	Cost Effectiveness Rankings		Efficacy Rankings		
	Average Cost per Pound as reported	Average Cost per Pound as corrected	Pounds per Day	Total Pounds per Program Type as corrected	Average Pounds per Program as corrected
Continuous Collection - Pharmacies	3	3	4	2	4
Continuous Collection - Law Enforcement	2	2	2	1	1
Continuous Collection – Household Hazardous Waste Facilities	1	1	4	3	3
Collection Events	4	4	1	4	5
Mail-back	5	5	3	5	2

Figure 21 shows the totals and average ranking for all the relative rankings across the 11 metrics. The totals are just the rankings added in each row, with the minimum possible of 11 and a maximum possible of 55. The average is the total divided by the 11 metrics. A lower total number suggests a better overall fulfillment of the four factors, while a higher number suggests worse overall performance in relation to these four factors, using this set of metrics.

Figure 21. Summary Rankings – Totals

	Total of Rankings	Average Ranking (Total Divided by 11 Criteria)
Continuous Collection - Pharmacies	34	3.1
Continuous Collection - Law Enforcement	20	1.8
Continuous Collection – Household Hazardous Waste Facilities	34	3.1
Collection Events	35	3.2
Mail-back	40	3.6

The totals of the summary rankings show law enforcement continuous collection programs as best overall in satisfying the four evaluation factors (safety, accessibility, cost effectiveness and efficacy). Pharmacy continuous collection programs and HHW continuous collection programs are next, followed extremely closely by collection events. Mail-back programs are last, but not that distant from the other program types (other than law enforcement). Law enforcement collection programs have the highest average ranking, with the others bunched somewhat closely together.

Because the rankings varied by the four factors and even by metric used within each factor, CalRecycle has no clear choice or recommendation for a program type to implement statewide. Because of local variables, differences in program implementation within each program type, and the different needs of populations to be served, there is not one best program for all locations and situations.

III. Challenges and Barriers

The survey data and survey respondent feedback revealed some challenges and barriers for current programs. This section discusses the following five challenges and barriers:

1. Safe Collection of Pharmaceuticals is Expensive
2. Lack of Public Awareness and Participation
3. Lack of Sustainable Funding
4. Lack of Goals
5. Unclear Requirements, Policies and Authorities

1. Safe Collection of Pharmaceuticals is Expensive.

Certain requirements in the Guidelines presented unique challenges to some programs. As discussed above, safety (security) issues are usually the primary reason why existing programs did not qualify as model programs. Meeting these safety issues often involve increased costs. Meeting the requirements can add more costs as specific participants are required (law enforcement personnel and registered haulers), more bins and pickups are needed (two key bins and secured containers), and special handling requirements are implemented (separate handling, weighing, and record keeping). A few of these issues are illustrated in this section.

COLLECTION OF CONTROLLED SUBSTANCES

Controlled substances represent approximately 10 percent of all prescriptions written in the United States. In the state of Maine's recent pilot mail-back program, controlled substances represented 17% of all drugs returned. Given many take back programs cannot accept controlled substances, mail back may offer convenience and privacy with these sensitive drugs.

Under Federal statute (the U.S. Controlled Substance Act), controlled substances cannot be collected unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these medications to prevent illegal diversion and abuse. Based on information available to CalRecycle, the United States is the only country that has these requirements.

Making it easier for non-law enforcement programs to collect controlled substances, and making it easier to dispose of all home-generated pharmaceutical waste within California, would decrease costs and make program implementation easier and more attractive.

REGISTERED WASTE HAULERS & DISPOSAL FACILITY OPTIONS

Transporting collected home-generated pharmaceutical waste using only haulers registered with CDPH may be more expensive than other options. At least nine pharmacies used the larger cardboard “mail-back” boxes described above but this method does not use a registered waste hauler.

Disposal requirements and disposal options vary depending on how the materials are collected, consolidated, mixed with other materials, and on who does the collecting. The costs of these options are very different and impact the costs of collection programs. It appears that law enforcement collection programs have the option of in-state incineration (at least for controlled substances). It also appears that HHW collection programs that mix medications and poisons may have the option of in-state hazardous waste landfills. Most other programs appear to use out-of-state incineration which is more costly. CalRecycle has requested information from CDPH and other agencies to clarify the requirements and options for disposal of home-generated pharmaceuticals.

TWO KEY LOCKING COLLECTION BINS

To save on waste hauling expenses, employees at many pharmacies with publicly accessible bins will empty the bin and store the bin contents behind the counter to avoid extra waste hauler trips. To meet the Guidelines, bins located at pharmacies must have a two key security system so that no individual may access the drug waste alone: the pharmacy’s designated responsible person would have one key and the licensed hauler would have the other key. Marin County, which began collection in 2004, would exceed its \$14,000 annual budget if the county paid for a two-key collection bin for each of its 24 participating pharmacies.

USE OF SECURE CONTAINERS AT HHW SITES

The majority of HHW facilities comingle drug waste with poisons—often in open 55-gallon drums to allow room for poisons to be easily deposited. Unfortunately, this also allows much easier access to deposited pharmaceuticals. To meet the Guidelines, an additional bin may be needed (at a cost of approximately \$600 each), so that materials are not co-mingled and remain secure. However, the relatively small amounts of pharmaceutical waste compared to poisons collected at HHW sites, makes it somewhat impractical for pharmaceuticals to be managed separately from poisons; it could lead to storage times exceeding the limits and much higher disposal costs (costs rise exponentially for smaller containers).

RECORD KEEPING AND DATA COLLECTION

Weighing, logging and tracking drug waste before and after transport is meant to prevent illegal diversion, and can also be useful in performance measures. Most survey respondents for HHW facilities reported they comingled pharmaceutical waste with poisons, which may make it more difficult to weigh, log and track pharmaceuticals separately. As discussed above, if HHW sites must treat poisons and pharmaceuticals differently their costs will be higher.

2. Lack of Public Awareness and Participation

A common challenge with any type of collection program is achieving high public awareness and participation. Given that program costs increase with more collection and that local governments fund most collection programs and face significant budget shortfalls, local governments are in one sense penalized as participation increases.

There is not enough data from programs outside of California to draw any conclusions about types of programs associated with high public participation, but anecdotally, public outreach and convenience play an important role.

3. Lack of Sustainable Funding

Local governments currently fund approximately 83% of collection programs. Of that amount, most of the funding is from counties, local waste and water agencies, and to a lesser extent cities. Pharmacies provide funding for 15% of collection programs. The other two percent comes from various other sources, such as non-profit and waste companies. Although SB 966 encourages a cooperative relationship with all stakeholders, CalRecycle is not aware of any funding from pharmaceutical manufacturers for collection programs in California. According to a recent survey of consumers in Washington and Oregon, 64% of those who responded agreed (strongly or somewhat) that pharmaceutical companies should be responsible for creating a take-back program for safe disposal of unused medicines.

This contrasts significantly with other countries (See Section IV. Overview of Programs Outside of California), where private sector manufacturers and retailers play a significant role in funding and managing pharmaceutical collection programs, many through product stewardship programs. Product stewardship programs use a private-sector approach to managing discards.⁹ Producers are generally able to implement programs either individually or by joining together with other producers through a Product Stewardship Organization that collects, properly manages, and interacts with the state oversight agency on its behalf.

4. Lack of Goals

SB 966 does not provide any performance goals to measure success. Performance goals similar to CalRecycle's goal of 50% waste diversion in California by the year 2000 could drive the creation of programs and help set realistic standards for pharmaceutical waste collection throughout California. Goals accompanied with incentives can be particularly effective in driving program activity. To be effective,

measures would require some knowledge of the amounts of pharmaceuticals sold/prescribed in California, the amounts that become home-generated waste, and the amounts that are eventually collected.

5. Unclear Requirements, Policies & Authority

The Guidelines state, “Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection.” However, the current patchwork of laws, regulations, and policies can be a challenge for any collection program. Entities may be discouraged from starting collection programs due to concerns and uncertainty about the applicable definitions, requirements and legal options for collecting, handling and disposing of home-generated pharmaceutical waste. In terms of potential recommendations to the Legislature, the following agencies and their respective laws, regulations, and policies may need to more directly address home-generated pharmaceutical waste collection programs.

U.S. DRUG ENFORCEMENT ADMINISTRATION (DEA)

There are no DEA regulations specific to home-generated drug collection, but under the U.S. Controlled Substances Act, DEA governs controlled substances (Title 21, Chapter 13, Drug Abuse Prevention and Control). These regulations oversee the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances and define who may possess controlled substances, which impacts disposal of a controlled substance. Two proposed national bills, HR 1191 and HR 1359 (See Section IV. Overview of Programs Outside of California), would amend the Controlled Substances Act to allow for the safe and effective destruction of controlled substances.

CALIFORNIA BOARD OF PHARMACY

Pharmacies lack provisions for pharmaceutical collection recently granted for sharps collection. Technically, California law currently does not authorize pharmacies to accept the return of home-generated pharmaceutical waste. SB 966 states programs consistent with the Guidelines are “...in compliance with state law and regulation...” The California Board of Pharmacy’s March 2010 newsletter stated, “The Board expects all pharmacies to use the [CalRecycle] Guidelines for any ‘Take Back’ program they offer the public.”

Likewise, California law did not authorize pharmacies to accept the return of sharps from the public until Senate Bill 821 added appropriate language to the Business and Professions Code in October 2009. Until that time, the California Board of Pharmacy had a stated policy that it did not anticipate intervening in sharps collection programs unless necessitated by a complaint or public safety issue. A similar provision in California law would clarify the requirements for home-generated pharmaceutical waste.

DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC)

DTSC regulates hazardous waste including some pharmaceutical waste, but does not regulate home-generated pharmaceutical waste. DTSC’s website states, “Pharmaceutical waste produced by a household is exempt from classification as hazardous waste or medical waste. This means that a household may legally dispose of their waste pharmaceuticals and personal care products in the solid waste stream or into

the sanitary sewer (“down the drain”). While these practices are legal, they may not be the environmentally preferred ways for a household to dispose of unwanted pharmaceuticals.”

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (CDPH)

The Medical Waste Management Program of the CDPH does not have statutory authority to regulate home-generated pharmaceutical waste. Instead, CDPH applies a best waste management policy consistent with current, existing waste collection models for home-generated pharmaceutical waste. This current policy monitors home-generated pharmaceutical waste at registered consolidation points to ensure proper containment, storage, and treatment. CDPH's policy is similar to its current regulation of home-generated sharps waste, which it defines as medical waste, when the sharps are collected at a consolidation point.

IV. Overview of Programs Outside of California

Other countries and states face similar challenges with managing unwanted pharmaceuticals. CalRecycle found examples of pharmaceutical collection programs in other countries and states and analyzed them for additional findings. Basic information about many of these programs is captured in the table in Appendix I (available under “Documents” at <http://www.calrecycle.ca.gov/Actions/PublicNoticeDetail.aspx?id=217&aiid=217>). Listed below are several programs that stand out for reasons noted. This is followed by discussion on common themes.¹⁰

1. International Guidelines and Programs

WORLD HEALTH ORGANIZATION (WHO)

- **World Health Organization**¹¹ issued guidelines for pharmaceuticals management in and after emergencies. These guidelines state that if take-back programs are not available and pharmaceuticals are treated prior to disposal by waste immobilization, it is acceptable to dispose of controlled substances in engineered or permitted landfills.¹² Immobilization refers to either encapsulation or inertization (removing the packaging materials from the pharmaceuticals, grinding pharmaceuticals and mixing them with water, cement, and lime).

EUROPEAN UNION

- **France: Cyclamed Program.** This national program allows consumers to return pharmaceuticals to local pharmacies for safe disposal. As the program is funded and managed by the private sector (industry, pharmacies and wholesalers), it can be described as a product stewardship program. It stands out for having relatively high per capita collection and participation rate as noted in Appendix I. Also, the amount of pharmaceuticals collected, reported in terms of with and without packaging, indicates that it is very important to understand to what extent packaging is included in measurements as it can

significantly impact the collection rates. This program offers more information on its performance than many other programs.

- **Portugal: Valormed Program.** This national program allows consumers to return unused pharmaceuticals to local pharmacies for safe disposal. As it is funded by members of pharmaceutical associations, including local pharmacies, manufacturers, distributors and chemical and pharmaceutical importers, it is a product stewardship program. This particular product stewardship program places an eco-fee of 0.00504 Euros on each package placed in the market. The program stands out as having a fairly high per capita collection as compared to other programs in this section. Significant information gaps include costs and to what extent the collection includes packaging.
- **Spain SIGRE Program.** This national program allows consumers to return unused pharmaceuticals to local pharmacies for recycling or safe disposal. As it is managed by SIGRE, a non-profit, and SIGRE is funded by members of pharmaceutical industry based on volume of sales, it is a product stewardship program. The program stands out as having fairly high per capita collection and is a product stewardship model that uses a stewardship organization. Significant information gaps include costs, to what extent the collection metrics include packaging, and to what extent recycling occurs.
- **Sweden Apoteket AB Program.** This national program allows consumers, along with other types of facilities such as care centers, dentists, hospitals, veterinarians, and farmers, to return leftover pharmaceuticals to the state-owned, non-profit retail pharmaceutical chain. The program stands out for being government managed and financed, and for having higher reported costs and lower collection rates. Significant information gaps include how the collection rate is calculated given the broader scope of the program and to what extent collection metrics include packaging.

CANADA

- **Alberta ENVIRx Program.** This province-wide program allows consumers to return pharmaceuticals to a majority of local pharmacies for safe disposal. It is mainly funded by industry, but also by small grants from the provincial government, so it could be considered a quasi-product stewardship program. The program stands out for being voluntary. Significant information gaps include costs and to what extent collection metrics include packaging.
- **British Columbia PCPSA Program.** This province-wide program allows consumers to return pharmaceuticals to a majority of local pharmacies for safe disposal. As the program is managed by a stewardship organization, PCPSA, and is funded by industry; it is a product stewardship program. The program stands out for having more complete reporting and cost information, and relatively low collection rates and high costs for a product stewardship program. Significant information gaps include to what extent collection metrics includes packaging, which can affect per capita costs and collection rates.

CalRecycle observed some common themes among these programs: All programs reviewed by CalRecycle seek to provide a secure system for pharmaceuticals and all programs in other countries use pharmacies as the collection point. It appears that other countries do not have laws on par with the U.S.

Controlled Substance Act, which only allows law enforcement officials to handle controlled substances (e.g., narcotics), and this means that in other countries, pharmacies can serve as convenient consumer drop-off locations for all types of pharmaceuticals. Also, most countries with collection programs have significant industry participation, including at least some industry funding, with the exception of Sweden, which operates collection through non-profit, state-run pharmacies.

When the private sector funds and manages collection programs and safe disposal of drugs, such a program is referred to as a Product Stewardship Program. As noted previously, product stewardship programs offer a private sector approach to waste management. Appendix I offers cost information on various pharmaceutical programs and this preliminary information suggests generally a lower cost per capita for those programs with greater industry funding. Overall, however, CalRecycle is not able to draw any specific conclusions about which of these programs are most effective due to data gaps and a lack of detailed information about the programs to ensure a fair comparison.

2. National Programs

No nationwide home-generated pharmaceutical waste collection programs currently exist in the United States; however, there are a few policies, laws, and regulations, along with nationally-based efforts, that address their disposal.

Federal Policy

- **White House Office of National Drug Control Policy** issued new guidelines to educate consumers on safe methods of pharmaceutical disposal in October 2009. These guidelines first recommend participating in take-back programs, if available. When that option does not exist, it recommends removing drugs from original containers and mixing them with undesirable substances, like coffee grounds or cat litter, and then sealing them in an impermeable container before throwing the unused drugs in the trash.¹³

FEDERAL LEGISLATION AND REGULATIONS

While, no national laws directly govern home-generated pharmaceutical waste, once home-generated pharmaceutical waste is collected at a consolidation point, the waste is governed by at least four national laws.

- **U.S. Controlled Substances Act** regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances and defines who may possess controlled substances, which impacts disposal of a controlled substance. Controlled substance must be collected by sworn law enforcement officers (pharmacies may only take back uncontrolled substances).

Program managers in California and in other states view the federal Controlled Substances Act as a barrier to collection because it limits unsorted returns of controlled substances to law enforcement, which generally is less convenient than local pharmacies. Also, consumers can't easily determine if a drug is a controlled substance or not.

- **Resource Conservation and Recovery Act (RCRA)** governs the management of hazardous wastes, including some drug waste.

- **The Health Insurance Portability and Accountability Act (HIPAA)** provides a Federal floor of privacy protections for individuals' individually identifiable health information where that information is held by a covered entity or by a business associate of the covered entity.
- **Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180)** determine how to classify and transport chemotherapeutic and pharmaceutical wastes.

PROPOSED FEDERAL LEGISLATION

Two federal laws are currently under consideration that would amend the Controlled Substances Act to make it easier to collect controlled substances, provide research and funding for pharmaceutical take-back programs, develop recommendations and educate the public on proper pharmaceutical disposal, and would educate the public on impacts from pharmaceuticals.

- **Safe Drug Disposal Act of 2009 (HR 1191 and S 1336)** Requires the DEA to design five drug disposal models for collecting controlled substances without law enforcement participation (may be used for other drugs). States would be required to pass legislation to adopt one or more of the models or propose an alternative. The second bill is more prescriptive, it does not mandate that five as opposed to only one model be developed, and no program managers or funders are specified.
- **Secure & Responsible Drug Disposal Act of 2009 (HR 1359 and S 1292)** Requires the DEA to create regulations allowing ultimate users or long-term care facilities to deliver unwanted drugs to other, authorized people for the purposes of disposal. The bill is less prescriptive than the HR 1191 and S 1336 and no program managers or funders are specified.

NATIONWIDE EFFORTS

- **Product Stewardship Institute (PSI)** works with stakeholders nation-wide to develop product stewardship approaches for the end of life management of unwanted/waste for many difficult-to-manage products, including pharmaceuticals. The main goals of the PSI multi-stakeholder dialogue are to increase awareness and to create a national, sustainable system for the end of life management of waste/unwanted pharmaceuticals.¹⁴
- **American Medicine Chest Challenge** is a nation-wide take-back event scheduled to occur in the US during fall of 2010.¹⁵

3. State Programs

At this point, several states are undertaking pilot programs, or recently finished pilot programs, to test methods for collecting home-generated pharmaceuticals. Several of these programs are listed below. These programs exclude controlled substances, unless noted:

- **Colorado:** The Colorado Department of Public Health and Environment and a consortium of concerned organizations launched a pilot program, to run through 2011. This program seeks to provide a secure and environmentally responsible way for people to dispose of unwanted medicines, excluding controlled substances. Tamper-resistant collection boxes are available at 10 locations around

the Denver metro area, including several stores, two county health department offices, and a health clinic. Funding is provided by a combination of federal, state and local government agencies (e.g., public health, water and environmental agencies), pharmaceutical and non-profit organizations.¹⁶

- **Iowa:** The Iowa TakeAway program aims to provide the public with a safe, easy way to properly dispose of unwanted and expired medications, excluding controlled substances. TakeAway uses community pharmacies across the state as take-back sites. Some participating pharmacies also sell TakeAway envelopes, pre-addressed, pre-postage paid large envelopes that can be taken into the home, filled with unused and expired medicine, and mailed through the United States Postal Service to the disposal facility. Funding was provided through Iowa Department of Natural Resources grants to the Iowa Board of Pharmacy, who worked closely with the Iowa Pharmacy Association, to offer the TakeAway pilot program. The \$165,000 grant paid for collection in 357 pharmacies and as of May 2010, 2,550 lbs were collected and destroyed (this does not count partially filled bins).^{17 18}
- **Maine:** The Safe Medicine Disposal for ME Program (mail-back) is a statewide pilot program for the disposal of unused household medications using a mail-back return envelope system.¹⁹ Established through state legislation and implemented in 2007 with a \$150,000 grant from the U.S. Environmental Protection Agency's Aging Initiative. The program was authorized to handle both controlled and non-controlled medications. All drugs collected undergo high-heat incineration, according to the procedure already established for Maine's law enforcement drug seizures. Costs were \$18.79/mailer, including both actual and in-kind costs during the start up (phase I and II); long term costs are anticipated to be \$7.50 /mailer (phase III). The average weight of a mailer with drug waste is seven ounces. A report on the statewide mail-back model concludes that mail-back offers "an element of confidentiality and anonymity not found with in-person take back programs and is the least burdensome of all models in terms of consumer access and utilization." It further states that "Maine's citizen mail-back program has demonstrated that this approach is not only feasible, but effective." More recently, Maine Department of Environmental Protection reported on research that found leachate in three lined landfills that contained a large variety of pharmaceuticals and personal care products.²⁰
- **Washington:** To address the need for a safe way to dispose of unwanted medicines, excluding controlled substance, a coalition of government, nonprofit, and business partners began a pilot in 2006 called Pharmaceuticals from Households: A Return Mechanism (PH:ARM) at Group Health Cooperative, a regional healthcare organization in Washington; Bartell Drug, a Western Washington retail pharmacy chain; and two boarding homes. Key findings of the PH:ARM pilot program are:
 - Medicine return programs can provide environmentally sound disposal of medicines.²¹
 - Returning medicines to a pharmacy with proper oversight and strict protocols can be safe and secure for any type of medicine, including controlled substances.
 - Medicine return programs are cost-effective to operate.
 - The Controlled Substances Act should be changed to allow collection of legally prescribed controlled substances at pharmacies.
 - A statewide program could collect a substantial amount of unwanted medicines.
 - Pharmacy-based medicine return is convenient and effective.
 - Community demand for safe disposal of medicines is high.
 - Sustainable funding is needed for a statewide medicine return program.

Additionally, many local governments and even groups of states host collection events. For example, in Maryland seven counties collect pharmaceuticals and a regional program is underway with the US EPA and four states that focuses on the Potomac watershed.²²

Of these pilots, Washington and Maine stand out for being completed and providing fairly detailed information on costs and collections rates. Overall, among pilot programs, common themes emphasize a need for:

- Sustainable funding;
- Safe and legal disposal for home-generated pharmaceuticals;
- Convenient collection through pharmacies, other collection sites and mail back programs; and
- Controlled Substances Act should be changed to allow for the collection of prescribed controlled substances at pharmacies.

PROPOSED STATE-LEVEL LEGISLATION

Several states (Florida, Maine, Maryland, Minnesota, Oregon, Rhode Island, and Washington) have proposed product stewardship legislation for pharmaceuticals, but as of June 2010, none have passed as product stewardship legislation. An amendment to Minnesota legislation (SF 1568) narrowed its scope and enables various parties including licensed HHW facilities and county collection programs to have possession of prescription drugs for the purpose of disposal.

V. Potential Options for Further State Action

This section includes a range of potential options for further state action. These options start with continuing the status quo and are followed by three options which present possible paths forward. At the end of this section, there are "Parting Comments" which discusses the possible application of the options.

For each option, CalRecycle includes some potential impacts, arranged by the:

- Four evaluation factors in SB 966 (safety, accessibility, cost effectiveness, and efficacy),
- Challenges and barriers discussed above (Expense of Safe Collection, Lack of Public Awareness and Participation, Lack of Sustainable Funding, Lack of Goals, Unclear Requirements, Policies and Authorities), and
- Environmental impacts that SB 966 addresses.

Option 1. Continue Current Practices

Under this option, the state could encourage consumers to follow federal Office of National Drug Control Policy guidelines and also allow disposal of pharmaceuticals in landfills, if local collection options are not available. Consequently, some pharmaceutical chemicals would likely be found in landfill leachate^{23 §§}

Under this option the Guidelines would continue to be optional. This option would require some tolerance of programs that do not follow the current Guidelines.

POTENTIAL IMPACTS:

- **Safety:** No change from current level. **Illegal diversion could still easily occur at waste disposal collection points (e.g., scavengers at trash bins, employees at materials recovery facilities). The described "treatments" in the Office of National Drug Control Policy do not appear to be a strong deterrent; e.g., mixing pharmaceutical waste with coffee grounds as the grounds are edible so drugs could still be consumable.**
- **Accessibility:** No change from current level. **A wide range of collection programs could continue as they currently exist, but as currently happens many consumers would be unaware of collection options or would not participate in available programs.**
- **Cost effectiveness:** No change from current level. **Would not reduce collection and management costs from current levels.**
- **Efficacy:** No change from current level. **Collection programs could continue to explore ways of providing more cost effective solutions without additional constraints or requirements. But this option would not significantly increase collection; as a consequence, pharmaceuticals would continue to be stored at home, disposed of in landfills or flushed down toilets, and eventually enter streams and groundwater. Collection levels would likely remain quite low compared to the total amount of home-generated pharmaceutical waste.**
- **Expense of Safe Collection:** No change from current challenge. **Because the Guidelines are voluntary, some requirements would continue to be ignored in order to reduce costs.**
- **Lack of Public Awareness and Participation:** No change from current challenge. **Would not address need for increased education.**
- **Lack of Sustainable Funding:** No change from current challenge. **Places no additional costs on state government, but would not address issue of insufficient funding or lack of sustainable funding source. Local governments would need to continue to find ways of funding these collection programs.**
- **Lack of Goals:** No change from current challenge.

^{§§} Landfill leachate is typically gathered in leachate collection systems, although it is possible that a small amount may eventually escape containment and enter streams and rivers. Instead, most collected leachate is discharged into wastewater treatment systems. However, wastewater treatment systems are not equipped to handle pharmaceuticals and so pharmaceuticals in leachate may eventually enter streams and rivers.

- **Unclear Requirements, Policies and Authorities:** No change from current challenge. Does not require new legislation. State agency roles and responsibilities would remain confusing and program managers would not have clear requirements to follow.
- **Environmental impacts:** No change from current impacts. Would not address potential impacts, such as bioaccumulation, sensitive species and/or synergistic effects, from wastewater treatment discharges (including materials originating from leachate).

Option 2. Improve Guidelines, Enforcement, and Establish Clear State Agency Roles and Responsibilities

The Legislature could direct CalRecycle or another state agency to develop regulations based on the Guidelines which have been the leading officially-sanctioned home-generated pharmaceutical waste collection guidelines in California since November 2008. This option assumes no additional funds.

POTENTIAL IMPACTS:

- **Safety:** The percentage of programs meeting the Guidelines would rise if it was mandatory.
- **Accessibility:** Because requirements will be clearer, the number of collection programs may increase and provide consumers with greater accessibility. However, the overall number of programs may not increase if the costs associated with meeting the Guidelines are too high.
- **Cost effectiveness:** Mandatory implementation of the Guidelines could result in higher costs and lower cost effectiveness. If clarification of the Guidelines identified additional options or flexibility, costs could be reduced.
- **Efficacy:** Some increase in collection is possible, but collection levels would likely remain quite low compared to the total amount of home-generated pharmaceutical waste.
- **Expense of Safe Collection:** Mandating use of the current Guidelines will likely make this challenge worse as all programs must meet all the criteria.
- **Lack of Public Awareness and Participation:** No change from current challenge.
- **Lack of Sustainable Funding:** Could place additional costs on state government for regulatory and enforcement activities. Would not address issue of insufficient funding or lack of sustainable funding source. Local governments would need to continue to find ways of funding these collection programs.
- **Lack of Goals:** No change from current challenge.
- **Unclear Requirements, Policies and Authorities:** Would provide an opportunity to update the Guidelines, set clear, consistent and enforceable standards. Could better define state agency roles and responsibilities through legislation or regulation.

- **Environmental impacts: Significant amounts of pharmaceuticals would continue to be stored at home, disposed of in landfills or flushed down toilets, and eventually enter streams and groundwater.**

Option 3. Implement Product Stewardship

Product stewardship programs use a private-sector approach to managing discards.²⁴ Product stewardship is a shared responsibility approach that could provide for safe, accessible, and cost-effective end-of-life management of home-generated pharmaceuticals. Product stewardship programs are working successfully in the United States, Canada, Europe, and elsewhere for products ranging from computers to paint to pharmaceuticals.

Conceptually, this approach appropriately places the primary responsibility for pharmaceuticals management with the pharmaceutical manufacturer and the consumers who use them, rather than local governments and ratepayers. In other words, those who benefit from pharmaceuticals pay for pharmaceuticals waste management costs.

Full product stewardship programs are industry-led, giving producers or manufacturers the flexibility to design and implement their own programs, with the state or national governments' role as setting ground rules and providing oversight. Program costs are covered in the product price so those who use the product pay for its full cost. Producers are generally able to implement programs either individually or by joining together with other producers through a Product Stewardship Organization that collects, properly manages, and interacts with the state oversight agency on its behalf.

Producers (or their Product Stewardship Organization) plan and implement collection programs. For example, the producer would select the collection system that it determines to best achieve goals for the lowest cost. It could be through a willing pharmacy, or through law enforcement, at events, through mail-back, or some combination of these; and as long as goals and related laws were met, state government would not be involved, except in an oversight capacity and to ensure all producers participate.

Under this option, legislation would mandate a private-sector designed and managed producer responsibility approach for pharmaceuticals. This would provide the authority for state oversight to ensure a level playing field, and address issues of state agency roles and responsibilities so it is less confusing and more streamlined. This option would support the CalRecycle Strategic Directive on producer responsibility and it also is consistent with the Extended Producer Responsibility Framework Document adopted in January 2008.²⁵

POTENTIAL IMPACTS:

- **Safety: An adequately funded and well coordinated, cooperative approach could result in safer handling of home-generated pharmaceutical waste. Better financing, consumer education, and more participation would likely increase the level of secure pharmaceutical management to prevent illegal diversion.**
- **Accessibility: Would likely result in increased consumer accessibility.**
- **Cost effectiveness: Creates an incentive for producers to more efficiently collect pharmaceuticals and considers product design changes that reduce management costs.**

- **Efficacy**: Private sector programs can adapt more readily to changes in laws and market conditions and modify their program to maximize effectiveness. A more comprehensive and cooperative approach could capture significantly more home-generated pharmaceutical waste.
- **Expense of Safe Collection**: This approach may find new ways to approach the current Guidelines.
- **Lack of Public Awareness and Participation**: Efforts to increase public awareness and participation would be part of the product stewardship program.
- **Lack of Sustainable Funding**: Offers an equitable system where those who benefit from a product, pay for its full costs. Creates a new role for pharmaceutical manufacturers, who may resist additional responsibility and additional costs. Would provide sustainable funding for all program activities. Could place additional requirements on state government for oversight activities but the cost of these activities would be funded by industry through the product stewardship organization. Could reduce burden on local governments.
- **Lack of Goals**: This option would likely have goals to strive for as part of its framework.
- **Unclear Requirements, Policies and Authorities**: Requires new legislation that may be difficult to enact. Would minimize government bureaucracy, provide for clear government regulatory roles and responsibilities that can reduce program implementation costs.
- **Environmental impacts**: Less home-generated pharmaceutical waste would enter the environment.

Option 4. Create a Statewide Collection Program Using an Advanced Disposal Fee and State Oversight

CalRecycle already manages several programs using an advanced disposal fee (ADF). Under these programs, consumers pay a fee at the time of purchase that is deposited in a fund managed by state government. Under this option, when consumers purchase pharmaceuticals they would pay a small fee that goes into an account to finance a collection program. CalRecycle, or other state agency, would establish the requirements for service providers participating in the collection program, certify or register service providers, pay service providers who collect the products covered under the program, and oversee compliance and enforcement.

POTENTIAL IMPACTS:

- **Safety**: An adequately funded and well regulated program could result in safer handling of home-generated pharmaceutical waste. Better financing, consumer education, and more participation would likely increase the level of secure pharmaceutical management to prevent illegal diversion.

- **Accessibility**: An ADF option could utilize any or all of the collection program types currently used, or could mandate more specific requirements. Would likely result in increased consumer accessibility as more programs were created to tap into the funds collected through the ADF.
- **Cost effectiveness**: There would be less incentive to be innovative or to more efficiently collect pharmaceuticals if the state requires specific method(s) and/or pays a standardized processing/collection payment to service providers. ADF programs are known to achieve high collection rates, but are expensive compared to a private sector designed and managed programs, such as those using a product stewardship approach. Would increase government bureaucracy.^{***}
- **Efficacy**: Private sector service providers would have an incentive (processing/collection payments) to create new programs and expand existing programs to gather more materials. A more comprehensive and regulated approach could capture significantly more home-generated pharmaceutical waste.
- **Expense of Safe Collection**: This approach could subsidize safe collection methods enough to make more programs feasible.
- **Lack of Public Awareness and Participation**: Private sector service providers would have an incentive (processing/collection payments) to educate the public about the services they provide and to compete for home-generated pharmaceutical waste.
- **Lack of Sustainable Funding**: Would provide sustainable funding for all program activities. Would place significant additional costs on state government for regulatory, fiscal and enforcement activities that would need to be funded by the ADF. Could greatly reduce burden on local governments. Would be a visible fee on consumers which may not be popular.
- **Lack of Goals**: This option would likely have goals to strive for as part of its framework.
- **Unclear Requirements, Policies and Authorities**: Requires new legislation that may be difficult to enact. Legislation would be needed to provide the authority for a state program and could result in clearer government regulatory roles and responsibilities, clearer requirements and a more uniform approach to home-generated pharmaceutical wastes.
- **Environmental impacts**: Less home-generated pharmaceutical waste would enter the environment.

^{***} For example, California's electronic waste (e-waste) program requires approximately 75 staff across state government. Among the twenty or more e-waste programs in the country, California is the only state using an ADF approach. In part, that is because it was the first program, but since then other states have opted for a product stewardship approach, which requires fewer government resources.

Parting Comments

The options above serve as starting points for further discussion and information gathering. It should be noted that some of the options may be combined.

Additionally, these options would allow multiple collection systems to co-exist, which may be necessary because CalRecycle has not found a single preferred collection system for all regions. Each system (continuous collection programs, collection events, and mail-back) has its merits when one considers programs budgets, available collection infrastructure, changing laws and regulations, and local public acceptance. Additionally, regardless of which option is implemented, much work lies ahead in finding solutions to financing, establishing clear goals, state agency responsibilities, and educating the public to meet the ultimate goal of providing safe and secure collection and management of home-generated pharmaceuticals.

VI. Source Reference Notes

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- ⁹ See www.calrecycle.ca.gov for more information on Product Stewardship, also known as Extended Producer Responsibility.
- ¹⁰ Health Canada, "Pharmaceutical Disposal Programs for the Public: A Canadian Perspective", Nov 6, 2009. Annex 6: International Programs. pgs 68

- ¹¹ Tim Grayling, Prepared for World Health Organization, "Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies" 1999. Available at: http://www.who.int/water_sanitation_health/medicalwaste/pharmaceuticals/en/
- ¹² Office of National Drug Control Policy, *Proper Disposal of Prescription Drugs*, October 2010 http://ondcp.gov/publications/pdf/prescrip_disposal.pdf
- ¹³ Office of National Drug Control Policy, *Proper Disposal of Prescription Drugs*, October 2010 http://ondcp.gov/publications/pdf/prescrip_disposal.pdfz
- ¹⁴ Product Stewardship Institute: Accessed on July 23, 2010, <http://www.productstewardship.us/displaycommon.cfm?an=1&subarticlenbr=181>
- ¹⁵ "American Medicine Chest Challenge" Nov. 13, 2010 is proposed as "The First in the Nation Day of Disposal of Unused, Unwanted, and Expired Medicine." Accessed on June 25, 2010, www.americanmedicinechest.org.
- ¹⁶ Colorado Department of Public Health and Environment, *Health Organizations Launch Take-Back Program for Unwanted Medicines*, press release, Dec 9, 2009, <http://www.cdphe.state.co.us/release/2009/121009.html>
- ¹⁷ Iowa Pharmacy Association, accessed on June 23, 2010: <http://www.iarx.org/TakeAway/Default.aspx#FAQ>
- ¹⁸ Thomas Anderson, Executive Officer II, Iowa Land Quality Bureau, E-mail communications June 24, 2010.
- ¹⁹ Lenard Kaye, Stevan Gressit, et al., "Safe Medicine Disposal for ME, A Handbook and Summary Report" Prepared, April 2010, Link to executive summary: <http://www.epa.gov/aging/RX-report-Exe-Sum/>
- ²⁰ Maine Department of Environmental Protection, Press Release, January 14, 2010, <http://www.maine.gov/tools/whatsnew/index.php?topic=DEP+News&id=88993&v=Article>
- ²¹ Cheri Grasso, et al., *Secure Medicine Return in Washington State, The PH:ARM Pilot*. 2009, <http://www.medicinereturn.com/resources/pharm-report/mar2010pharmareport.pdf>
- ²² Hilary Miller, Maryland Dept of the Environment, email communication on June 23, 2010.
- ²³ Maine Department of Environmental Protection, Press Release, January 14, 2010, <http://www.maine.gov/tools/whatsnew/index.php?topic=DEP+News&id=88993&v=Article>
- ²⁴ See www.calrecycle.ca.gov/tires/tda for more information on Product Stewardship, also known as Extended Producer Responsibility.
- ²⁵ CalRecycle, "Overall Framework for an Extended Producer Responsibility System in California" <http://www.calrecycle.ca.gov/EPR/Framework/Framework.pdf>

Appendix 1: Overview of Home-Generated Pharmaceutical Collection Programs Outside of California

International Programs	Canada: Alberta	Canada: British Columbia	Canada: Nova Scotia	Canada: Saskatchewan	Australia: Return Unwanted Medicines (RUM) Project	France: Cyclamed Program	Portugal: Valormed Program	Spain Integrated Waste Management System (SIGRE)	Sweden: Apoteket AB Environmental Program
Sources	1	1	1	1	1	1	1	1	1
Start date	1988	1996	Mid 90s	1997	1999	1993	2001	2002	2006
Population (2006)*	3,300,000	4,300,000	930,000	990,000	20,000,000	63,000,000	10,600,000	45,200,000	9,100,000
Total program cost (US \$, 2006), except as noted	NA	\$333,606	\$34,808	NA	\$1,144,802	\$3,878,534	NA	NA	\$1,149,775
Cost(\$)/capita (preliminary estimate)	NA	\$0.08	\$0.04	NA	\$0.06	\$0.06	NA	NA	\$0.13
Cost (\$)/unit collected	NA	\$0.006/pill	\$0.001/pill	NA	NA	4 euros/ kilo	NA	NA	1.6 eruo/ kilo
EOL materials management (% of total program cost)	NA	NA	NA	NA	NA	63%	NA	NA	NA
Environmental									
Product (with its packaging) collected (tons)	37 tons	23 tons	10.6 tons	16.4 tons	NA	13,169 tons	576 tons	2300 tons	910 tons
Percent collected (from available for collection)	NA	NA	NA	NA	NA	80%	NA	NA	65-75%
Percent other (e.g. landfilled, incinerated for energy recovery, etc.)	NA	NA	NA	NA	11% diverted for incineration	NA	NA	NA	NA
Program effectiveness									
Pharmacy Participation (Total #)	900	985	259	350	5000	22,500	2,786	20,406	980
Pharmacy Participation (Percent)	100	96	100	90	100	85	98.5	100	100
Collection Per Capita (kilograms/capita)	0.01	0.005	0.01	0.02	0.017	0.21 (0.09 w/o pkg)	0.054	0.058	0.01
Public awareness/participation	NA	NA	NA	NA	60%	77%	NA	NA	43%

Appendix 1 (continued)

State Programs

	Colorado: Pilot	Iowa: Pilot	Maine: pilot	Washington State: Pharmaceuticals from Households: A Return Mechanism (PH:ARM)
Sources	3, 8, 9	3, 5, 7	2, 3	3, 4, 5
Start date	2009	2009	2007	2006
Population (2006)*	4,751,474	2,967,270	1,313,355	6,360,529
Total program cost (US \$, 2006), except as noted	Unclear. Variety of sources and many amounts not specified.	\$165,000 (over 3 years)	\$150,000 (over 2 years)	NA
Cost(\$)/capita	NA	NA	NA	NA
Cost (\$)/unit collected			\$18.79/mailer (actual & in-kind costs phase I and II), \$7.50 /mailer phase III (longer term), ave weight of mailer is 7 ounces	NA
EOL materials management (% of total program cost)	NA	NA	NA	NA
Environmental				
Product (with its packaging)	NA	NA	1.15 tons	5 tons
Percent collected (from available for collection)	NA	NA	NA	NA
Percent other (e.g. landfilled, incinerated for energy recovery, etc.)				
Program effectiveness				
Pharmacy Participation (Total #)	NA	NA	NA	54 MWR facilities, 1,300 pharmacies
Pharmacy Participation (Percent)	NA	NA	NA	NA
Collection Per Capita (kilograms/capita)	NA	NA	NA	NA
Public awareness/participation	NA	NA	NA	NA

Sources	Type of Resource	Date	Weblink
1. Health Canada Environmental Impact Initiative	Report	November 1, 2009	http://www.enviroadvisory.com/pdf/Takeback.pdf
2. EPA website	Executive Summary to ME report	April 1, 2010	http://www.epa.gov/aging/RX-report-Exe-Sum/
	Access to full ME report	April 1, 2010	http://www.surveymonkey.com/s/HSGKBDD
3. US census	Database	2006	http://www.census.gov/popest/states/tables/NST-EST2008-01.xls
4. Snohomish County Solid Waste Management Division	Presentation	June 30, 1905	http://www.productstewardship.us/associations/6596/files/Sego_Jackson_presentation2.ppt
5. Oregon Pharmaceutical Take Back Stakeholder Group	Report	July 1, 2007	http://www.oracwa.org/downloads/drugtakeback-rpt_0907.pdf
6. Iowa Pharmacy Association	Frequently Asked Questions	2007	http://www.iarx.org/TakeAway/Default.aspx#FAQ
7. Iowa	Article Souix City Journal	February 1, 2010	http://www.cdphe.state.co.us/release/2009/121009.html
8. Colorado Department of Public Health and Environment	Press Release	2009	http://www.cephweb.com/documents/MedicationTake-BackPilotProjectCEHAPowerpoint.ppt
9. Colorado Department of Public Health and Environment	Presentation	October 2, 2009	

Pharmaceutical Waste Collection Program Survey

Events	
Please fill in all fields in white as completely as you can and return by Thursday, June 10, 2010.	
At what type of location(s) did you hold your event(s) (e.g., mobile event in parking lot, school, with flu vaccination in hospital, see comments, etc.)	
Number of sites participating in collection event	
Enter typical hours per location when the public could drop off drug waste (e.g., Saturday 10a-6p, etc.)*	*if hours are different for different sites, enter each in "Additional Comments"
Enter event date(s) - answer one Excel file survey per event or combine them (e.g., 7/18/2009; 10/17/2009-10/24/2009; 3rd Saturday of each month, etc.)	
Funder #1 (if applicable)	
Please list the entity that funds the program (if more than one funder, use separate columns)	
if more than one funder is listed above, what percent of the collection program does each funding source pay for?	
Check activity funded for each funding source above (if applicable)	<input type="checkbox"/> Ads <input type="checkbox"/> Hauler/processing fees <input type="checkbox"/> Admin/staff time <input type="checkbox"/> Hauler/processing fees <input type="checkbox"/> Admin/staff time <input type="checkbox"/> Ads <input type="checkbox"/> Hauler/processing fees <input type="checkbox"/> Admin/staff time
How is funding generated (e.g., tipping fees, sanitation district environmental funds, drug prevention budget, added pharmacy customers...)	
Total event costs:	
Costs include (send us your spreadsheet for a breakdown if possible)	<input type="checkbox"/> Ads <input type="checkbox"/> Hauler/processing fees <input type="checkbox"/> Admin/staff time
Total pounds collected	
Was there any cost to the consumer at the time of collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did you encourage removing pills from bottle and placing in a Ziploc?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did you collect controlled substances?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Law enforcement was present and maintained custody through incineration
Did signage indicate it's illegal to drop off controlled substances?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n/a law enforcement was present
Did any participants have access to drugs without a witness or surveillance?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Only law enforcement and/or registered waste haulers
Did you use a CDPH-registered medical or hazardous waste hauler?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Select registered hauler (if known):
Disposal method (e.g., incineration in Utah, ask hauler, etc.)?	
Are you maintaining a log containing contact information, collection and access dates, weight, and final disposition of drug waste?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> For controlled substances, log accompanies waste through the point of destruction <input type="checkbox"/> We also commit to keeping logs for three years after the collection event
Did you see any signs of illegal drug diversion?	<input type="checkbox"/> Yes <input type="checkbox"/> No
To your best knowledge, was your event consistent with the model program guidelines?	<input type="checkbox"/> Yes <input type="checkbox"/> No (please explain why in comments) (link to model program guidelines)
Additional Comments (e.g., • describe any other costs • highlight your successes • describe any lessons learned • describe any policy or legal barriers • describe key relationships or processes that had a significant impact on program costs, success, outcome, etc. • how have your events changed over time - including waste haulers - and why • if your program is not consistent with the model program guidelines, please explain why • is there anything else that is difficult to quantify or otherwise account for, and if so, why? • What other measures do you employ to prevent drug diversion?)	

Pharmaceutical Waste Collection Program Survey

Mailers

Please fill in all fields in white as completely as you can and return by **Thursday, May 20, 2010.**

	Location Type #1 (e.g., HW)	Location Type #2 (if applicable)	Location Type #3 (if applicable)
Type of location(s) where mailers have been available to the public			
Number of sites for each type listed above where mailers are available			
Enter typical hours per week per location type when the public can pick up mailers (e.g., M-F, 8a-5p, etc.). List in "Additional Comments" if necessary.			
Mailer program start date (mm/dd/yyyy)			
Please list the entity that funds the program (if more than one funder, use separate columns)			
If more than one funder is listed above, what percent of the collection program does each funding source pay for?			
Check activity funded for each funding source above (if applicable)	<input type="checkbox"/> Ads <input type="checkbox"/> Hauler/processing fees <input type="checkbox"/> Admin/staff time	<input type="checkbox"/> Ads <input type="checkbox"/> Hauler/processing fees <input type="checkbox"/> Admin/staff time	<input type="checkbox"/> Ads <input type="checkbox"/> Hauler/processing fees <input type="checkbox"/> Admin/staff time
How is funding generated (e.g., tipping fees, sanitation district environmental funds, drug prevention budget, added pharmacy customers...)			
Were all mailers purchased with prepaid postage?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> postage paid based on # mailed		
Mailer unit cost			
Total costs incurred (program start to March 1, 2010)*	<input type="checkbox"/> Ads <input type="checkbox"/> Hauler/processing fees <input type="checkbox"/> Admin/staff time		
Costs include (send us your spreadsheet for a breakdown if possible):			
Total number of mailers purchased			
Type of mailer purchased (if Sharps Compliance™, look on mailer for #)	Sharps Compliance™ Mailer Item #17010 <input type="checkbox"/> Rev A <input type="checkbox"/> Rev B <input type="checkbox"/> Rev C <input type="checkbox"/> Other (list in comments)		
Total number of mailers distributed (through March 1, 2010)*			* or list alternative date range in "Additional Comments" below if necessary (e.g., Jan. 1-Dec. 31, 2009)
Total number of mailers incinerated (through March 1, 2010)*			
Total pounds collected (program start to March 1, 2010)*			
Is there any cost to the consumer when mailers are given out?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
In addition to the standard instructions provided with your mailers (e.g., "Rx TakeAway™ Instructions for Use"), do you provide any additional education to mailer recipients?*	<input type="checkbox"/> Yes, additional written instructions <input type="checkbox"/> Yes, specific verbal instructions <input type="checkbox"/> No		** If yes, please send a copy of written or typical verbal instructions and describe how they are provided.
Have you seen any signs of illegal drug diversion?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
To your best knowledge, is your program consistent with the model program guidelines?	<input type="checkbox"/> Yes <input type="checkbox"/> No (please explain why in comments) (link to model program guidelines)		
Additional Comments (e.g., describe any other costs • highlight your successes • describe any lessons learned • describe any policy or legal barriers • if advertising was used, where and how was the program advertised • describe key relationships or processes that had a significant impact on program costs, success, outcome, etc. • how has the program changed over time and why • if your program is not consistent with the model program guidelines, please explain why • is there anything else that is difficult to quantify or otherwise account for, and if so, why? • what other measures do you employ to prevent drug diversion?)			

ATTACHMENT 6

Business and Professions Code Section

4067. Internet; Dispensing Dangerous Drugs or Devices without Prescription

- (a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.
- (b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars (\$25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars (\$25,000) per occurrence.
- (c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).
- (d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.
- (e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.
- (f) For the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242 and the requirements for a veterinarian in Section 2032.1 of Title 16 of the California Code of Regulations.

State of California Board of Pharmacy
Citation and Fine

CITATIONS BY VIOLATION CODES

Reporting from 07/01/2009 to 06/10/2010

Year	Case #	Name	Issue Date	Violation Code	Fine Amount	Collected Amount	Status
2006	33905	NICHOLS HILL PRESCRIPTION PHARMACY	7/21/2009	4067(a)	11,700,000.00	0.00	OPEN
2008	37322	ADVANCE PHARMACY	11/23/2009	4067(a)	71,275,000.00	0.00	OPEN
2008	37409	HOUSE OF MEDICINE	3/10/2010	4067(a)	775,000.00	0.00	OPEN
2008	38090	PATTERSON FAMILY PHARMACY	12/14/2009	4067(a)	20,300,000.00	0.00	OPEN
2008	39142	ACTON PHARMACY	1/5/2010	4067(a)	6,400,000.00	0.00	OPEN
2008	39565	THE MEDICINE SHOPPE	1/19/2010	4067(a)	4,650,000.00	0.00	OPEN
2008	39566	THE MEDICINE SHOPPE	4/28/2010	4067(a)	1,200,000.00	0.00	OPEN
2008	39567	HACIENDA PHARMACY	1/19/2010	4067(a)	6,400,000.00	0.00	OPEN
2008	39568	HOUSE OF MEDICINE	3/10/2010	4067(a)	4,100,000.00	0.00	OPEN
2008	39569	REDLANDS PHARMACY	4/21/2010	4067(a)	2,950,000.00	0.00	OPEN
2008	39633	BOULEVARD PHARMACY	11/12/2009	4067(a)	7,700,000.00	0.00	OPEN
2008	40588	SOUTH FIGUEROA DRUGS	5/6/2010	4067	52,300,000.00	0.00	OPEN
2009	40806	BYUNG SIK YUH	7/21/2009	4067(a)	11,700,000.00	0.00	OPEN
2009	41999	BENJAMIN FRIEDMAN	11/12/2009	4067(a)	3,125,000.00	0.00	OPEN
2009	42000	PHILIP AARON ETTEGGUI	11/12/2009	4067(a)	4,575,000.00	0.00	OPEN
2009	42050	WAYNE J STOLFUS	11/23/2009	4067(a)	62,775,000.00	0.00	OPEN
2009	42051	JOHN ALPHONSE MATUNAS	11/23/2009	4067(a)	8,500,000.00	0.00	OPEN
2009	42198	HANNAH MASON	1/5/2010	4067(a)	6,400,000.00	0.00	OPEN
2009	42451	WILLIAM THOMAS BRAGDON JR	12/14/2009	4067(a)	5,925,000.00	0.00	OPEN
2009	42452	JOHN F WONG	12/14/2009	4067(a)	8,475,000.00	0.00	OPEN
2009	42752	DANIEL KAIWAI HO	1/19/2010	4067(a)	6,400,000.00	0.00	OPEN
2009	42768	ALBERT S WONG	1/19/2010	4067(a)	4,650,000.00	0.00	OPEN
2009	43420	JAHANGIR S JANFAZA	3/10/2010	4067(a)	775,000.00	0.00	OPEN
2009	43421	JAHANGIR S JANFAZA	3/10/2010	4067(a)	4,100,000.00	0.00	OPEN

2009	43744	JENNIFER LU CHANG	4/28/2010	4067(a)	300,000.00	0.00	OPEN
2009	43745	CHY SUZIE CHAING	4/28/2010	4067(a)	900,000.00	0.00	OPEN
2009	44168	TONI GAYLE WALKER	5/6/2010	4067	52,300,000.00	0.00	OPEN
2009	44208	KEN CHU	4/21/2010	4067(a)	2,950,000.00	0.00	OPEN

Total Amount: 373,600,000.00 0.00

Total Issued: 28

Total Open: 28

Total Closed: 0

ATTACHMENT 7

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 board investigations within 6 months.
Measure:	Percentage of cases closed.
Tasks:	<ol style="list-style-type: none"> 1. Complete all desk investigations within 90 days (for cases closed during quarter). 2. Complete all field investigations within 120 days (for cases closed during quarter). 3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.
Objective 1.2	Manage enforcement activities for achievement of performance expectations
Measure:	Percentage compliance with program requirements
Tasks:	<ol style="list-style-type: none"> 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. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.
Objective 1.3	Achieve 100 percent closure on all administrative cases (excluding board investigation time) within one year by June 30, 2011.
Measure:	Percentage closure of administrative cases within one year.
Objective 1.4	Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011.
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.
Tasks:	<ol style="list-style-type: none"> 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 initially before licensure and annually before renewal. 3. Initiate investigations based upon violations discovered during routine inspections.

<p>Objective 1.5</p> <p>Measure:</p> <p>Tasks:</p>	<p>Initiate policy review of 25 emerging enforcement issues by June 30, 2011.</p> <p>The number of issues.</p> <ol style="list-style-type: none"> 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. Monitoring the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-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. 13. Participate in Department of Consumer Affairs Consumer Protection Enforcement Initiative to strengthen board enforcement activities and reduce case investigation completion times for formal discipline. 14. Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions. 15. Complete comprehensive review of investigative and enforcement internal processing to identify process improvements.
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ATTACHMENT 8



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

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

DATE: June 16, 2010

LOCATION: Bonderson Building
901 P Street, Hearing Room 102
Sacramento, CA 95814

COMMITTEE MEMBERS

PRESENT: Randy Kajioka, PharmD, Chair
Ramón Castellblanch, Public Member
Greg Lippe, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Shirley Wheat, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel
Tessa Fraga, Staff Analyst

Call to Order

Chair Kajioka called the meeting to order at 9:37 a.m.

General Announcements

1. Discussion Regarding the Drug Enforcement Administration's Proposed Regulations for the E-Prescribing of Controlled Substances

Dr. Randy Kajioka stated that the federal Drug Enforcement Administration (DEA) released on March 22, 2010 proposed requirements to enable e-prescribing of controlled drugs. He stated that until June 1, 2010, federal law did not allow the electronic prescribing of written prescriptions for controlled drugs. Dr. Kajioka indicated that the comment period on the proposed interim final rule ended on May 31, 2010.

Dr. Kajioka provided that at the April 2010 Board Meeting, the board was led in a discussion of the proposed, highly technical requirements by Deputy Attorney General Joshua Room. He stated that after a short discussion, the board agreed to send a request to the DEA to extend the comment period another 120 days so that the board and others could carefully read and consider the more than 330 pages of requirements and policy statements released by the DEA.

Executive Officer Virginia Herold advised the committee that the DEA has not responded to the board's request and has not yet trained field agents in this area. She recommended that the board consider convening a summit to discuss the guidelines in detail and provide guidance to industry on implementation. Ms. Herold indicated that this issue will be discussed during the July 2010 Board Meeting by e-prescribing advocates.

Dr. Kajioka made a recommendation that an ad hoc subcommittee be established.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided that Kaiser is encouraged that the guidelines have been released. He indicated that state law requires that the board and the Department of Justice (DOJ) must ratify the system for e-prescribing developed by the DEA. Dr. Gray suggested that the ad hoc committee should consider this as part of the process. He recommended that because the standards are so high, the board should consider adopting the regulations/guidelines as established by the DEA. Dr. Gray advised that Kaiser anticipates that it will take at least one year to modify the systems to conform to the DEA rules.

Dr. Kajioka indicated that the DOJ and other stakeholders will be invited to participate in this process.

Dr. Ramón Castellblanch asked if other entities have indicated where they are with respect to implementation.

Ms. Herold stated that she is unsure where others are in terms of implementation.

There was no additional board discussion or public comment.

MOTION: Establish an ad hoc committee to review and provide guidelines on the Drug Enforcement Administration's proposed regulations for the e-prescribing of controlled substances.

M/S: Kajioka/Lippe

Support: 3 Oppose: 0 Abstain: 0

2. Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding the Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area

Background

In 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. This was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Basically, a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. The machine was to be located near – specifically adjacent -- to the physical area of the pharmacy.

A number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive.

This regulation was promulgated cautiously. Throughout 2006, the board modified and adopted the regulation now in effect as section 1713. In January 2007, the regulation actually took effect.

Dr. Kajioka provided that at the January 2010 Board Meeting, Phil Burgess representing Asteres made a presentation to the board seeking a waiver from 1713(d) to allow automated dispensing machines to be located in areas other than the requirements of this section. He stated that at the meeting, the board asked Mr. Burgess to refine his request and return to the board so the board would more fully understand the proposal.

Dr. Kajioka provided that during the December 2009 Enforcement Committee Meeting and the subsequently January 2010 Board Meeting, Phil Burgess requested a waiver to the requirements in 1713 (d)(6) which requires that the delivery device be located adjacent to the secure pharmacy area. He indicated that in making the request, Mr. Burgess stated that his client Asteres would like to place the device in a secure area that is readily accessible to the patient and that a telephone would be placed adjacent to the device for patients that wished to speak with a pharmacist. Dr. Kajioka explained that whereas the initial proposal was to place the device in a hospital waiting room for refills for employees, at the board meeting, the request was far broader and would allow

the machines to be placed anywhere and could be used for patient delivery of refill medications as well.

Mr. Burgess discussed the importance of patient access as a means to improve patient compliance.

Mr. Burgess requested that the board waive regulation section 1713(d)(6) regarding the placement of automated medication dispensing machines in hospitals to allow for the installation of the ScriptCenter "pickup" system in a hospital environment whereby the unit is not directly attached to the pharmacy. He made a second request for a special waiver to allow for a pilot of this system to demonstrate that improved access will increase medication adherence. Mr. Burgess indicated that he would like the waiver for a five-year period.

Ms. Herold asked how many employees would be involved in this system.

Mr. Burgess indicated that he believes several thousand employees could participate.

Dr. Kajioaka asked how the system impacts the patients relationship with the pharmacist.

Mr. Burgess provided that the refills are personally filled by a pharmacist. He stated that patients elect to be involved in the system and can easily call a pharmacist when picking up their prescriptions.

Dr. Castellblanch asked how the system is being used in other states.

Mr. Burgess indicated that a variety of other states are utilizing the machines for both new prescriptions and refills.

Ms. Herold reviewed the experimental programs provision in section 1706.5.

Mr. Burgess requested that the board allow schools of pharmacy to work with the hospitals that are utilizing the system to assess the positive benefit.

The committee discussed the need for specific measurements to assess this process.

Robert Ratcliff, Supervising Inspector, requested clarification on the definition of "secured area."

Mr. Burgess reviewed the elements of a secured area including video cameras monitoring the machine and the individuals accessing the machine, signature logs, thumb print records, external monitoring of the machine, and audit trails. He stated that the machines can be located at each hospital campus and can be

bolted to the floor of the facility. Mr. Burgess added that patients will have telephone access to an inpatient pharmacist within the hospital that can access the patient's drug information history via an integrated computer system.

Public Comment

Dr. Steve Gray, representing Kaiser Permanent, provided support for the proposal and the system's ability to improve compliance. He stated that a collaboration with schools of pharmacy may be a viable way to determine how this system impacts the pharmacist-patient relationship and quality of care. Dr. Gray encouraged the committee to recommend that the board consider the waiver and support the collaboration with schools of pharmacy.

Dr. Kajioka asked if the machines would only be located in licensed hospitals.

Mr. Burgess stated that the machines would only be in licensed hospital pharmacies.

Dr. Kajioka recommended that Asteres partner with a school of pharmacy to establish a pilot program and identify some measures to assess the program.

Dr. Kajioka indicated that this proposal will be reviewed by the board's legal counsel.

There was no additional board discussion or public comment.

3. Presentation of a Drug Distribution Model Proposed by Medco Health Solutions, Using Two Pharmacies, Each with Specialized Functions

Dr. Dennis McAllister, representing Medco Health Solutions, presented a proposed drug distribution model whereby services are provided to community pharmacies in a Central Fill/Central Processing arrangement. He indicated that Medco patients will elect to participate in this process. Dr. McAllister stated that the model meets the requirements of section 1707.4 as all prescriptions will be dispensed in California by a licensed California pharmacy. He advised that the model does not include controlled substances.

Dr. McAllister provided that the model is currently in operation in several states. He indicated that Rite Aid is currently partnering with the project and it is intended that other chain stores will participate as well. Dr. McAllister added that Medco has established 14 therapeutic resource centers to provide patients with improved and specialized care.

The committee discussed the model process. It was clarified that in instances where the medication is not picked up by the patient, the pharmacy will destroy

the medication through a reverse distributor. All documentation and records will be available for the board for inspection. Medco is the owner of the prescriptions filled at the central fill center. It was indicated that the model provides labor savings for the participating chain pharmacies.

Ms. Herold suggested that the prescription label include information indicating that the prescription was filled by Medco. She recommended that Medco locate a therapeutic resource center in California.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, offered support for this concept and discussed the error reduction achieved in this refill process. He stated that the DEA has approved this concept and has adapted rules that may allow for “depoting” of controlled substances. He expressed concern regarding dual labeling as it leads to confusion by the patient.

Dr. McAllister asked whether the board considers a renewed prescription to be a refill.

Dr. Kajioka indicated that a renewed prescription is considered a refill.

There was no additional board discussion or public comment.

4. Update on the Board’s Efforts to Implement Components of the Department of Consumer Affairs’ Consumer Protection Enforcement Initiative

Dr. Kajioka provided that since July 2009, the Department of Consumer Affairs has been working with the health care boards to upgrade their capabilities to investigate and discipline errant licensees to protect the public. He stated that the proposed changes have taken various forms. Dr. Kajioka advised that the goal is to ensure the average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months. He advised that formal discipline means those cases which are the most serious, and for which license removal or restriction is being sought.

Dr. Kajioka provided that in addition to the additional staff resources being sought, board staff completed a comprehensive review of our internal processes to identify ways to streamline our processes, reduce timelines and improve our effectiveness. He stated that board staff identified 18 improvements and is working towards full implementation. Dr. Kajioka referenced to the following summary of changes initiated to date as well as the status.

1. Complete case assignments on line.

Status: Completing testing of the new process. Staff is working to finalize written procedures.

2. Complete review of draft accusations on line
Status: Accusations are now reviewed on line by field staff. Staff will finalize written procedures.
3. Prescreen complaints at assignment with an AGPA - AGPA would follow up to ensure that complaints are assigned. Screen out non-jurisdictional and close or refer as appropriate.
Status: Training is complete and this provision is implemented. As indicated in previous months, this is a temporary solution, and full implementation cannot be achieved without staff resources.
4. AGPA to complete license history instead of board inspector including past CI's, assignments, violations and outcomes of those. Past inspections, date and who completed them.
Status: A draft template is developed, however pre-populated reports are not yet in place. Initiated pilot with limited investigator staff.
5. Develop a method to automatically populate information on the investigation report instead of using expensive inspector time.
Status: A draft template is developed, however pre-populated reports are not yet in place. Initiated pilot with limited investigator staff.
6. Train non-attorney staff to prepare default decisions to speed investigation closures.
Status: Training completed. Board staff preparing some default decisions in-house.
7. Secure automated fingerprint background checks and criminal record information from the Department of Justice.
Status: Implemented and staff trained.
8. Begin drafting some Petitions to Revoke Probation in house.
Status: Internal staff completed first PTR. Draft is currently undergoing review.

Ms. Herold provided that board staff is moving towards the electronic transfer of documents to field staff. She indicated that the staff is also working towards providing the board the ability to vote online.

No public comment was provided.

5. Update on California's Drug "Take Back" Programs from Patients

Dr. Kajioka provided that in the February 2010 *The Script*, the board promoted the take-back guidelines developed by the California Integrated Waste Management Board pursuant to SB 966 (Simitian, Chapter 542, Statutes of 2007) with the assistance of the Board of Pharmacy.

Dr. Kajioka provided that since April 2010, board inspectors have been directed to take pictures of drug take back programs in place in pharmacies, and to encourage compliance with the state's guidelines.

Dr. Kajioka provided that the Drug Enforcement Administration (DEA) continues to be concerned about these programs nationally, and is working with counties that are establishing principally short-term take back programs for controlled drugs. He indicated that in some communities, law enforcement is working with the DEA to take back controlled drugs at law enforcement facilities.

Dr. Kajioka provided that on July 20, 2010 the CalRecycle Program, which took the place of components of the California Integrated Waste Management Board, will hold a workshop on home-generated pharmaceutical waste collection and disposal. He stated that the purpose is to generate data that will be included in a report to the Legislature by the end of 2010.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided comment on several initiatives for the adoption of take back programs. He discussed a city ordinance to require pharmacies to take back needles. He stated that this ordinance could be expanded to also require the take back of drugs.

Phil Burgess, representing Asteres, provided that there is a demand for pharmacies to be involved in take back programs.

There was no additional board discussion or public comment.

6. Question and Answer Session on the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound, and Sections 1751 1751.8, Pharmacies That Compound Sterile Injectable Medications

Supervising Inspector Robert Ratcliff reviewed the following questions and answers that have been submitted to the board regarding the board's compounding regulations.

- 1735.3(a)(6) & 1751.2(a) – For the purposes of these sections, would patients of an infusion center (those receiving chemotherapy administered in a clinic setting) be considered “inpatients” and therefore be exempt from such labeling requirements?

1735.3(a)(6) provides for the exemption for records of the manufacturer and lot number for products compounded on a one time bases for administration within 24 hours to an inpatient in a health care facility licensed under § 1250.

- 1735.8(c):

1. What is the board's expectation for the frequency of quantitative and qualitative analysis of a given product?
2. Does every product and/or formulation compounded by a pharmacy have to undergo qualitative and quantitative analysis? If not, can the board provide guidance for selecting products to be analyzed?
3. Do cytotoxic agents and other hazardous substances have the same requirements for qualitative and quantitative analysis?

The board's expectation is that the compounded product meets the prescriber's prescription requirements. The pharmacy needs to have policies and procedures in place to insure said compliance. It will be up to the pharmacy to determine this compliance.

Batch produced sterile compounding from one or more non-sterile ingredients requires documented end product testing for sterility and pyrogens and shall be quarantined pending results (1751.7(c)).

1751.7(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

- Are gowns required when preparing cytotoxic agents if using barrier isolator?

1751.5(c) The requirements of ~~this~~ subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients

- Is an NRP providing compounded product into CA required to meet the same staffing requirements as CA pharmacies?

No, the NRP must comply with the requirements of their resident state.

- What constitutes sterile compounding?

Refer to section 1735.

§1735. Compounding in Licensed Pharmacies.

(a) “Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a drug product from chemicals or bulk drug substances

§1751. Sterile Injectable Compounding; Compounding Area.

(a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

- Is it any IV admixture, such as adding 20 mEq KCl to 1000ml NS?

Yes.

- What happens in a situation where an IV is made to be used on a one time basis for administration within 24 hours for a registered inpatient of a health care facility and product is not used and returned to the pharmacy? Can it be reused?

No.

- Is a master formula record equivalent to a “recipe card?”

Yes.

- When compounding a product, is it required to have master formula record available and used when the product is compounded?

Yes, the master formula record is required to be available pursuant to section 1735.3(a).

§1735.3. Records of Compounded Drug Products.

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

...

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

- Is it required to inspect the master formula record as part of pre-check process?

Refer to section 1735.2 (f)(i). It is recommended that the master formula record is reviewed prior to compounding.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

- What are the requirements for compounding documentation?

§1735.3. Records of Compounded Drug Products.

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) The equipment used in compounding the drug product.

(8) A pharmacy assigned reference or lot number for the compounded drug product.

(9) The expiration date of the final compounded drug product.

(10) The quantity or amount of drug product compounded.

- When using exemption to compound a one time Vancomycin IV with a seven day expiration date and to be used within 24 hours, is the manufacturer and lot number required?

No.

- When must the manufacturer and lot number be recorded?

This information must be documented if the product is not for a one time use for a specific patient to be used within 24 hours.

- How will the board insure compliance by NRP's?

Refer to section 4127.2. NRP's will also submit appropriate Compounding Self Assessment forms to the board.

4127.2. Nonresident Pharmacy – License to Compound and Ship Injectable Drug Products into California Required

(a) A nonresident pharmacy may not compound injectable sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

- Please clarify a question regarding reconstitution and compounding (i.e. – The package insert of an IV antibiotic states to reconstitute and then dilute in 100ml of D5W before administration).

Refer to section 1735.

§1735. Compounding in Licensed Pharmacies.

(b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

- Is the dilution per the manufacturer’s instructions and adding to the IV solution considered compounding?

Yes.

- What specifically will be required or what process is acceptable to achieve such quality assurance?

Refer to sections 1735.8 and 1735.7.

§1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

§1735.7. Training of Compounding Staff.

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug

- Are proprietary drug delivery systems such as ADD-Vantage, Mini-Bag Plus, and At Eas considered compounded products after the vials have been attached to the IV bags?

Refer to sections 4127.1 and 1735.

4127.1. License to Compound Injectable Sterile Drug Products Required

...

(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:

- (1) The sterile powder was obtained from a manufacturer.
- (2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

§1735. Compounding in Licensed Pharmacies.

(b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

- When recycling an IV that was previously compounded by the pharmacy, can the previous lot number of the recycled IV be used as long as the lot number can be traced to all the requirements listed in section 1735.3?

Yes.

- What is a “reliable supplier?”

Refer to section 4163 and 1783.

4163. Unauthorized Furnishing by Manufacturer or Wholesaler

(a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices....

1783. Manufacturer or Wholesaler Furnishing Drugs and Devices.

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also

means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

- Can a pharmacy mix three liquids (Maalox, Benadryl, and Xylocaine) in equal parts? Can a pharmacy mix two creams in equal parts?

Yes, a pharmacy may do both. Both activities are considered compounding.

- Can a pharmacy do the above compounding without having a special certification for compounding, or being held to all the requirements?

There is no special certification/licensure for non-sterile compounding. However, all the other requirements of section 1735 et seq. must be complied with.

- Our medical center's policies and procedures have the initial dose of an IV admixture compounded in the pharmacy satellite to assure timely initiation of therapy, with all subsequent doses mixed in the central pharmacy. Is the initial IV admixture compounded in the satellite subject to the recording requirements?

All record documentation is required with the possible exception of 1735.3(a)(6).

- Does section 1735.5 require a pharmacy to test each and every compounded product for integrity, potency, quality, and labeled strength of the compounded product?

No. However, if the compounded product involves a complex process it would seem prudent to have documentation of the final product. This is even more important when the product is compounded on a more routine basis.

Compounding involves not just the QA process, but staff training, equipment maintenance, proper documentation and appropriate analysis of products compounded.

§1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

§1735.7. Training of Compounding Staff.

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

§1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

7. Pharmacies Dispensing Prescriptions for Internet Web Site Operators

Dr. Kajioka provided that at the December Enforcement Committee, the committee was advised that the board's inspectors have investigated a number of cases where California pharmacies are filling prescriptions from Internet Web sites in situations where patients are in a number of states, a prescriber is writing prescriptions for the patients from a single state, and the California pharmacy is filling the prescription.

Dr. Kajioka provided that many times these prescriptions are not valid because an appropriate exam by a prescriber has not occurred. He stated that California law allows the board to issue citations at \$25,000 per invalid prescription delivered to patients in California.

Dr. Kajioka provided that over the last 18 months, the board has issued multiple million dollar fines to California pharmacies for filling such false prescriptions. He stated that the Drug Enforcement Administration is also involved in some of these Web site investigations and has fined California pharmacies for their participation.

Dr. Kajjoka provided that The *July 2008 The Script* reminded pharmacies not to participate in such scams. He stated that at public speaking events, this is one area touched on by board speakers.

Dr. Kajjoka provided that one project recently initiated by board staff is the development of a short video on the dangers of purchasing drugs online. He stated that the board is working with the Department of Consumer Affairs on this video, which we plan to have completed by the end of the summer.

Mr. Ratcliff provided that pharmacies are facilitating the illegal distribution of prescription drugs from the Internet. He stated that from discussion with the owners of several of these pharmacies investigated by the board, the pharmacies receive an offer via a faxed notice offering amounts as low as between \$3 and \$6 per prescription plus drug costs to fill these orders. Mr. Ratcliff advised that the economics greatly benefit the Web site operator. He indicated that the patient may pay \$100 to \$200 purchase a prescription from the Internet – the pharmacy may get \$6 or \$10 from such a sale.

Ms. Herold advised that this issue is a serious concern for the board. She stated that the board will issue substantial fines for pharmacies participating in this activity.

Public Comment

Dr. Gray, representing Kaiser Permanente, suggested that the board provide more information regarding what is not considered an internet pharmacy.

Ms. Herold provided that these cases typically involve controlled drugs where numerous patients in California and other states get prescription drugs they order from a Web site. She stated that these prescriptions are written by a physician that is contracted with the Web site and is located in a state different than where the patient lives.

Dr. Castellblanch asked whether this issue should be referred to the Legislation and Regulation Committee.

Ms. Herold provided that many of these cases are referred for administrative action. She stated that additional legislation in this area may be needed. Ms. Herold suggested that the Enforcement Committee continue to identify solutions in this area prior to referring it to the Legislation and Regulation Committee.

There was no additional board discussion or public comment.

8. Post Implementation Review of the Board's Criminal Conviction Unit

Dr. Kajioka provided that included as part of last year's budget, was a staff augmentation for the board to establish the Criminal Conviction Unit within the board.

Dr. Kajioka provided that as of July 1, 2009, there were 1708 investigations pending. He indicated that as of June 1, 2010, that number was reduced 629 investigations pending. Dr. Kajioka stated that additionally over 1900 cases have been completed. He referenced to the following snapshot of the final disposition of those cases.

Referred for Formal Discipline	190
Citation and Fine Issued	112
Letter of Admonishment Issued	152
B&PC 4301 Letter Issued	633
Closed No Further Action	785
Closed Referred to PRP	2
Closed Other	30
Closed No Violation	<u>1</u>
	1905

Dr. Kajioka provided that this unit was envisioned to be a "beginning to end" unit, meaning that the staff would not only complete the investigation, but also complete the final processing as well, e.g. issue the citation and fine, refer the matter to the Office of the Attorney General, etc.

Assistant Executive Officer Anne Sodergren provided that these results demonstrate that appropriate resources allow the board to effectively meet its consumer protection mandate.

No public comment was provided.

9. Update of the Committee's Strategic Plan 2010-11

Dr. Kajioka provided that at the July 2010 Board Meeting, the board will update its 2010-11 Strategic Plan. He stated that the Enforcement Committee's strategic goals, objectives and tasks are being updated and will be provided at the meeting.

Ms. Sodergren provided that the Enforcement unit managers reviewed the plan in advance of this meeting and are recommending inclusion of the following task:

- Identify investigative and enforcement internal processes improvement.

Ms. Herold suggested that the committee also consider including a review of pharmacies dispensing drugs for internet providers.

Public Comment

Dr. Steve Gray, representing Kaiser Permanente, suggested that the board evaluate language requiring clinical experience referenced in section 4052.2. He also recommended that the board discuss the requirement that the board report its actions to the National Practitioner Database.

Ms. Herold provided that the board is reporting to the database.

Dr. Castellblanch sought clarification regarding any preventative programs offered by the board or by any other states.

Ms. Herold provided that education is facilitated through the Pharmacists Recovery Program. She stated that the Enforcement Committee and the Communication and Public Education Committee can collaborate in this area.

Ms. Sodergren provided that the department is looking at improving proactive actions. She stated that inspectors educate licensees regarding the legal requirements during routine inspections and with self assessment forms.

There was no additional board discussion or public comment.

MOTION: Approve the 15 tasks identified in Objective 1.5 in the Enforcement Committee's Strategic Plan and add the following additional tasks:

16. Complete review of pharmacies dispensing prescriptions for Internet web site operators
17. Evaluate language requiring clinical experience referenced in section 4052.2
18. Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB)

M/S: Lippe/Kajioka

Support: 3 Oppose: 0 Abstain: 0

10. Enforcement Statistics

Dr. Kajioka provided that the Enforcement statistics will be compiled at the end of the fiscal year and will be provided for the July 2010 Board Meeting along with a three year fiscal comparison.

No public comment was provided.

11. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 1:05 p.m.

ATTACHMENT 9

Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

Senate Bill 1441 (Ridley-Thomas)

Implementation by
Department of Consumer Affairs,
Substance Abuse Coordination Committee



Brian J. Stiger, Director

April 2010 (Corrected Version)

November Corrections shown underlined

December Corrections shown double underlined

April Corrections shown *italics and underlined*



Substance Abuse Coordination Committee

Brian Stiger, Chair
Director, Department of Consumer Affairs

Elinore F. McCance-Katz, M.D., Ph. D.
CA Department of Alcohol & Drug Programs

Janelle Wedge
Acupuncture Board

Kim Madsen
Board of Behavioral Sciences

Robert Puleo
Board of Chiropractic Examiners

Lori Hubble
Dental Hygiene Committee of CA

Richard De Cuir
Dental Board of California

Joanne Allen
Hearing Aid Dispensers

Linda Whitney
Medical Board

Heather Martin
Board of Occupational Therapy

Mona Maggio
Board of Optometry

Donald Krpan, D.O.
Osteopathic Medical Board/Naturopathic Medicine

Virginia Herold
Board of Pharmacy,

Steve Hartzell
Physical Therapy Board

Elberta Portman
Physician Assistant Committee

Jim Rathlesberger
Board of Podiatric Medicine

Robert Kahane
Board of Psychology

Louise Bailey
Board of Registered Nursing

Stephanie Nunez
Respiratory Care Board

Annemarie Del Mugnaio
Speech-Language Pathology & Audiology Board

Susan Geranen
Veterinary Medical Board

Teresa Bello-Jones
Board of Vocational Nursing & Psychiatric Technicians

Staff Working Group

Susan Lancara, DCA, Legislative & Policy Review
LaVonne Powell, DCA Legal Counsel
Laura Edison Freedman, DCA Legal Counsel
Katherine Demos, DCA, Legislative & Policy Review
Kristine Brothers, Acupuncture Board
Kim Madsen, Board of Behavioral Sciences
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Table of Contents

Uniform Standard #1	4
Uniform Standard #2	6
Uniform Standard #3	7
Uniform Standard #4	8
Uniform Standard #5	9
Uniform Standard #6	10
Uniform Standard #7	11
Uniform Standard #8	13
Uniform Standard #9	14
Uniform Standard #10	15
Uniform Standard #11	17
Uniform Standard #12	18
Uniform Standard #13	19
Uniform Standard #14	23
Uniform Standard #15	24
Uniform Standard #16	25

#1 SENATE BILL 1441 REQUIREMENT

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

#1 Uniform Standard

~~Any licensee in a board diversion program or whose license is on probation, who the board has reasonable suspicion has a substance abuse problem shall be required to undergo a clinical diagnostic evaluation at the licensee's expense. The following standards apply to the clinical diagnostic evaluation.~~

If a healing arts board orders a licensee who is either in a diversion program or whose license is on probation due to a substance abuse problem to undergo a clinical diagnosis evaluation, the following applies:

~~1. The clinical diagnostic evaluation shall be paid for by the licensee;~~

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:
 - holds a valid, unrestricted license, which includes scope of practice to conduct a clinical diagnostic evaluation;
 - has three (3) years experience in providing evaluations of health professionals with substance abuse disorders; and,
 - 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.

Uniform Standards

April 2010

The evaluator shall not have a financial relationship, personal relationship, or business relationship with the licensee within the last five years. 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 ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.

#2 SENATE BILL 1441 REQUIREMENT

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.

#2 Uniform Standard

The following practice restrictions apply to each licensee who undergoes a clinical diagnostic evaluation:

1. ~~His or her license shall be automatically suspended placed on inactive status~~ The Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the diversion program/board staff.
2. While awaiting the results of the clinical diagnostic evaluation required in Uniform Standard #1, the licensee shall be randomly drug tested at least two (2) times per week.

After reviewing the results of the clinical diagnostic evaluation, and the criteria below, a diversion or probation manager shall determine, whether or not the licensee is safe to return to either part-time or fulltime practice. However, no licensee shall be returned to practice until he or she has at least ~~one (1) month~~ 30 days of negative drug tests.

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

#3 SENATE BILL 1441 REQUIREMENT

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

#3 Uniform Standard

If the licensee who is either in a board diversion program or whose license is on probation has an employer, the licensee shall provide to the board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.

#4 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomness, 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.

#4 Uniform Standard

The following drug testing standards shall apply to each licensee subject to drug testing:

1. Licensees shall be randomly drug tested at least 104 times per year for the first year and at any time as directed by the board. After the first year, licensees, who are practicing, shall be randomly drug tested at least 50 times per year, and at any time as directed by the board.
2. Drug testing may be required on any day, including weekends and holidays.
3. The scheduling of drug tests shall be done on a random basis, preferably by a computer program.
4. Licensees shall be required to make daily contact to determine if drug testing is required.
5. Licensees shall be drug tested on the date of notification as directed by the board.
6. 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.
7. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.
8. 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.
9. Collection of specimens shall be observed.
10. Prior to vacation or absence, alternative drug testing location(s) must be approved by the board.
11. Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) 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.

#5 SENATE BILL 1441 REQUIREMENT

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.

#5 Uniform Standard

If a board requires a licensee to participate in group support meetings, the following shall apply:

When determining the frequency of required group meeting attendance, the board shall give consideration 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.

Group Meeting Facilitator Qualifications and Requirements:

1. The meeting facilitator must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or other nationally certified organizations.
2. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years.
3. The group meeting facilitator shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.
4. The facilitator shall report any unexcused absence within 24 hours.

#6 SENATE BILL 1441 REQUIREMENT

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

#6 Uniform Standard

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.

#7 SENATE BILL 1441 REQUIREMENT

Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

#7 Uniform Standard

A board may require the use of worksite monitors. If a board determines that a worksite monitor is necessary for a particular licensee, the worksite monitor shall meet the following requirements to be considered for approval by the board.

1. The worksite monitor shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
2. The worksite monitor's license scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional if no monitor with like practice is available.
3. The worksite monitor shall have an active unrestricted license, with no disciplinary action within the last five (5) years.
4. The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
5. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.

Reporting by the worksite monitor to the board shall be as follows:

1. Any suspected substance abuse must be verbally reported to the board and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
2. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;
 - any indicators that can lead to suspected substance abuse.

The licensee shall complete the required consent forms and sign an agreement with the worksite monitor and the board to allow the board to communicate with the worksite monitor.

#8 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee tests positive for a banned substance.

#8 Uniform Standard

When a licensee tests positive for a banned substance, ~~the board shall:~~

1. ~~The licensee's license shall be automatically suspended; Place the licensee's license on inactive status~~ The board shall order the licensee to cease practice; ~~and~~
2. ~~Immediately~~ The board shall contact the licensee and instruct the licensee to leave work; and
3. The board shall notify the licensee's employer, if any, and worksite monitor, if any, that the licensee may not work.

Thereafter, the board should determine whether the positive drug test is in fact evidence of prohibited use. If so, proceed to Standard #9. If not, the board shall immediately lift the ~~suspension of reactivate the license~~ cease practice order.

In determining whether the positive test is evidence of prohibited use, the board should, as applicable:

1. Consult the specimen collector and the laboratory;
2. Communicate with the licensee and/or any physician who is treating the licensee; and
3. Communicate with any treatment provider, including group facilitator/s.

#9 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

#9 Uniform Standard

When a board confirms that a positive drug test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Uniform Standard #10 and the board shall impose the consequences set forth in Uniform Standard #10.

#10 SENATE BILL 1441 REQUIREMENT

Specific consequences for major and minor violations. In particular, the committee shall consider the use of a “deferred prosecution” stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

#10 Uniform Standard

Major Violations include, but are not limited to:

1. Failure to complete a board-ordered program;
2. Failure to undergo a required clinical diagnostic evaluation;
3. Multiple minor violations;
4. Treating patients while under the influence of drugs/alcohol;
5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;
6. Failure to obtain biological testing for substance abuse;
7. Testing positive and confirmation for substance abuse pursuant to Uniform Standard #9;
8. Knowingly using, making, altering or possessing any object or product in such a way as to defraud a drug test designed to detect the presence of alcohol or a controlled substance.

Consequences for a major violation include, but are not limited to:

1. ~~Inactivation-Automatic-Suspension~~ Licensee will be ordered to cease practice.
 - a) the licensee must undergo a new clinical diagnostic evaluation, and
 - b) the licensee must test *negative* for at least a month of continuous drug testing before being allowed to go back to work. ~~(, and)~~
2. Termination of a contract/agreement.
3. Referral for disciplinary action, such as suspension, revocation, or other action as determined by the board.

Minor Violations include, but are not limited to:

1. Untimely receipt of required documentation;
2. Unexcused non-attendance at group meetings;
3. Failure to contact a monitor when required;
4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to:

1. Removal from practice;
2. Practice limitations;
3. Required supervision;
4. Increased documentation;
5. Issuance of citation and fine or a warning notice;
6. Required re-evaluation/testing;
7. Other action as determined by the board.

#11 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

#11 Uniform Standard

“Petition” as used in this standard is an informal request as opposed to a “Petition for Modification” under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

1. Demonstrated sustained compliance with current recovery program.
2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee’s substance abuse.
3. Negative drug screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of the program.

#12 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

#12 Uniform Standard

“Petition for Reinstatement” as used in this standard is an informal request (petition) as opposed to a “Petition for Reinstatement” under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.
2. Demonstrated successful completion of recovery program, if required.
3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.
4. Demonstrated that he or she is able to practice safely.
5. Continuous sobriety for three (3) to five (5) year.

#13 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, (1) standards for immediate reporting by the vendor to the board of any and all noncompliance with process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; (3) standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and (4) standards for a licensee's termination from the program and referral to enforcement.

#13 Uniform Standard

1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.
2. A vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors is as follows:

Specimen Collectors:

- a) The provider or subcontractor shall possess all the materials, equipment, and technical expertise necessary in order to test every licensee for which he or she is responsible on any day of the week.
- b) The provider or subcontractor shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.
- c) The provider or subcontractor must provide collection sites that are located in areas throughout California.
- d) The provider or subcontractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for drug testing.
- e) The provider or subcontractor must have or be subcontracted with operating collection sites that are engaged in the business of collecting urine, blood, and hair follicle specimens for the testing of drugs and alcohol within the State of California.
- f) The provider or subcontractor must have a secure, HIPAA compliant, website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

Uniform Standards

April 2010

- g) The provider or subcontractor shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory drug test results, medical histories, and any other information relevant to biomedical information.
- h) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.
- i) Must undergo training as specified in Uniform Standard #4 (6).

Group Meeting Facilitators:

A group meeting facilitator for any support group meeting:

- a) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;
- b) must be licensed or certified by the state or other nationally certified organization;
- c) must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years;
- d) shall report any unexcused absence within 24 hours to the board, and,
- e) shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

Work Site Monitors:

1. The worksite monitor must meet the following qualifications:
 - a) Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
 - b) The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional, if no monitor with like practice is available.
 - c) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

- d) Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
2. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.
 3. Any suspected substance abuse must be verbally reported to the contractor, the board, and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
 4. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;
 - any indicators that can lead to suspected substance abuse.

Treatment Providers

1. Treatment facility staff and services must have:
 - a) Licensure and/or accreditation by appropriate regulatory agencies;
 - b) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;
 - c) Professional staff who are competent and experienced members of the clinical staff;

- d) Treatment planning involving a multidisciplinary approach and specific aftercare plans;
 - e) Means to provide treatment/progress documentation to the provider.
2. The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:
- a) The vendor is fully responsible for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them. No subcontract shall relieve the vendor of its responsibilities and obligations. All state policies, guidelines, and requirements apply to all subcontractors.
 - b) If a subcontractor fails to provide effective or timely services as listed above, but not limited to any other subcontracted services, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.
 - c) The vendor shall notify the appropriate board within five (5) business days of termination of said subcontractor.

#14 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

#14 Uniform Standard

The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.

- Licensee's name;
- Whether the licensee's practice is restricted, or the license is on inactive status;
- A detailed description of any restriction imposed.

#15 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

#15 Uniform Standard

1. If a board uses a private-sector vendor to provide monitoring services for its licensees, an external independent audit must be conducted at least once every three (3) years by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the vendor providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the board. The independent reviewer or review team must consist of individuals who are competent in the professional practice of internal auditing and assessment processes and qualified to perform audits of monitoring programs.
2. The audit must assess the vendor's performance in adhering to the uniform standards established by the board. The reviewer must provide a report of their findings to the board by June 30 of each three (3) year cycle. The report shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's monitoring services that would interfere with the board's mandate of public protection.
3. The board and the department shall respond to the findings in the audit report.

#16 SENATE BILL 1441 Requirement

Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

#16 Uniform Standard

Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program.

- Number of intakes into a diversion program
- Number of probationers whose conduct was related to a substance abuse problem
- Number of referrals for treatment programs
- Number of relapses (break in sobriety)
- Number of cease practice orders/license in-activations
- Number of suspensions
- Number terminated from program for noncompliance
- Number of successful completions based on uniform standards
- Number of major violations; nature of violation and action taken
- Number of licensees who successfully returned to practice
- Number of patients harmed while in diversion

The above information shall be further broken down for each licensing category, specific substance abuse problem (i.e. cocaine, alcohol, Demerol etc.), whether the licensee is in a diversion program and/or probation program.

If the data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of a program. It may also be used to determine the risk factor when a board is determining whether a license should be revoked or placed on probation.

The board shall use the following criteria to determine if its program protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

- At least 100 percent of licensees who either entered a diversion program or whose license was placed on probation as a result of a substance abuse problem successfully completed either the program or the probation, or had their license to practice revoked or surrendered on a timely basis based on noncompliance of those programs.

Uniform Standards

April 2010

- At least 75 percent of licensees who successfully completed a diversion program or probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

Board of Pharmacy

Standard # 1 – Clinical Evaluation

Summary: The board's disciplinary guidelines include a provision requiring a clinical evaluation for certain conditions of probation. Additionally, the board uses the Pharmacists Recovery Program (PRP) to monitor pharmacists and interns with substance abuse violations, and a clinical evaluation is a key component of this program as well.

Administrative and Board Policy Changes Required:

Licensees: the board has incorporated the DCA requirements for the diagnostic report into its routine processes for probationers with substance abuse violations.

As the DCA is the contractor for the health care boards' monitoring program vendor, board staff will assist the DCA in securing this standard as a contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Pharmacists and Interns: the board will require a regulation and contractual change to make this a formal requirement.

Pharmacy Technicians and/or Designated Representatives: Statutory and regulation changes are required.

Standard # 2 – Removal from Practice

Summary: When negotiating stipulations, many times a provision is incorporated to require a licensee to undergo an evaluation by either a clinician or by the PRP to determine someone is safe to practice. The licensee is typically suspended from practice until such time as the evaluation is completed and the results are received. (This is typically used on pharmacists and interns, but could expand to other licensees as a probationary term should the case warrant.) Additionally, the PRP places a cease practice treatment contract term upon entry into the program or upon a confirmed positive drug screen while evaluations are underway.

Administrative and Board Policy Changes Required:

All Licensees: None

Statutory Changes and/or Regulation Changes Required:

All Licensees: SB 1172 (currently pending in the California Legislature) will provide the statutory authority for this DCA standard; the board will need to promulgate regulations if SB 1172 is enacted.

Standard # 3 – Communication with the Employer

Summary: The board's disciplinary guidelines includes a provision requiring employment notification and often also supervised practiced. As part of the PRP, participants are required to have a worksite monitor who is responsible to provide reports to the PRP. Further, a pharmacy technician, by virtue of their scope of practice, cannot work without a pharmacist also on duty.

Administrative and Board Policy Changes Required:

Pharmacists and interns: As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

All Licensees: Regulations are needed to secure the consent of the participant for the board's designee to speak with the worksite monitor. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Standard # 4 – Drug Testing

Summary: The board's disciplinary guidelines includes a provision requiring drug testing and specifies in many instances that a positive drug screen will result in the automatic suspension of the license. The board's current drug testing contract fulfills the requirements detailed in this standard. However, the testing frequency is determined on a case by case basis by the board.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required. Since the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

All Licensees: Statutory or regulatory change is required to standardize the testing frequency established in the DCA uniform standard.

Standard # 5 – Group Meeting Standards

Summary: The board's disciplinary guidelines includes a provision requiring attendance at support groups. Additionally, through the PRP, pharmacists and interns are required as part of their treatment contracts to attend support groups.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract amendment is required. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist this securing contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: A statutory or regulatory change is necessary to establish the financial relationship criteria specified in this uniform standard.

Standard # 6 – Treatment Evaluation Criteria

Summary: In putting someone on probation and/or in the PRP, these criteria are routinely considered, but on a case by case basis. Further, the board contracts with the PRP vendor, who employs licensed clinicians specializing in the monitoring of substance abuse and treatment, to obtain this type of consistent expertise and assessment.

Administrative and Board Policy Changes Required:

None

Statutory Changes and/or Regulation Changes Required

Licensees: Standardization of these requirements would require a statutory or regulatory change.

Standard # 7 – Worksite Monitoring requirements

Summary: The board's disciplinary guidelines includes a provision requiring employment notification and many times also supervised practiced. As part of the PRP, participants are required to have a worksite monitor, who is responsible to provide reports to the PRP. Further, a pharmacy technician, by virtue of his or her scope of practice cannot work without a pharmacist also on duty.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: Regulations are needed to secure the consent of the participant to authorize the worksite monitor to speak with the program. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Standard # 8 – Actions After Receiving a Positive Drug Test

Summary: In practice, after a positive drug is confirmed, the board requires the immediate removal of the licensee from practice if a participant in the PRP. The board's disciplinary guidelines includes a provision requiring drug testing and specifies in many instances that a positive drug screen will result in the automatic suspension of the license.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: SB 1172 (currently pending) will provide the statutory authority for this standard term.

Standard # 9 – Affirmation of Positive Drug Screen

Summary: In practice, after a positive drug is confirmed, the board requires the immediate removal of the licensee from practice if the positive drug screen is of a participant in the PRP. The board's disciplinary guidelines includes a provision requiring drug testing and specifies in many instances that a positive drug screen will result in the automatic suspension of the license.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required to effect this change. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: SB 1172 (currently pending in the CA Legislature) will provide the statutory authority for this standard.

Standard # 10 – Major Violations

Summary: The board's disciplinary guidelines detail which violations constitute a violation of probation. Further, some specific terms and conditions call for the automatic suspension of a license for failure to comply. In practice, unresolved non-compliance as well as egregious non-compliance with the PRP treatment contract provisions, results in removal of the licensee from practice if a participant in the PRP.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: To more formally and uniformly remove licensees from practice for major violations, statutory change is required.

Standard # 11 – Return to Full Time Practice

Summary: In practice, these requirements are followed in the PRP.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required to formally incorporate this standard. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: To more formally and uniformly apply the standard, a statutory change is required.

Standard # 12 – Petition for Reinstatement of a Full License

Summary: In practice, these requirements are followed by the PRP.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required for formally incorporate this standard. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist this contract amendment (if pursued).

Statutory Changes and/or Regulation Changes Required:

Licensees: To establish this uniform standard, the board needs a regulation or statutory change.

Standard # 13 – Private Sector Vendors

Summary: The board contracts with a vendor for PRP administration. The board does not have the authority to use a vendor for these services for pharmacy technicians and designated representatives.

Administrative and Board Policy Changes Required:

None

Statutory Changes and/or Regulation Changes Required:

Pharmacy Technicians and Designated Representatives: A statutory change is required.

Standard # 14 – Public Disclosure for PRP Participation

Summary: The board publishes its disciplinary actions on its web site for all licensees. All terms and conditions of probation, including the term requiring participation in the PRP, are contained in this document.

Administrative and Board Policy Changes Required:

None

Statutory Changes and/or Regulation Changes Required:

A regulation change may be necessary per counsel's guidance.

Standard # 15 – Audit of Vendor

Summary: The DCA recently conducted an audit of the current vendor, with a report provided to the Legislature.

Administrative and Board Policy Changes Required:

The board would need funding to hire an independent auditor to comply with this standard.

Statutory Changes and/or Regulation Changes Required:

None.

Standard # 16 – Measurable Criteria

Summary: The board already receives information from the PRP vendor providing various statistical reports identified in this standard.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required to formally incorporate all of the information contained in this standard. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Pharmacy Technicians and Designated Representatives: The board would need to secure funding for an AGPA to collect and analyze this data.

Statutory Changes and/or Regulation Changes Required:

None

ATTACHMENT 10

Board of Pharmacy Enforcement Statistics

Fiscal Year 2009/2010

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 09/10**

Complaints/Investigations

Initiated	520	539	542	635	2236
Closed	1087	1241	1508	1092	4928
Pending (at the end of quarter)	2346	2204	1566	1374	1374

Cases Assigned & Pending (by Team)

Compliance Team	85	149	232	131	131
Drug Diversion/Fraud	60	80	97	73	73
Probation/PRP	25	30	92	67	67
Mediation/Enforcement	5	38	15	10	10
Criminal Conviction	1277	987	616	501	501

Application Investigations

Initiated	167	111	391	174	843
Closed					
Approved	39	58	193	262	552
Denied	33	7	12	47	99
Total*	90	82	246	361	779
Pending (at the end of quarter)	420	451	597	412	412

Citation & Fine

Issued	495	396	537	396	1824
Citations Closed	210	214	376	666	1466
Total Fines Collected	\$298,575.00	\$229,215.00	\$417,975.00	\$1,548,810.00	\$2,494,575.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics

Fiscal Year 2009/2010

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 09/10**

Administrative Cases (by effective date of decision)

Referred to AG's Office*	78	91	99	75	343
Pleadings Filed	49	65	61	89	264
Pending					
Pre-accusation	160	180	216	185	185
Post Accusation	138	178	188	217	217
Total	205	458	464	432	432
Closed**					
Revocation					
Pharmacist	3	3	2	4	12
Pharmacy	0	1	1	0	2
Other	3	10	26	32	71
Revocation, stayed; suspension/probation					
Pharmacist	2	4	2	3	11
Pharmacy	2	1	1	0	4
Other	0	2	0	0	2
Revocation, stayed; probation					
Pharmacist	1	0	2	5	8
Pharmacy	0	0	0	0	0
Other	1	0	3	4	8
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	0	2	1	6	9
Pharmacy	0	1	0	3	4
Other	1	0	6	8	15
Public Reproval/Reprimand					
Pharmacist	0	1	0	0	1
Pharmacy	0	0	0	0	0
Other	0	0	0	1	1
Cost Recovery Requested	\$43,046.75	\$84,477.00	\$66,557.50	\$118,759.50	\$312,840.75
Cost Recovery Collected	\$38,423.20	\$68,175.75	\$183,797.09	\$45,024.54	\$335,420.58

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics

Fiscal Year 2009/2010

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 09/10**

Probation Statistics

Licenses on Probation

Pharmacist	106	103	98	101	101
Pharmacy	6	6	6	8	8
Other	14	20	21	29	29
Probation Office Conferences	22	25	21	30	98
Probation Site Inspections	36	23	31	20	110
Probationers Referred to AG for non-compliance	2	2	9	2	13

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 6/30/2010)

Program Statistics

In lieu of discipline	0	0	0	1	1
In addition to probation	1	3	1	1	6
Closed, successful	5	0	4	2	11
Closed, non-compliant	0	4	0	0	4
Closed, other	3	5	1	5	14
Total Board mandated Participants	50	46	44	47	47
Total Self-Referred Participants*	27	27	32	29	29
Treatment Contracts Reviewed	48	46	50	57	201

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, 2010

Board of Pharmacy Enforcement Statistics Five Year Comparison

Workload Statistics	FY 05/06	FY 06/07	FY 07/08	FY 08/09	FY 09/10
	FY 05/06	FY 06/07	FY 07/08	FY 08/09	FY 09/10
Initiated	1998	2417	2706	3191	2559
Closed	1977	1655	1850	2040	4795

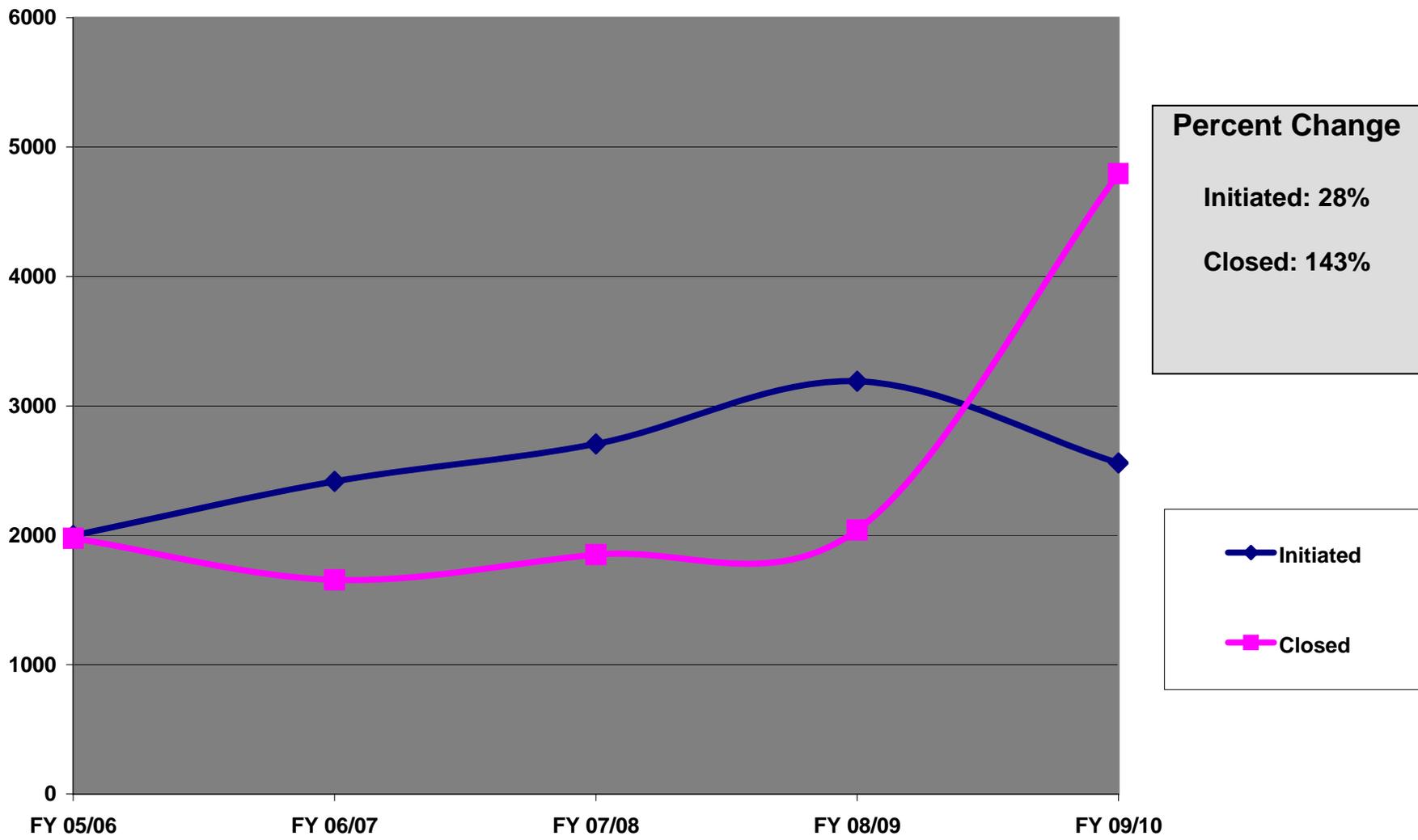
Application Investigations	FY 05/06	FY 06/07	FY 07/08	FY 08/09	FY 09/10
Initiated	100	300	337	369	846
Closed	111	152	262	281	777

Citation & Fine	FY 05/06	FY 06/07	FY 07/08	FY 08/09	FY 09/10
Issued	781	737	1003	968	1829
Citations Closed	729	693	767	1023	1510

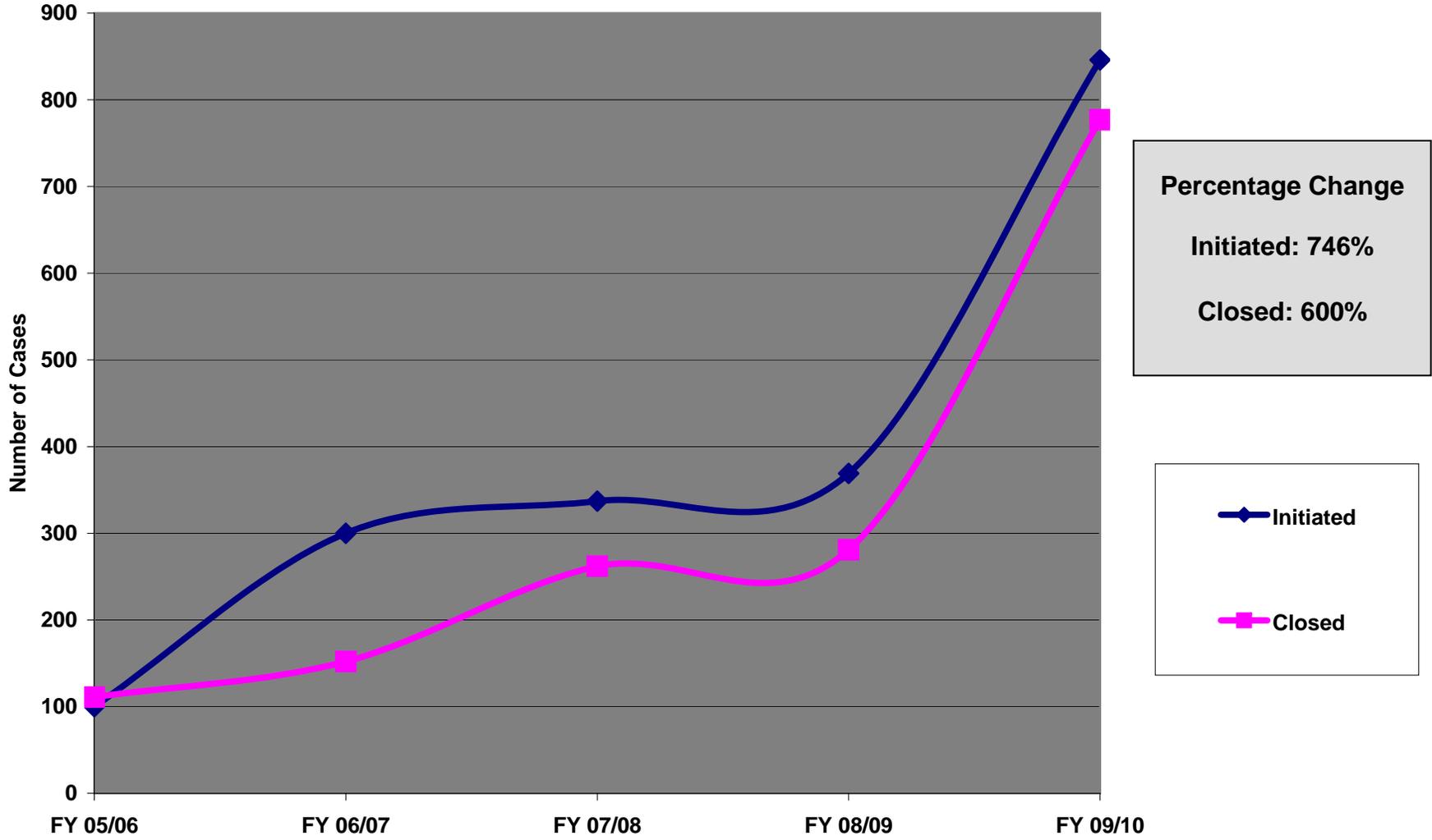
Administrative Cases (by eff)	FY 05/06	FY 06/07	FY 07/08	FY 08/09	FY 09/10
Referred to AG's Office*	126	95	97	205	351
Pleadings Filed	119	88	84	125	268

Closed	FY 05/06	FY 06/07	FY 07/08	FY 08/09	FY 09/10
Revocation	59	66	33	31	85
Revocation, stayed; suspen	16	10	14	9	16
Revocation, stayed; probati	15	19	10	19	20
Suspension, stayed; probat	0	0	0	0	0
Surrender/Voluntary Surre	18	34	17	11	30
Public Reproval/Reprimand	2	1	1	0	2

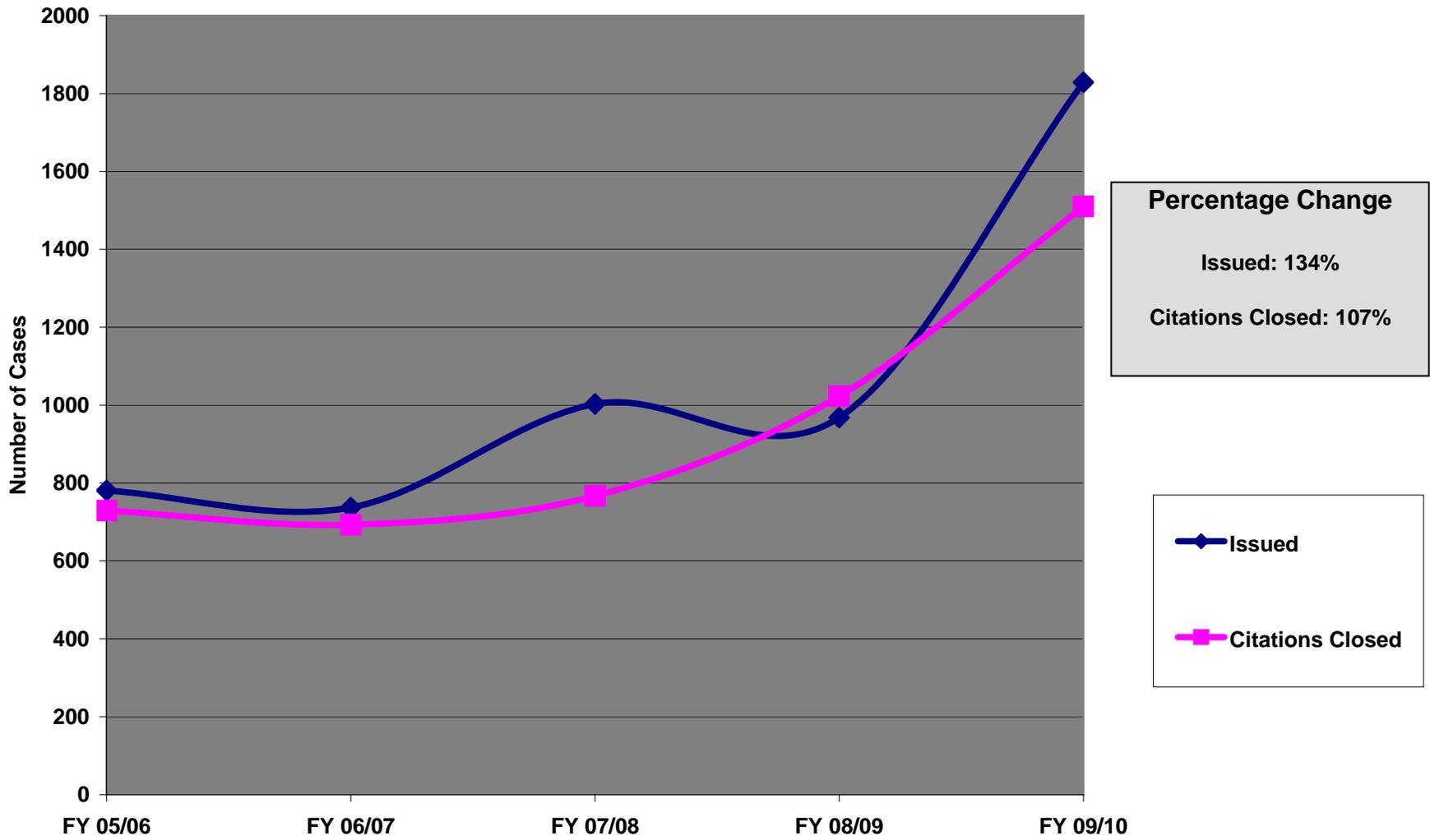
Complaints/Investigations



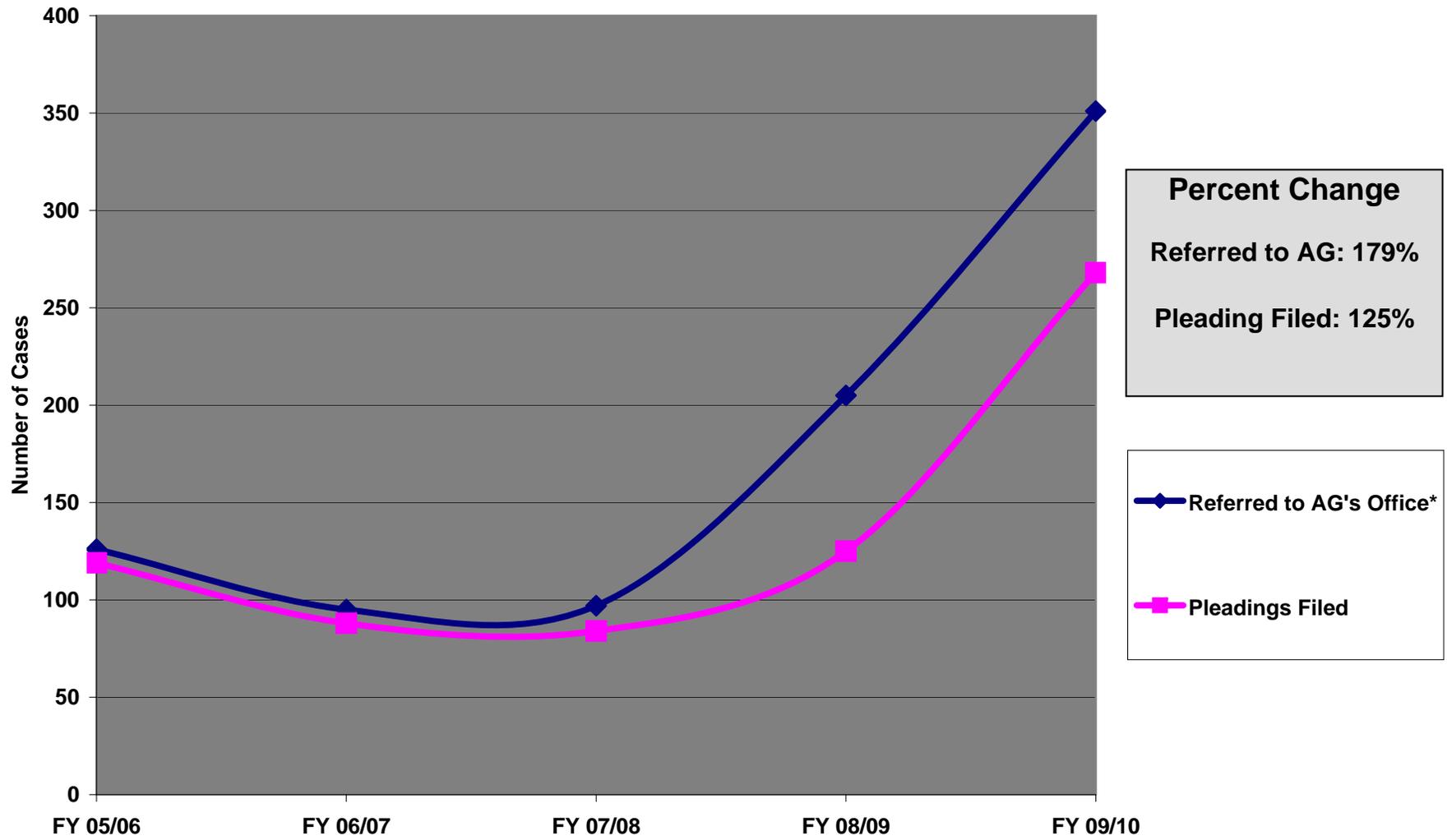
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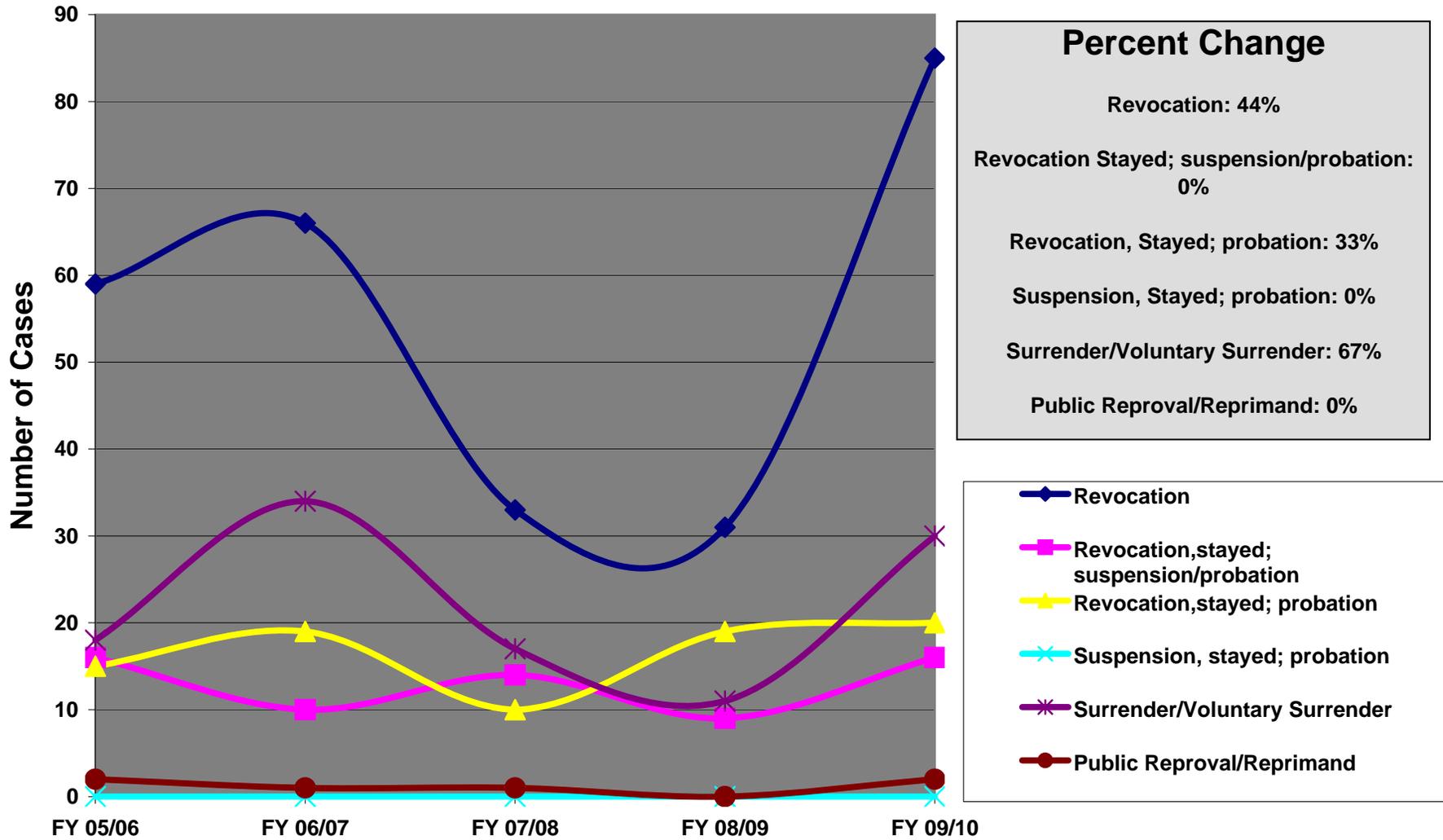
Citation and Fine



Administrative Cases



Administrative Cases Closed by Action



ATTACHMENT 11

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. Complete all desk investigations within 90 days (for cases closed during quarter).						
		<u>N</u>	< 90 days	< 120 days	< 180 days	Longer	<u>Average Days</u>
	Qtr 1	710	351	10	26	323	364
			50%	1%	4%	45%	
	Qtr 2	800	156	16	26	602	494
			19%	2%	3%	75%	
	Qtr 3	979	158	27	82	711	390
			16%	3%	8%	73%	
	Qtr 4	913	275	92	93	453	262
			30%	10%	10%	50%	
	2. Complete all field investigations within 120 days (for cases closed during quarter).						
		<u>N</u>	< 120 days	< 180 days	< 270 days	Longer	<u>Average Days</u>
	Qtr 1	269	121	34	56	58	208
			45%	13%	21%	22%	
	Qtr 2	286	68	61	60	97	265
			24%	21%	21%	34%	
	Qtr 3	509	93	32	64	320	327
			18%	6%	13%	63%	
	Qtr 4	286	45	92	66	83	256
			16%	32%	23%	29%	
	Data is calculated from date received to the date the report was accepted by SI/Manager. Does not include split cases.						

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	357	172	67	36	82
Rap sheet/CCU - 4301 letters and license denials	168	10	4	9	145
Cite and/or fine letter of admonishment	358	249	18	17	74
Attorney General's Office	90	6	11	15	58
Qtr 2	N	< 180	< 270	< 365	> 365
Closed, no additional action	623	231	56	69	267
Rap sheet/CCU - 4301 letters and license denials	145	7	7	19	112
Cite and/or fine letter of admonishment	232	70	45	16	101
Attorney General's Office	86	19	19	19	30
Qtr 3	N	< 180	< 270	< 365	> 365
Closed, no additional action	651	296	68	97	190
Rap sheet/CCU - 4301 letters and license denials	240	47	34	49	110
Cite and/or fine letter of admonishment	490	98	41	89	262
Attorney General's Office	106	15	12	16	63
Qtr 4	N	< 180	< 270	< 365	> 365
Closed, no additional action	629	392	105	37	98
Rap sheet/CCU - 4301 letters and license denials	172	36	28	63	45
Cite and/or fine letter of admonishment	313	120	47	42	104
Attorney General's Office	82	21	14	12	35

Data is calculated from date received to date closed or referred to the AG.
 One case may have multiple respondents. The actual number of citations and letters of admonishment issued are shown on the next page.

Objective 1.2	Manage enforcement activities for achievement of performance expectations.																																																														
Measure:	Percentage compliance with program requirements.																																																														
Tasks:	<p>1. Administer the Pharmacists Recovery Program.</p> <table border="1"> <thead> <tr> <th></th> <th>Voluntary Participants</th> <th>Participants Mandated Into Program</th> <th>Noncompliant, Terminated From Program</th> <th>Successfully Completed Program</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>27</td> <td>50</td> <td>3</td> <td>5</td> </tr> <tr> <td>Qtr 2</td> <td>27</td> <td>46</td> <td>4</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td>32</td> <td>44</td> <td>1</td> <td>4</td> </tr> <tr> <td>Qtr 4</td> <td>29</td> <td>47</td> <td>5</td> <td>2</td> </tr> </tbody> </table>		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program	Qtr 1	27	50	3	5	Qtr 2	27	46	4	0	Qtr 3	32	44	1	4	Qtr 4	29	47	5	2																																					
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<p>These data are actual number of citations and letters of admonishment (LOA) issued. One investigation may have multiple licensees that are issued a citation or LOA (split cases).</p>																																																															

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	<u>N</u>
Qtr 1	0	0	0	0
Qtr 2	1	0	0	1
Qtr 3	2	0	0	2
Qtr 4	1	0	1	2

Objective 1.3	Achieve 100 percent closure on all administrative cases within 1 year.							
Measure:	Percentage of administrative cases closed within 1 year.							
Tasks:		<u>N</u>	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	<u>Average</u>
	Qtr 1	15	4 27%	7 47%	0 0%	3 20%	1 7%	537
	Qtr 2	41	22 54%	12 29%	4 10%	0 0%	2 5%	379
	Qtr 3	49	25 31%	22 45%	2 4%	0 0%	0 0%	398
	Qtr 4	69	24 35%	30 43%	9 13%	4 6%	1 1%	434

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/11.																																																							
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																																																							
Tasks:	<p data-bbox="370 220 1479 289">1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.</p> <table border="1" data-bbox="370 289 1479 506"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Aggregate Inspections This Cycle</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>351</td> <td>4,273</td> <td>62%</td> </tr> <tr> <td>Qtr 2</td> <td>349</td> <td>4,350</td> <td>63%</td> </tr> <tr> <td>Qtr 3</td> <td>354</td> <td>4,395</td> <td>64%</td> </tr> <tr> <td>Qtr 4</td> <td>383</td> <td>4,454</td> <td>65%</td> </tr> </tbody> </table> <p data-bbox="370 548 1414 617">2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</p> <table border="1" data-bbox="370 617 1166 833"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>76</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>112</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td>64</td> <td>0</td> </tr> <tr> <td>Qtr 4</td> <td>51</td> <td>0</td> </tr> </tbody> </table> <p data-bbox="370 875 1471 909">3. Initiate investigations based upon violations discovered during routine inspections.</p> <table border="1" data-bbox="370 909 1479 1125"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number of Investigations Opened</th> <th>Percent Opened</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>351</td> <td>0</td> <td>0%</td> </tr> <tr> <td>Qtr 2</td> <td>349</td> <td>5</td> <td>1%</td> </tr> <tr> <td>Qtr 3</td> <td>354</td> <td>0</td> <td>0%</td> </tr> <tr> <td>Qtr 4</td> <td>345</td> <td>8</td> <td>2%</td> </tr> </tbody> </table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	351	4,273	62%	Qtr 2	349	4,350	63%	Qtr 3	354	4,395	64%	Qtr 4	383	4,454	65%		Number of Inspections	Number Inspected Late	Qtr 1	76	0	Qtr 2	112	0	Qtr 3	64	0	Qtr 4	51	0		Number of Inspections	Number of Investigations Opened	Percent Opened	Qtr 1	351	0	0%	Qtr 2	349	5	1%	Qtr 3	354	0	0%	Qtr 4	345	8	2%
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Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1487 695"> <p>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</p> <p><i>Oct. 2009: Executive Officer provides information about California's e-pedigree requirements at a SecurePharma Conference of drug manufacturers and wholesalers in Philadelphia and at a SpecialtyPharma Conference (contract drug manufacturers) in Phoenix.</i></p> <p><i>Dec. 2009: Executive Officer provides information about California's e-pedigree requirements at the Health Care Distributors Association Trace and Track Conference in Washington D.C.</i></p> <p><i>March 2010: Executive Officer provides information about California's e-pedigree requirements via a Webinar hosted by IBS.</i></p> <p><i>April 2010: Board reviews Food and Drug Administration guidance on a unique serialized identifier released March 26.</i></p> <li data-bbox="370 695 1487 919"> <p>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.</p> <p><i>Sep. 2006: Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.</i></p> <p><i>Oct. 2006: Board adds Consumer friendly materials regarding sales of these drugs to its website.</i></p> <li data-bbox="370 919 1487 1396"> <p>3. Monitoring the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.</p> <p><i>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.</i></p> <p><i>Sep. 2008: Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.</i></p> <p><i>Dec. 2009: Executive Officer meets with DEA officials in Washington D.C. to discuss interest in e-prescribing of controlled drugs.</i></p> <p><i>April 2010: Board reviews proposed Drug Enforcement Administration requirements for electronic prescribing of controlled substances.</i></p> <p><i>June 2010: Enforcement Committee received updates on DEA rule change.</i></p> <li data-bbox="370 1396 1487 1696"> <p>4. Evaluate establishment of an ethics course as an enforcement option.</p> <p><i>Oct. 2008: Board holds regulation hearing on proposed requirements for the ethics class.</i></p> <p><i>Jan. 2009: Board adopts regulation.</i></p> <p><i>Sept. 2009: Regulation takes effect.</i></p> <p><i>3rd Qtr 09-10: Board subcommittee of two board members begins work with staff on suggested specific components and topics for the program, in compliance with board regulations.</i></p> <li data-bbox="370 1696 1487 1948"> <p>5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.</p> <p><i>Dec. 2009: Executive Officer provides presentation on California's e-pedigree requirements to three national association meetings.</i></p> <p><i>3rd Qtr 09-10: Board initiates rulemaking on a regulation to establish requirements for patient-centered prescription container labels (see report on Legislation and Regulation Committee's Goals, Outcomes, Objectives and Measures).</i></p>

	<p>6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.</p> <p><i>Sep. 2007: Provided comments on proposed statutory requirements.</i></p> <p><i>Dec 2007: Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.</i></p> <p><i>Provided comments on proposed e-prescribing initiatives.</i></p> <p>Oct. 2008: <i>Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.</i></p> <p>Nov. 2008: <i>Board hosts conference on e-prescribing as part of department's professionals</i></p> <p><i>Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.</i></p> <p>Jan. 2009: <i>Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.</i></p> <p>March 2009: <i>Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.</i></p> <p>April 2010: <i>Board reviews Drug Enforcement Agency proposed regulations on e-prescribing of controlled substance.</i></p> <p>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.</p> <p>Oct. 2008: <i>Requirements for security forms in place..</i></p> <p>2nd Qtr 09-10: <i>Board executive staff and several board members attend California Healthcare Foundation's annual summit to implement e-prescribing.</i></p>
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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.*

2nd Qtr 09/10: *Executive staff meet with Department of Health Care Services staff on mutual investigations; DEA staff in Washington D.C. on enforcement issues involving controlled drugs; the U.S. Attorney General's office in Sacramento on two major enforcement matters; and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

3rd Qtr 09/10: *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

Board staff redirected to complete HIPDB reporting.

4th Qtr 09/10: *Board staff continue to report to HIPDB.*

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.*
- Jan. 2010:** *Board writes article on the guidelines for publication in the next issue of The Script. Board executive staff attend meetings on "take back drugs" at a statewide conference of the California Integrated Waste Management Board. Executive Officer provides presentation on the CIWMB Model Guidelines at a meeting of 20 rural California counties.*
- March 2010:** *Board publishes the guidelines in The Script.*
- April 2010:** *Board inspector will collect information about take back programs in California pharmacies during inspections.*

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 stakeholder meeting convened. Development of model guidelines for recalls underway.*

Sep. 2009: *Stakeholder meeting convened.*

Recall guidelines evaluated and additional comments solicited.

Jan. 2010: *Board reviews final version of recommended steps for addressing recalls in hospitals.*

April 2010: *Manuscript of addressing recalls in hospitals completed, compiled into finished report and posted on Website.*

Executive officer works with the Healthcare Distributors Management Association (representing drug wholesalers) to secure notices of recalls more timely to share with board subscriber list.

Appeals of citations and fines nearly complete.

May 2010: *Outstanding enforcement/compliance completed.*

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.
1st Qtr 09/10: Draft proposals for required components 7-13 developed.
3rd Qtr 09/10: Board hears presentation on uniform standards. Staff/counsel identifies changes required to implement standards.
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.
2nd Qtr 09/10: Contract awarded.
13. **Participate in Department of Consumer Affairs Consumer Protection Enforcement Initiative to strengthen board enforcement activities and reduce case investigation completion times for formal discipline.**
1st & 2nd Qtr 09/10: Work with Department of Consumer Affairs on identification of Enforcement Best Practices.
Board discusses SB 1441 components for Diversion Programs to strengthen consumer protection enforcement staff attend Enforcement Best Practices work group.
3rd Qtr 09/10: Board senior staff and Board President meet with Department of Consumer Affairs to discuss enforcement program enhancements in SB 1111.
Board staff begin submitting monthly reports detailing workload and improvement efforts to the department.
4th Qtr 09/10: Board hears presentation on CPEI and current status of department and board efforts.
14. **Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions.**
1st Qtr 09/10: Unit created via budget change proposal, 6.5 staff hired, trained, initiate work.
There are 1,287 rapsheet investigations under review.
2nd Qtr 09/10: There are 1,037 rapsheet investigations under review.
3rd Qtr 09/10: There are 652 rapsheet investigations under review.
4th Qtr 09/10: Post implementation review of Criminal Conviction Unit completed.
Enforcement Committee advised of new unit outcomes.
15. **Complete comprehensive review of investigative and enforcement internal processing to identify process improvements.**
1st Qtr 09/10: Board staff implemented on-line assignment of investigations.
Board staff implemented on-line review of draft pleadings.
2nd Qtr 09/10: Board staff began drafting Default Decision and Orders.
4th Qtr 09/10: Board staff began drafting Petition to Revoke Probation Pleadings.
Board staff implemented a pilot program to provide pre-populated investigation reports to the Compliance Team.