



**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

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**Enforcement Committee Report**

Randy Kajioka, PharmD, Chair  
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Tappan Zee, Public Board Member

***ENFORCEMENT COMMITTEE REPORT AND ACTION***

**Report of the Meeting Held March 29, 2011**

- a. **FOR POSSIBLE ACTION: Requests for Exemptions from 16 California Code of Regulations Section 1707.5, Label Requirements for Prescription Drug Containers, as Authorized by Section 4076.5 (SB 1489, Negrete-McLeod, Chapter 653, Statutes of 2010)**

**Attachment 1**

Effective January 1, 2011, the board's requirements for patient-centered labels went into effect as 16 California Code of Regulations section 1707.5. A copy of the final text for the regulation is provided in **Attachment 1**.

Also effective January 1, 2011, provisions enacted by SB 1489 (Senate Business and Professions Committee, Chapter 653, Statutes of 2010) as amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments. The exemptions are provided as subdivisions (d) and (e) below.

SEC. 25.1. Section 4076.5 of the Business and Professions Code is amended to read:

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

- (1) Medical literacy research that points to increased understandability of labels.
- (2) Improved directions for use.
- (3) Improved font types and sizes.
- (4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

**(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional.**

**Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.**

**(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:**

**(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.**

**(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.**

**(C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.**

**(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.**

**(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.**

**(f) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report. (2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.**

*Note: for reference, the text of Health and Safety Code section 1250 is provided in Attachment 1*

This law directs that the board "may exempt," so to allow such an exemption, the board will need to promulgate regulations.

At the December 2010 and March 2011 Enforcement Committee Meetings, the committee heard presentations from four groups seeking an exemption from the labeling requirements for their specialized patient populations. Two were to exempt labels on infusion products, one from pharmacies serving skilled nursing facilities, and a fourth from a radiopharmacy.

The committee has requested that any exemption include at least: 1. an explanation as to why the company cannot comply with the new requirements and 2. information

regarding policies or procedures in place that address the policy concerns behind the adopted regulations.

At the March Enforcement Committee Meeting, the committee heard three exemption requests:

1. to exempt radiologic pharmacies from GE Healthcare
2. to exempt parenteral nutrition labeling from Walgreens specialty pharmacies and
3. to exempt long-term care labels from CPhA.

A prior request from Medco to exempt infusion labels was dropped after the February Board Meeting.

The committee heard presentations from all three requestors. The minutes of the March meeting detail the discussion (these are provided as an attachment to this report).

There are three outcomes from the March Enforcement Committee that are being brought forward to the board for the May Board Meeting

**FOR INFORMATION AND POSSIBLE ACTION:** Regarding a request from GE Healthcare to exempt labels prepared for radiopharmacy products compounded for specific patients for diagnostic evaluations

GE Healthcare provided information about how they compound radioactive compounds that are used typically for diagnosis purposes. That these products are used primarily for diagnostics and are not distributed directly to the patient, although they may be label as specific to a patient.

Board Counsel Kristy Shellans stated that in such case, the requirements for a patient-centered label do not apply if the medication is not dispensed directly to patients in California. Deputy Attorney General Joshua Room also agreed that such products when never dispensed to the patient would not be required to be labelled according to the patient-centered regulation.

The committee took no action on the request because of this advice.

**FOR INFORMATION AND POSSIBLE ACTION:** Regarding a request from Walgreen to exempt total parenteral nutritional labeling

Walgreen has specialized pharmacies that prepare total parenteral nutritional products. However, during the discussion it was learned that these Walgreens specialty pharmacies are not accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), but by the Accreditation Commission for Health Care or ACHC. The exemption language in Business and Professions Code section 4076.5(e)(1)(A) only exempts pharmacies accredited by JCAHO from consideration for the labeling exemption; as such, Walgreen cannot qualify.

Sterile injectable compounding pharmacies (such as those that prepare products for infusion) are licensed by the board or in place of licensure, may be accredited by

JCAHO or by another accrediting agency approved by the board. Currently the board has approved three: ACHC, DNV or CHAP. The board recently accepted each of these agencies as appropriate accrediting agencies for sterile injectable compounding pharmacies.

The board needs to determine if it wishes to expand the list of accrediting agencies in the Business and Professions Code 4076.5(e)(1)(A) that could qualify as an entity seeking an exemption for the patient-centered labeling requirements. This would require a statutory amendment. Walgreen may also want to pursue such an amendment on its own.

**FOR ACTION: ENFORCEMENT COMMITTEE:**

**Recommend an exemption to the patient-centered label requirements for unit dose medications dispensed via an automated dispensing machine in skilled nursing facilities pursuant to Business and Professions Code section 4076.5(d).**

The committee had a detailed discussion with CPhA long-term care members about the method of drug distribution within skilled nursing facilities, continuing discussions started at the prior Enforcement Committee and February Board Meeting. Of particular concern to the committee was that if the exemption were provided to pharmacies dispensing drugs to skilled nursing facilities (SNFs), how will the pharmacies, particularly those dispensing medications in the bingo-cards that are often used in SNFs, be able to ensure that these discharged patients can readily read the labels when they leave the facility.

When reviewing the bingo-type cards in use in SNFs, the committee generally concluded that these cards should be labelled according to the patient-centered requirement because they are potentially likely to be taken home with patients because they may contain a seven or 30 day supply of drugs. The committee noted that there appears to be adequate space on the bingo cards to label the product according to the patient-centered requirements.

However, the committee agreed that unit-dose medications dispensed via an automated dispensing machine in SNFs could be exempt from the patient-centered labeling requirements. The committee's motion appears in bold, above.

**b. FOR DISCUSSION AND POSSIBLE ACTION: DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program**

**Attachment 2**

Background

Senate Bill 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

To facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for SACC consideration during public meetings.

Below is a brief description of each of the 16 standards in their current form.

1. Clinical diagnostic evaluation

- Specifies that if a licensee in a diversion program or on probation is required to undergo a clinical evaluation it shall comply with :
  - i. Qualifications for the licensed practitioner performing the evaluation
  - ii. Acceptable standards for such evaluations
  - iii. Identified elements of the report
  - iv. Timeframes to complete the process and prohibition of the evaluator having a financial relationship, etc. with the licensee.

2. Temporary removal of practice for clinical evaluation

- Specifies that board will issue a cease practice order during the evaluation and review of the results by board staff.
- Specifies that the licensee will be subject to random drug testing at least two times per week.
- Sets forth the evaluation criteria that must be considered by the diversion or probation manager when determining if a licensee is safe to return to work and under what conditions.

3. Communication with a licensee's employer, if applicable

- Requires a licensee to notify the board of the names, physical addresses, mailing addresses and telephone numbers of all employers.
- Requires a licensee to give written consent authorizing the board and employers and supervisors to communicate regarding the licensee's work status, performance and monitoring.

4. Drug testing

- Sets forth a minimum testing frequency of at least 52 random drug tests per year for the first year and a minimum of 36 random drug tests per year (from then on) and establishes some exceptions to this including:
  - i. Previous testing/sobriety
  - ii. Violations(s) that occur outside of employment (e.g. DUI)
  - iii. Not working in health care field
  - iv. Tolling
  - v. Substance use disorder not diagnosed
- Specifies that testing shall be observed; conducted on a random basis, as specified; and may be required on any day, including weekends or holidays.
- Requires licensees to check daily to determine if testing is required and specifies that the drug test shall be completed on the same day as notification.
- Establishes criteria for the collection sites and laboratories processing the results.
- Establishes data collection and reporting requirements on every drug screen collected.

5. Group meeting attendance

- Sets forth the evaluation criteria that must be considered when determining the frequency of group support meetings.
- Specifies the qualifications and reporting requirements for the meeting facilitator.

6. Type of treatment

- Sets for the evaluation criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.

7. Worksite monitoring

- Allows for the use of worksite monitors.
- Specifies the criteria for a worksite monitor.
- Establishes the methods of monitoring that must be performed by the worksite monitor.
- Sets forth the reporting requirements by the worksite monitor; specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day; and specifies that a written report must be provided to the board within 48 hours of the occurrence.
- Requires the licensee to complete consent forms and sign an agreement with the worksite monitor and board to allow for communication.

8. Positive drug test

- Requires the board to issue a cease practice order to a licensee's license and notify the licensee, employee and worksite monitor that the licensee may not work.
- Specifies that after notification, the board should determine if the positive drug test is evidence of prohibited use and sets forth the criteria the board must follow when making such a determination.
- Specifies that if the board determines that it was not a positive drug test, it shall immediately lift the cease practice order.

9. Ingestion of a banned substance

- Specifies that when a board confirms a positive drug test as evidence of use of a prohibited substance, the licensee has committed a major violation.

10. Consequences for major and minor violations

- Specifies what constitutes a major violation including: failure to complete a board ordered program or undergo a clinical diagnostic evaluation; treating patients while under the influence of drugs/alcohol, and drug/alcohol related acts which would constitute a violation of the state/federal laws, failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
- Specifies the consequences for a major violation including: issuing a cease practice order to the licensee; requiring a new clinical evaluation; termination of a contract/agreement; referral for disciplinary action.
- Specifies what constitutes a minor violation including: untimely receipt of required documentation; unexcused group meeting absence; failure to contact a monitor when required; any other violations that does not present an immediate threat to the violator or the public.
- Specifies the consequences for a minor violation including: removal from practice; practice restrictions; required supervision; increased documentation; issuance of a citation and fine or working notice; re-evaluation/testing; other actions as determined by the board.

11. Return to full time practice

- Establishes the criteria to return to full time practice, including demonstrated sustained compliance, demonstrated ability to practice safely, negative drug screens for at least six months, two positive worksite monitor reports and compliance with other terms and conditions of the program.

12. Unrestricted practice

- Establishes the criteria for a licensee to request unrestricted practice including sustained compliance with a disciplinary order, successful completion of the recovery program, consistent and sustained participation in recovery activities, demonstrated ability to practice safely and continued sobriety of three to five years, as specified.

13. Private-sector vendor

- Specifies that the vendor must report any major violation to the board within one business day and any minor violation within five business days.
- Establishes the approval process for providers or contractors that work with the vendor consistent with the uniform standards.
- Requires the vendor to discontinue the use of providers or contractors that fail to provide effective or timely services as specified.

14. Confidentiality

- For any participant in a diversion program whose license is on an inactive status or has practice restrictions, requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed.
- Specifies that the disclosure will not include that the restrictions are as a result of the licensee's participation in a diversion program.

15. Audits of private-sector vendor

- Requires an external independent audit every three years of a private-sector vendor providing monitoring services.
- Specifies that the audit must assess the vendor's performance in adhering to the uniform standards and requires the reviewer to provide a report to the board by June 30 of each three year cycle.
- Requires the board and department to respond to the findings of the audit report.

16. Measurable criteria for standards

- Establishing annual reporting to the department and Legislature and details the information that must be provided in the report.
- Sets forth the criteria to determine if the program protects patients from harm and is effective in assisting licensees in recovering from substance abuse in the long term.

Committee Discussion/Action

The committee discussed in general the uniform standards as well as the process used to develop them. The committee was advised that some of the proposed changes to the Disciplinary Guidelines would facilitate implementation of portions of these standards.

**COMMITTEE RECOMMENDATION:** Direct staff to develop regulatory language to modify the disciplinary guidelines to implement the SB 1441 standards.

The most recent version of the standards was approved in April 2011. **Attachment 2** contains a copy of the standards in their current form as well as the proposed changes that have been identified and drafted thus far for board consideration to incorporated into the board's Disciplinary Guidelines.

c. **FOR INFORMATION: Question and Answer Document Explaining 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**

**Attachment 3**

Relevant Regulations

Sections 1735 – 1735.8 establish requirements for pharmacies that compound medicine.

Sections 1751 - 1751.8 establish requirements for pharmacies that compound sterile injectable medications.

Background

Effective July 7, 2010, new and amended regulations took effect regarding pharmacies that compound medications as well as pharmacies that compound sterile injectable medications.

Since the approval of these regulations, board staff has been educating licensees on the requirements. Additionally, during enforcement committee meetings, Supervising Inspector Robert Ratcliff has been providing a question and answer session on the new compounding regulations. During the October 2010 Board Meeting, the board voted to create a subcommittee to further vet the questions and answers received thus far, as well as to respond to any new questions.

The subcommittee, comprised of Dr. Kajioka, Dr. Schell, Dr. Dang, Dr. Ratcliff and Ms. Herold met January 5, 2011.

**Attachment 3** contains the questions and answers that are posted on the board's web site.

Committee Discussion/Action:

The committee discussed the Q&A's and requested that future questions be submitted in writing and forwarded to the subcommittee to evaluate.

The committee did not take action on this item.

Recent Update

The board has not received any additional items.

d. **FOR INFORMATION: Summary of Meeting of March 29, 2011**

**Attachment 4**

**Attachment 4** contains a copy of the meeting summary.

e. **FOR INFORMATION and POSSIBLE DISCUSSION: Discussion on the President's Comments to the Federal Food and Drug Administration Pursuant to Determination of System Attributes for Tracking and Tracing of Prescription Drugs; Public Workshop (Document ID FDA-2010-N-0633-001)**

**Attachment 5**

Background

California law has the strongest pharmaceutical supply chain security requirements of any state. These provisions require that for almost any prescription drug sold in California, that an electronic pedigree be established that starts with the manufacturer and that traces any changes in ownership until the drug reaches a pharmacy. The requirements will take effect over a 2.5 year period from 2015 through 2017. California's laws in this area were enacted in 2004, and amended in 2006 and 2008. California is viewed as the leader in this area, and the provisions in our law originate with a 2004 FDA Counterfeit Task Force Report.

During the March 2011 Board Meeting, the board discussed the opportunity to provide comments to the FDA on its proposal. During the meeting the board directed staff to draft a response to the FDA regarding the components of California's requirements for the tracking and tracing of prescription drugs to be reviewed by the board president, and upon completion, provide a copy to the members of the board.

Update

Comments were drafted and approved for release, however because of the timing, the comments were not submitted. The FDA needs to reopen the docket to allow for additional comments to be submitted because of some procedural issues. The board's comments will be submitted when the docket is reopened.

**Attachment 5** contains a summary from the FDA detailing the comments from its February 2011 workshop as well as the comments the board will be submitting.

f. **FOR INFORMATION: Discussion on CalRecycle's Report to the Legislature "Recommendations for Home-Generated Pharmaceutical Collection Programs in California"**

**Attachment 6**

Background

California's Senate Bill 966 passed in 2007 and required CalRecycle to work with other state agencies and stakeholders to develop voluntary Model Guidelines for home-generated pharmaceutical collection programs, then report to the Legislature with recommendations for the potential implementation of a statewide program and statutory changes.

During the February 2001 Board Meeting, the board discussed the previously released report from CalRecycle and decided not to submit comments to the legislature on this earlier report.

Update

The report completed by CalRecycle is now available. CalRecycle noted some key findings in its announcement including:

- Based on survey results (with an 86% response rate), CalRecycle found that local governments currently fund more than 80 percent of collection programs in California and pharmacies fund another 15 percent.
- CalRecycle found that only about one-third of existing programs in California met the voluntary Model Guidelines. Of the major types of programs (law enforcement collection, pharmacy collection, household hazardous waste collection, periodic collection “events,” and mail-back programs), each has advantages and barriers in being able to meet the voluntary Model Guidelines.
- CalRecycle recommends the Legislature adopt a combination of two options:
  - “Establish Clear State Agency Roles and Responsibilities, Improve Model Guidelines and Enforcement, and Convert Guidelines to Regulation” and
  - “Implement Product Stewardship”

A copy of this report is provided in **Attachment 6**.

**g. FOR ACTION: Selection of Enforcement Committee Dates for 2011**

We need to schedule committee meetings through the end of the year. Below are proposed dates for consideration:

June 6, 2011 or June 20 – 24, 2011  
September 6 – 9, 2011 or September 12-16, 2011  
December 5 – 9, 2011

**h. FOR INFORMATION: Review of Enforcement Statistics and Performance Standards of the Board**

**ATTACHMENT 7**

**Attachment 7** contains the board’s enforcement statistics as well as the Department’s performance standards report for our board.

**i. FOR INFORMATION: Third Quarterly Report of the Committee’s Goals for 2010/11**

**ATTACHMENT 8**

**Attachment 8** contains the third quarter’s report on the committee’s strategic plan.

# **Attachment 1**

**Order of Adoption**  
**Board of Pharmacy**  
**California Code of Regulations**

**Specific Language to Add Section 1707.5.**

Add Section 1707.5. to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

- (A) Take 1 [insert appropriate dosage form] at bedtime
- (B) Take 2 [insert appropriate dosage form] at bedtime
- (C) Take 3 [insert appropriate dosage form] at bedtime
- (D) Take 1 [insert appropriate dosage form] in the morning
- (E) Take 2 [insert appropriate dosage form] in the morning
- (F) Take 3 [insert appropriate dosage form] in the morning
- (G) Take 1 [insert appropriate dosage form] in the morning, and  
Take 1 [insert appropriate dosage form] at bedtime
- (H) Take 2 [insert appropriate dosage form] in the morning, and  
Take 2 [insert appropriate dosage form] at bedtime
- (I) Take 3 [insert appropriate dosage form] in the morning, and  
Take 3 [insert appropriate dosage form] at bedtime
- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert  
appropriate dosage form] at noon, and 1 [insert appropriate dosage  
form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert  
appropriate dosage form] at noon, and 2 [insert appropriate dosage  
form] in the evening

- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
- (P) If you have pain, take [insert appropriate dosage form] at a time. Wait at least [ ] hours before taking again. Do not take more than [ ] [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in

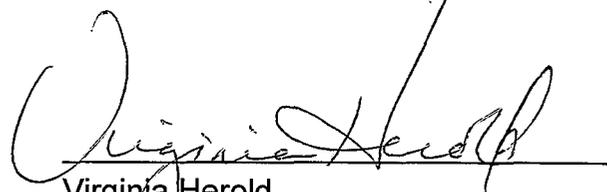
subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.

Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

A handwritten signature in black ink, appearing to read "Virginia Herold", written over a horizontal line.

Virginia Herold  
Executive Officer  
Board of Pharmacy

# **Attachment 2**

# **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 2011



**Substance Abuse Coordination Committee**

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Francine Davies  
**Naturopathic Medicine Committee**

Virginia Herold  
**California State Board of Pharmacy**

Steve Hartzell  
**Physical Therapy Board of California**

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 of California**

Annemarie Del Mugnaio  
**Speech-Language Pathology & Audiology &  
Hearing Aid Dispenser Board**

Susan Geranen  
**Veterinary Medical Board**

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**#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**

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 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.

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. 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 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, randomicity, 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 standards shall govern all aspects of testing required to determine abstention from alcohol and drugs for any person whose license is placed on probation or in a diversion program due to substance use:

**TESTING FREQUENCY SCHEDULE**

A board may order a licensee to drug test at any time. Additionally, each licensee shall be tested RANDOMLY in accordance with the schedule below:

Level	Segments of Probation/Diversion	Minimum Range of Number of Random Tests
I	Year 1	52-104 per year
II*	Year 2+	36-104 per year

\*The minimum range of 36-104 tests identified in level II, is for the second year of probation or diversion, and each year thereafter, up to five (5) years. Thereafter, administration of one (1) time per month if there have been no positive drug tests in the previous five (5) consecutive years of probation or diversion.

Nothing precludes a board from increasing the number of random tests for any reason. Any board who finds or has suspicion that a licensee has committed a violation of a board's testing program or who has committed a Major Violation, as identified in Uniform Standard 10, may reestablish the testing cycle by placing that licensee at the beginning of level I, in addition to any other disciplinary action that may be pursued.

**EXCEPTIONS TO TESTING FREQUENCY SCHEDULE**

I. PREVIOUS TESTING/SOBRIETY

In cases where a board has evidence that a licensee has participated in a treatment or monitoring program requiring random testing, prior to being subject to testing by the board, the board may give consideration to that testing in altering the testing

frequency schedule so that it is equivalent to this standard.

## II. VIOLATION(S) OUTSIDE OF EMPLOYMENT

An individual whose license is placed on probation for a single conviction or incident or two convictions or incidents, spanning greater than seven years from each other, where those violations did not occur at work or while on the licensee's way to work, where alcohol or drugs were a contributing factor, may bypass level I and participate in level II of the testing frequency schedule.

## III. NOT EMPLOYED IN HEALTH CARE FIELD

A board may reduce testing frequency to a minimum of 12 times per year for any person who is not practicing OR working in any health care field. If a reduced testing frequency schedule is established for this reason, and if a licensee wants to return to practice or work in a health care field, the licensee shall notify and secure the approval of the licensee's board. Prior to returning to any health care employment, the licensee shall be subject to level I testing frequency for at least 60 days. At such time the person returns to employment (in a health care field), if the licensee has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

## IV. TOLLING

A board may postpone all testing for any person whose probation or diversion is placed in a tolling status if the overall length of the probationary or diversion period is also tolled. A licensee shall notify the board upon the licensee's return to California and shall be subject to testing as provided in this standard. If the licensee returns to employment in a health care field, and has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

## V. SUBSTANCE USE DISORDER NOT DIAGNOSED

In cases where no current substance use disorder diagnosis is made, a lesser period of monitoring and toxicology screening may be adopted by the board, but not to be less than 24 times per year.

## **OTHER DRUG STANDARDS**

Drug testing may be required on any day, including weekends and holidays.

The scheduling of drug tests shall be done on a random basis, preferably by a computer program, so that a licensee can make no reasonable assumption of when he/she will be tested again. Boards should be prepared to report data to support back-to-back testing as well as, numerous different intervals of testing.

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

Licensees shall be drug tested on the date of notification as directed by the board.

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.

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

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.

Collection of specimens shall be observed.

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

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.

A board may use other testing methods in place of, or to supplement biological fluid testing, if the alternate testing method is appropriate.

### **PETITIONS FOR REINSTATEMENT**

Nothing herein shall limit a board's authority to reduce or eliminate the standards specified herein pursuant to a petition for reinstatement or reduction of penalty filed pursuant to Government Code section 11522 or statutes applicable to the board that contains different provisions for reinstatement or reduction of penalty.

### **OUTCOMES AND AMENDMENTS**

For purposes of measuring outcomes and effectiveness, each board shall collect and report historical and post implementation data as follows:

#### **Historical Data - Two Years Prior to Implementation of Standard**

Each board should collect the following historical data (as available), for a period of two years, prior to implementation of this standard, for each person subject to testing for banned substances, who has 1) tested positive for a banned substance, 2) failed to

appear or call in, for testing on more than three occasions, 3) failed to pay testing costs, or 4) a person who has given a dilute or invalid specimen.

### **Post Implementation Data- Three Years**

Each board should collect the following data annually, for a period of three years, for every probationer and diversion participant subject to testing for banned substances, following the implementation of this standard.

### **Data Collection**

The data to be collected shall be reported to the Department of Consumer Affairs and the Legislature, upon request, and shall include, but may not be limited to:

Probationer/Diversion Participant Unique Identifier  
License Type  
Probation/Diversion Effective Date  
General Range of Testing Frequency by/for Each Probationer/Diversion Participant  
Dates Testing Requested  
Dates Tested  
Identify the Entity that Performed Each Test  
Dates Tested Positive  
Dates Contractor (if applicable) was informed of Positive Test  
Dates Board was informed of Positive Test  
Dates of Questionable Tests (e.g. dilute, high levels)  
Date Contractor Notified Board of Questionable Test  
Identify Substances Detected or Questionably Detected  
Dates Failed to Appear  
Date Contractor Notified Board of Failed to Appear  
Dates Failed to Call In for Testing  
Date Contractor Notified Board of Failed to Call In for Testing  
Dates Failed to Pay for Testing  
Date(s) Removed/Suspended from Practice (identify which)  
Final Outcome and Effective Date (if applicable)

**#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 within the last year.
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, be another health care professional if no monitor with like practice is available, or, as approved by the board, be a person in a position of authority who is capable of monitoring the licensee at work.
3. If the worksite monitor is a licensed healthcare professional he or she 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:

1. The board shall order the licensee to cease practice;
2. 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 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. 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.
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) years.

**#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:

(a) Specimen Collectors:

- (1) 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.
- (2) 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.
- (3) The provider or subcontractor must provide collection sites that are located in areas throughout California.
- (4) 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.
- (5) 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.
- (6) 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.

- (7) 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.
- (8) 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.
- (9) Must undergo training as specified in Uniform Standard #4 (6).

(b) Group Meeting Facilitators:

A group meeting facilitator for any support group meeting:

- (1) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;
- (2) must be licensed or certified by the state or other nationally certified organization;
- (3) must not have a financial relationship, personal relationship, or business relationship with the licensee within the last year;
- (4) shall report any unexcused absence within 24 hours to the board, and,
- (5) 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.

(c) Work Site Monitors:

The worksite monitor must meet the following qualifications:

- (1) 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 monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored, be another health care professional if no

monitor with like practice is available, or, as approved by the board, be a person in a position of authority who is capable of monitoring the licensee at work.

- (3) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.
  - (4) 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.

(d) Treatment Providers

Treatment facility staff and services must have:

- (1) Licensure and/or accreditation by appropriate regulatory agencies;
- (2) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;
- (3) Professional staff who are competent and experienced members of the clinical staff;
- (4) Treatment planning involving a multidisciplinary approach and specific aftercare plans;
- (5) Means to provide treatment/progress documentation to the provider.

(e) General Vendor Requirements

The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:

- (1) 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.
- (2) 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.
- (3) 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.
- 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.

## Potential Revisions to Disciplinary Guidelines to Incorporate SB 1441 Uniform Standards and Staff Proposals<sup>1</sup>

Changes in blue reflect the Uniform Standards (green is used for subcommittee edits)

Changes in red reflect staff proposals that predated incorporation of the Uniform Standards

**18. ~~Mental Health Examination~~ Clinical Diagnostic Evaluation**<sup>2</sup> (Appropriate for those cases where evidence demonstrates that mental illness, substance abuse, or disability was a contributing cause of ~~the a violation or~~ violations.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter if as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric clinical diagnostic evaluation(s) by a ~~board-appointed or board-approved~~ licensed ~~mental health~~ practitioner selected or approved prior to the evaluation by the board or its designee. The approved evaluator shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a ~~pharmacist~~ [pharmacist, pharmacy technician, or designated representative] with safety to the public. ~~Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee. If the evaluator recommends restrictions or conditions on respondent's practice, including but not limited to other terms and conditions listed in these guidelines (e.g., required psychotherapy, prescription coordination and monitoring, restricted practice), the board or its designee may by written notice to respondent adopt these restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation.~~

~~If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.~~

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<sup>1</sup> This document is limited to those terms and conditions in the Disciplinary Guidelines that would be affected by the SB 1441 Uniform Standards. For those, it shows both the proposed changes necessary to conform to the SB 1441 Uniform Standards and the changes separately proposed by staff. There are other terms and conditions where staff have proposed changes that are not included here, because this discussion is focused on the Uniform Standards.

<sup>2</sup> The changes to this term are those necessary to make it consistent with Uniform Standards # 1 and # 2.

~~Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.~~

~~Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.~~

~~If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently as a pharmacist, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.~~

**Option #1 (mandatory in all cases involving alcohol or substance abuse):** The evaluation(s) shall be conducted in accordance with acceptable professional standards for alcohol or substance abuse clinical diagnostic evaluations. The written report(s) shall set forth, at least, the opinions of the evaluator as to: whether respondent has an alcohol or substance abuse problem; whether respondent is a threat to him/herself or others; and recommendations for alcohol or substance abuse treatment, practice restrictions, or other steps related to respondent's rehabilitation and safe practice. If the evaluator determines during the evaluation process that respondent is a threat to him/herself or others, the evaluator shall notify the board within twenty-four (24) hours.

Commencing on the effective date of this decision, respondent is suspended from practice and shall not practice as a [pharmacist, pharmacy technician, or designated representative] until:

- Respondent has undergone and completed clinical diagnostic evaluation(s);
- The report(s) of the evaluation(s) has/have been received by the board or its designee;
- One or more report(s) has concluded that respondent is safe to return to practice as a [pharmacist, pharmacy technician, or designated representative];
- Respondent has submitted to observed bodily fluid testing for the presence of alcohol, dangerous drugs, or controlled substances [pursuant to Term and Condition ??] ~~at least twice per week~~ for at least thirty (30) days;
- During the testing period, respondent has not had a confirmed positive test result for alcohol, or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment, ~~for at least thirty (30) days;~~

- The board or its designee has determined that respondent is safe to return to either full-time or part-time practice as a [pharmacist, pharmacy technician, or designated representative], after considering the evaluation report(s), the results of the fluid testing, and criteria including the license type, respondent's history, respondent's documented period of sobriety or documented time since last use, respondent's scope and pattern of use, respondent's treatment history, respondent's medical history and current medical condition, the nature, duration, and severity of respondent's alcohol or substance abuse, and whether respondent is a threat to him/herself or others; and
- Respondent receives written notice that practice may resume.

[Staff propose moving this paragraph from the guidelines to the form used to select evaluators:]

The board or its designee shall select or approve evaluator(s) holding a valid, unrestricted license to practice, with a scope of practice that includes the conduct of clinical diagnostic evaluations and at least three (3) years experience conducting such evaluations of health professionals with alcohol or substance abuse problems. The evaluator(s) shall not have a financial relationship, personal relationship, or business relationship with respondent within the last five (5) years. The evaluator(s) shall provide an objective/ unbiased, and independent evaluation of respondent.

For all such 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 thirty (30) days.~~ completes the evaluation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices.

**Option #2 (optional in all other cases):** Commencing on the effective date of this decision, respondent ~~is suspended from practice and shall not engage in the practice of pharmacy practice as a [pharmacist, pharmacy technician, or designated representative] until notified in writing by the board that respondent has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation~~ the evaluator recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice that practice may resume.

The final written report of the evaluation 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 thirty (30) days. completes the evaluation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and or~~ devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)

**Option #3 (optional in all other cases):** ~~If recommended by the evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until respondent's treating therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.~~ evaluator, the board or its designee may suspend respondent from practice as a [pharmacist, pharmacy technician, or designated representative] by providing written notice of suspension. Upon suspension, respondent shall not resume practice as a [pharmacist, pharmacy technician, or designated representative] until another evaluation done at respondent's expense by a licensed practitioner selected or approved by the board or its designee recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice that practice may resume.

The report(s) from any such additional evaluation(s) 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 thirty (30) days. completes the evaluation.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs

~~and or~~ devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During ~~any such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, ~~pharmacy technician, or designated representative~~. Respondent shall not direct or control any aspect of the practice of pharmacy, ~~or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices~~. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ ~~any such~~ suspension shall be considered a violation of probation.

**NEW TERM & CONDITION (applicable in cases involving alcohol or substance abuse):**  
**??.** **Reporting of Employment; Consent.**<sup>3</sup> Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of all of [his/her] employer(s), and the name(s) and telephone number(s) of all of [his/her] direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, or other compliance supervisor(s). Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring.

**22.** ~~Random Drug Screening~~ **Drug and Alcohol Testing**<sup>4</sup> (If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required **Mandatory in all cases involving alcohol or substance abuse; may be combined with PRP.**)

Respondent, at ~~his or her~~ ~~[his/her]~~ own expense, shall participate in random testing, ~~including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program~~ as directed by the board or its designee. ~~Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples~~ for the detection

<sup>3</sup> This term would comply with Uniform Standard # 3.

<sup>4</sup> This term would comply with Uniform Standard # 4.

~~of alcohol, narcotics, hypnotics, controlled substances, and dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.~~

~~By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any necessary information and documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate in a timely fashion shall be considered a violation of probation.~~

~~Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day. Though the frequency of testing will be determined by the board or its designee, and shall be designed so as to prevent respondent from anticipating testing dates (either randomized testing or unpredictable dates), the frequency of testing shall be at least the following: at least fifty two (52) test dates during the first year of probation; at least thirty six (36) test dates during the second, third, fourth, and fifth years of probation; and at least one (1) test per month in each year of probation after the fifth so long as there have been no positive test results during the previous five (5) years. The board or its designee may require less frequent testing if any of the following applies:~~

- ~~• Where respondent has previously participated in a treatment or monitoring program requiring testing, the board or its designee may consider that prior testing record in applying the three-tier testing frequency schedule described above;~~
- ~~• Where the basis for probation or discipline is a single incident or conviction involving alcohol or drugs, or two incidents or convictions involving alcohol or drugs that were at least seven (7) years apart, that did not occur at work or on the way to or from work, the board or its designee may skip the first year testing frequency requirement(s);~~

- ~~Where respondent is not employed in any health care field, frequency of testing may be reduced to a minimum of twelve (12) tests per year. If respondent wishes to thereafter return to employment in a health care field, respondent shall be required to test at least once a week for a period of sixty (60) days before commencing such employment, and shall thereafter be required to test at least once a week for a full year, before [he/she] may be reduced to a testing frequency of at least thirty-six (36) tests per year, and so forth;~~
- ~~Respondent's testing requirement may be suspended during any period of tolling of the period of probation;~~
- ~~Where respondent has a demonstrated period of sobriety and/or non-use, the board or its designee may reduce the testing frequency to no less than twenty-four (24) tests per year.~~

Any detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, may cause the board or its designee to increase the frequency of testing, in addition to any other action including but not limited to further disciplinary action.

Prior to any vacation or other period of absence from the geographic area of the approved testing vendor, respondent shall seek and receive approval from the board or its designee of an alternate testing vendor in the geographic area to be visited or resided in by respondent. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide that alternate vendor with any necessary information and documentation, including any necessary for payment by respondent. During the period of visitation or residence in the alternate geographic area, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection through testing of a controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [pharmacist, pharmacy technician, or designated representative] until notified by the board in writing that [he/she] may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of

drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and or~~ devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

[Staff propose including these elements of Uniform Standard # 4 in the testing vendor contract]:

The board may be required to report data to support testing on consecutive days as well as numerous different testing intervals, and shall require cooperation from the vendor to do so.

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

The board will be required to collect and report historical and post implementation data on testing as follows, and shall require cooperation from the vendor to do so:

For the two-year period prior to implementation of the Uniform Standards, the board shall collect and report data (as available) for each person subject to testing who has (1) tested positive for a banned substance, (2) failed to appear or call in for testing on more than three occasions, (3) failed to pay testing costs, or (4) given a dilute(d) or invalid specimen.

For a period of three years following implementation of the Uniform Standards, the board shall collect and report the data including but not limited to the following to the Department of Consumer Affairs and/ upon request, to the Legislature:

Probationer/Diversion Participant Unique Identifier

License Type

Probation/Diversion Effective Date

General Range of Testing Frequency by/for Each Probationer/Diversion Participant

Dates Testing Requested

Dates Tested

Identify the Entity that Performed Each Test

Dates Tested Positive

Dates Contractor (if applicable) was informed of Positive Test

Dates Board was informed of Positive Test

Dates of Questionable Tests (e.g. dilute, high levels)

Date Contractor Notified Board of Questionable Test

Identify Substances Detected or Questionably Detected

Dates Failed to Appear

Date Contractor Notified Board of Failed to Appear

Dates Failed to Call In for Testing

Date Contractor Notified Board of Failed to Call In for Testing

Dates Failed to Pay for Testing

Date(s) Removed/Suspended from Practice (identify which)

Final Outcome and Effective Date (if applicable)

# **Attachment 3**

## Compounding Questions and Answers

JANUARY 10, 2011

**1. Question: What is a “reliable supplier?”**

**Answer:** Some examples of reliable suppliers are FDA licensed manufacturers, CA Department of Public Health – Food and Drug Branch licensed drug repackagers; CA licensed pharmacies and wholesalers; CA licensed non-resident wholesalers.

Prior to making a purchase, it is recommended to check the board’s website – [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) – to verify if the wholesaler or non-resident pharmacy is licensed by the board.

If purchasing chemicals from another country, obtain a certificate issued by the FDA authorizing shipment of the product into the U.S. and a certificate of analysis printed in English.

As a reminder, any pharmacy purchasing, trading, selling, or transferring drugs to an entity not licensed by the board could be cited and fined up to \$5000 per transaction

Reference: B&P §§ 4160, 4163, 4126.5, 4169(a)(1); CCR §§ 1780, 1783, 1735.3(c)

**2. Question: Do cytotoxic agents and other hazardous substances have the same requirements for qualitative and quantitative analysis?**

**Answer:** Yes.

**3. Question: Is a non-resident pharmacy (NRP) that provides compounded product into CA required to meet the same staffing requirements as CA pharmacies?**

**Answer:** No.

A non-resident pharmacy (NRP) is a pharmacy located in another state that furnishes dangerous drugs to patients in CA, and is required to be licensed with the board. Part of the licensure requirement is that the NRP be in compliance with pharmacy laws in the state where it is located.

The board has no authority to dictate staffing requirements for pharmacies located in states other than CA. The board expects the NRP to be staffed in accordance with requirements where it is located.

Reference: Business and Professions Code § 4112(a); 4112(d)

**4. Question: What constitutes sterile compounding?**

**Answer:** First, let's define "compounding" in general:

"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

With the above in mind, sterile compounding is a specific sub-type of general compounding whereby there is a requirement for the compounded drug product to be sterile. Sterile compounding almost exclusively involves sterile parenteral compounding for which there are additional requirements.

Reference: CCR §§ 1735(a) 1735(d); 1751 et seq.5.

**5. Question: Is the adding of 20 mEq of potassium chloride to 1000cc of normal saline for intravenous administration considered sterile compounding.**

**Answer:** Yes, and this is also considered sterile parenteral compounding.

Reference: CCR 1735(a)6.

**6. Question: Can a pharmacy mix three liquids (Maalox, Benadryl, and Xylocaine) in equal parts or two creams in equal parts, and would this be considered compounding.**

**Answer:** Yes in the examples given, a pharmacy may mix those products

in equal parts. And yes, it is considered compounding.

Reference: CCR 1735(a)7.

7. **Question: 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 in-patient of a health care facility and the IV product is not used and returned to the pharmacy? Can it be reused?**

**Answer:** No.

The compounding regulations require specific records for compounded drug products. 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 of this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient in a health care facility.
- (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.

If all the information is not recorded [as provided by the exemption in (6)] then there is a lack of complete traceability and accountability for the compounded drug product and thus it

cannot be reused.

Reference: CCR 1735.3(a)8.

8. **Question:** **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 pharmacy subject to the record keeping requirements?**

**Answer:** Yes, with the possible exception of documenting the manufacturer and lot number of each component of the admixture.

Reference: CCR 1735.3(a)(6)9.

9. **Question:** **Is a master formula record equivalent to a “recipe card?”**

**Answer:** Basically, yes.

Like a recipe card the master formula record includes the active and inactive ingredients to be used, the process and/or procedure used to prepare the drug, quality reviews required at each step in the preparation of the drug, post-compounding process or procedures required, and the expiration dating requirements.

The master formula record must be created prior to compounding the drug product.

The prescription document itself may be used as the master formula record If a pharmacy does not routinely compound a particular drug product.

Reference: CCR 1735.2(d)10.

10. **Question:** **When compounding a product, is it required to have master formula record available and used when the product is compounded?**

**Answer:** Yes, the master formula record must be created prior to compounding the drug product and its use will provide guidance

for compounding personnel and consistency in the product produced.

Reference: CCR 1735.2(d)11.

**11. Question: Is it required to review the master formula record as part of pre-check process?**

**Answer:** The law is silent on a “pre-check process.” However, the master formula record will provide guidance to compounding personnel in what to use and how to compound the particular drug product. So the master formula record could be used in a “pre-check” process to insure consistency in the compounding process.

Reference: CCR 1735.3 12.

**12. Question: What are the requirements for compounding documentation?**

**Answer:** The compounding regulations require specific records for compounded drug products. 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 of this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient in a health care facility.
- (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.

Reference: CCR 1735.313.

- 13. Question: When using the record-keeping exemption in 1735.3(a)(6) 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?**

**Answer:** No.

The regulations provide for an exemption for sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient of a health care facility.

Reference: CCR 1735.3(a)(6)14.

- 14. Question: When must the manufacturer and lot number be recorded?**

**Answer:** 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.

Reference: CCR 1735.3(a)(6)15.

- 15. Question: How will the board insure compliance by non-resident pharmacies (NRP's) that provide compounded drug products into CA?**

**Answer:** The board does not have the ability to inspect NRPs. However, NRPs are required to be licensed with the board and to maintain compliance with pharmacy regulations of their home state. Also, a NRP performing sterile parenteral compounding as a condition of renewal will be encouraged to submit a completed Compounding Self Assessment Form.

Reference: B&P §§ 4112, 4127.216.

- 16. Question: Is the dilution per the manufacturer's instructions and adding to the IV solution considered compounding?**

**Answer:** Yes, if done in a pharmacy. However, statute provides for exemption from sterile compounding licensure if the sterile powder was obtained from a manufacturer and the drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection.

Reference: CCR 1735(a)(1); B&P 4127.1(e)17.

**17. Question: 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?**

**Answer:** These types of delivery systems are exempt from the compounding requirements if the sterile powder was obtained from a manufacturer and the drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection.

Reference: CCR 1735(a)(1); B&P 4127.1(e) 18.

**18. Question: What specifically will be required or what process is acceptable to achieve quality assurance?**

**Answer:** Quality assurance, as the term implies, is designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded products.

A quality assurance plan will touch all parts of the compounding process – drug product and equipment acquisition/storage; compounding processes; documentation of compounding and related analysis; employee training and monitoring; recall procedure; etc

Reference: CCR §§ 1735.8; 1735.3; 1735.5; 1735.6; 1735.7; 1751 et seq19.

**19. Question: 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(a)?**

**Answer:** Yes.

Reference: CCR 1735.3(a)20.

- 20. Question: 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?**

**Answer:** The pharmacy, and the pharmacist, are responsible for insuring the compounded product complies quantitatively and qualitatively with the prescriber's prescription.

For compounded product that is compounded on a one-time basis for immediate dispensing, it would not be likely there would be a quantitative or qualitative analysis conducted.

For products compounded for on-going therapy it would be expected there would be analysis done initially and on a periodic basis to validate the product and compounding process.

The same holds true for sterile injectable drug products too.

However, if two or more sterile injectable drug products being compounded from one or more non-sterile ingredients, these end-products shall be quarantined until end-product testing confirms sterility and acceptable levels of pyrogens.

Reference: CCR §§ 1735.2(f); 1735.2(i); 1751.7(a); 171621.

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

**Answer:** 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.

Reference: CCR 1735.8; 1735.3; 1735.5; 1735.6; 1735.7; 1751 et seq.22.

22. **Question:** For the purposes of CCR section 1735.3(a)(6) and 1751.2(a), would patients receiving chemotherapy administered in an infusion center that is part of a health care facility be considered “in-patients” and exempt from the labeling requirements?

**Answer:** If the infusion center is part of the licensed health care facility and the patients receiving care there are registered as hospital in-patients, then yes the exemption provided by CCR 1735(a)(6) would apply. However, the labeling requirements as defined in CCR 1751.2 would apply and compliance would be expected.

Reference: B&P §§ 4027, 4019, 4029; CCR 1735.3(a)(6), 1751.223.

23. **Question:** CCR section 1735.3 defines what must be recorded for each compounded drug product. CCR 1735.3(a)(7) states, “The equipment used in compounding the drug product.” Does this include tubing sets, spikes, needles, syringes, etc.?

**Answer:** Yes, all equipment used for compounding the drug product must be recorded – TPN compounders, homogenizers, scales, syringes, needles, tubing sets, spikes, filters, mortar and pestle, pill making device, infusion devices. If there are more than one of the same device (e.g. - scales, laminar flow hoods) it is recommended to label them in some manner to distinguish which one was used in the process for appropriate completion of the compounding record.

Reference: CCR 1735.3(a)(7)24.

24. **Question:** Where would the lot number, manufacturer, and expiration date be recorded?

**Answer:** The law does not specify where or how the information is to be recorded. A pharmacy may develop its own form(s) for the proper documentation. The pharmacy shall maintain the record for three

years from the date it was created.

Reference: CCR 1735.325.

- 25. Question: CCR section 1751.2(d) states, “All cytotoxic agents shall bear a special label which states ‘Chemotherapy – Dispose of Properly.’” This appears to give no wiggle room for the text of the message.**

**Answer:** There are no exceptions. If a drug is classified as a cytotoxic agent then the special label must be used.

Reference: CCR 1751.2(d)26.

- 26. Question: Gancyclovir is a cytotoxic agent but is not a chemotherapeutic agent. Does the special label need to be applied?**

**Answer:** Yes, the regulation does not provide for exceptions. However, nothing prevents the pharmacist from consulting the patient on the drugs classification and use.

Reference: CCR 1751.2(d)27.

- 27. Question: CCR section 1751.5(b)(1) states, in pertinent part, “Cleanroom garb consisting of low-shedding coverall, head cover...must be worn inside the designated area at all times.” USP 797 does not require the use of a coverall, only a gown.**

**Answer:** The board does not enforce USP 797, but expects compliance with board regulations.

A coverall is much more encompassing than a gown and would provide better protection during the compounding process.

Reference: CCR 1751.5(b)(1)28.

- 28. Question: For a compounded drug product can a pharmacy use an expiration date, or beyond use date, of greater than 180**

**days?**

**Answer:** Yes, if the longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging.

Reference: CCR 1735.2(h)29.

**29. Question: If a pharmacy makes a compounded drug product and does the qualitative and quantitative testing that demonstrates it has a stability expiration dating greater than 180 days, can another pharmacy use the same formula, with minor changes, use the same extended expiration date?**

**Answer:** No. To use another pharmacy's extended expiration date the formula must use the same components and packaging.

Reference: CCR 1735.2(h)30.

**30. Question: Master formulas and compounding records are filed in separate locations, can easily be linked together, and are readily retrievable. Is it an absolute requirement to file these documents together?**

**Answer:** No, there is no such requirement for the above records to be maintained together as long as they are readily retrievable and available for inspection. These records may be maintained in a paper or electronic manner.

However, qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated (kept together) with the compounding record and master formula.

Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge or the pharmacist on duty shall during business hours be able to produce a hard copy and electronic copy.

Reference: CCR 1735.8(c); B&P 4105(d)31.

**31. Question: Is record keeping for compounding just referring to products**

**that are administered intravenously or intraocular (e.g. where sterile preparation is imperative) or does it extend to oral and topical compounding?**

**Answer:** The regulations apply to all forms of compounding – oral, inhalation, topical, sterile parenteral, etc. The record keeping requirements for sterile compounding are more extensive

Reference CCR §§ 1735 et seq & 1751 et seq.32.

**32. Question: What is meant by proper acquisition?**

**Answer:** Records of proper acquisition of dangerous drugs and dangerous devices would include purchase records that correctly give the date, the names and address of the supplier and the buyer, the drug or device, and its quantity.

Also, refer to Question #1 and its answer.

Reference: B&P § 4059(b)

# **Attachment 4**



**California State Board of Pharmacy**

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

**DATE:** March 29, 2011

**LOCATION:** First Floor Hearing Room  
400 R Street  
Sacramento, CA 95816

**COMMITTEE MEMBERS**

**PRESENT:** Randy Kajioka, PharmD, Chair  
Greg Lippe, Public Member  
Neil Badlani, RPh

**COMMITTEE MEMBERS**

**NOT PRESENT:** Tappan Zee, Public Member

**STAFF**

**PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Robert Ratcliff, Supervising Inspector  
Joshua Room, Deputy Attorney General  
Kristy Shellans, DCA Staff Counsel  
Carolyn Klein, Legislation and Regulation Manager  
Tessa Miller, Staff Analyst

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**Call to Order**

Chair Randy Kajioka called the meeting to order at 9:33 a.m.

Chair Kajioka conducted a roll call. Board Members Badlani, Lippe, and Kajioka were present.

1. **Presentations to Request Exemptions from 16 California Code of Regulations Section 1707.5 Label Requirements for Prescription Drug Containers as Authorized by Section 4076.5 (SB 1489, Negrete-McLeod, Chapter 653, Statutes of 2010)**

Chair Report

Chair Kajioka provided that on January 1, 2011, the board's requirements for patient-centered labels went into effect as 16 California Code of Regulations section 1707.5.

Chair Kajioka provided that also effective January 1, 2011, provisions enacted by SB 1489 (Senate Business and Professions Committee, Chapter 653, Statutes of 2010) as amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments.

Chair Kajioka advised that to allow such an exemption, the board will need to promulgate regulations.

Chair Kajioka provided that the committee will hear presentations from three groups, Walgreens, GE Healthcare, and the California Pharmacists Association (CPhA), to seek an exemption from the labeling requirements for their specialized patient populations. He stated that each group has been asked to demonstrate why they cannot comply with the labeling requirements and how they can provide appropriate consumer protection and information without the patient-centered labels.

Request 1: From Walgreens For Pharmacies Making Total Parenteral Therapy (TPN)

Al Carter, Manager of Pharmacy Affairs, and Tom Rout, Regional Pharmacy Director of Infusion and Respiratory Services – West, provided a presentation requesting an exemption from labeling requirements for TPN products at Walgreens homecare facilities. Mr. Carter presented the committee with a sample label handout that is currently in use.

Mr. Rout provided an overview on TPN solutions and the challenges in achieving compliance with the labeling requirements for these products. He discussed that TPN solutions provide patients with all of their needed nutrients intravenously and can contain 12-30 different ingredients in addition to additives that are added at the time of infusion. Mr. Rout explained that the solutions are packaged in a large volume bag and generally provide a 24-hour supply.

Mr. Rout stated that it is difficult to include the large array of ingredients included in the TPN solutions on the label in a 12-point font.

Mr. Rout reviewed a label handout exhibiting a complex ingredient solution and a simple ingredient solution. He reviewed components of current TPN labels including 8-point font text as well as a fixed amount of white space to accommodate the ingredient list.

Mr. Rout discussed that an exemption to the labeling requirements will not compromise patient safety as the patients are at home in a hospital-like administration scenario with assistance and training on how to use the medication and equipment by health care professionals including a home care nurse. He stated that patients are assessed prior to discharge from the hospital to ensure that they are capable of participating in this treatment. Mr. Rout discussed that the general goal is to train the patient to manage this treatment independently. He provided that the label is a minor part in what is used to correctly manage this therapy.

Mr. Rout provided the committee with sample training materials for patients.

### Discussion

Mr. Lippe inquired about the sample label and asked if information on the label could be bolded or otherwise emphasized.

Mr. Route indicated that he would need to confirm this with his IT staff. Mr. Route also indicated that one of the elements of the training is to provide the patient with information on how to read the label and to understand when information is different and what could cause a change. He stated that all changes to the solution are communicated and explained verbally with the patient or caregiver.

Chair Kajioka asked whether written communication is also provided to the patient.

Mr. Route explained that this is dependant on the type of change and on the judgment of the pharmacist.

Chair Kajioka asked whether the infusion rate instructions on the label could be printed in a larger font or highlighted.

Mr. Route indicated that Walgreen's goal has been to be compliant with the requirements of the regulation. He stated that if the exemption is granted, Walgreens will still make every effort to be partially compliant.

Joshua Room, Deputy Attorney General, asked whether all of these specialty pharmacies are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). He stated that the statute that gives the board the authority for the exemption for infusion pharmacies occurs in Business and Professions Code section 4076.5(e) which requires that the drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.

Mr. Route provided that the pharmacies are accredited by the Accreditation Commission for Health Care (ACHC).

Chair Kajioka discussed that Walgreens specialty pharmacies do not satisfy all of the statutory requirements for the exemption as they are not JCAHO accredited.

The committee further evaluated the infusion process, the role of the patient, and the training that they receive.

Mr. Room reviewed the other exemption requirements of Section 4076.5(e) including the following:

- The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
- The patient receives weekly or more frequent follow-up contacts by a nurse or pharmacist.
- Care is provided under a formal plan of care based upon a physician and surgeon's orders.

Mr. Route indicated that all of these requirements are satisfied.

Mr. Room discussed the intent of the legislature with regards to the JCAHO accreditation requirement. He stated that it is not within the board's purview to determine whether ACHC is an acceptable alternative for this requirement.

Executive Officer Virginia Herold provided the committee with a sample label in 12-point font that was drafted by board staff. She stated that the sample does not include the physician's name, expiration date, and the name of the pharmacy. (A copy of this label is attached, following this meeting summary.)

The committee discussed this sample and the use of a 12-point font. Concern was expressed that the sample may not be a fair comparison as it missing certain information and includes only a small number of ingredients.

Mr. Room asked whether there are physical and/or cost limitations that restrict the size of the label being used for TPN solutions.

Mr. Rout provided that both factors have an impact. He discussed that the thermal printers that are used limit the width of the label; however, the label could be longer. Mr. Rout indicated that the regulation requirement that at least 50 percent of the label be dedicated to certain information is presenting the biggest challenge.

Chair Kajioka clarified that the 50 percent requirement is regarding dedicated space and not the actual text. He explained that white space can be included in this 50 percent dedicated space.

Supervising Inspector Robert Ratcliff discussed that many community pharmacies changed to different printers in order to comply with the new requirements. He provided comment on the sample label that was drafted by board staff and indicated that there is a sufficient amount of blank space to accommodate the missing information.

Dr. Ratcliff expressed concern regarding the abbreviation used for the manufacturer on the sample label provided by Walgreens. He discussed that use of common abbreviations is required by statute.

Neil Badlani asked whether two labels in 12-point font can be put onto one solution bag.

Mr. Rout indicated that he does not believe that this option has been explored.

Ms. Herold reiterated that Walgreens does not meet the requirements as required in Section 4076.5(e) and, as such, a statutory change is needed prior to considering the exemption.

It was the consensus of the committee to take no action on this request.

Chair Kajioka encouraged Walgreens to incorporate a 10-point font and use of bolding on their TPN labels.

No public comment was provided.

#### Request 2: From GE Healthcare for Radiopharmaceuticals

Jaime Herner, Janet Reuther, and Randy Kohen, representing GE Healthcare, provided a presentation to request an exemption from the patient-centered labeling requirements for radiopharmaceuticals.

Ms. Reuther provided that GE Healthcare, part of Medi-Physics, Inc., is a licensed Nuclear Pharmacy that dispenses patient specific unit dose radiopharmaceutical prescriptions and bulk radiopharmaceutical products to other radioactive materials licensees authorized to use these products.

Ms. Herner indicated that GE Healthcare is regulated by several different regulating bodies including the California Radiologic Health Branch (RHB), the Nuclear Regulatory Commission (NRC), and the Board of Pharmacy. She discussed that GE Healthcare has encountered a problem with complying with the patient-centered label requirements because of radioactive symbols that are required on the labels for radiopharmaceuticals.

Ms. Herner reviewed the dispensing process for radiopharmaceuticals. She indicated that the products are not distributed to the general public, nor directly to the patient.

Mr. Kohen discussed that there is a closed system in which all prescriptions dispensed by GE Healthcare facilities are distributed to, received and are administered by licensed health care professionals only.

Chair Kajioka discussed that these products are used primarily for diagnostics and are not distributed directly to the patient. He requested legal clarification as to whether the regulation applies to this scenario.

Kristy Shellans, DCA Staff Counsel, provided that the regulation is not applicable if the medication is not dispensed directly to patients in California.

Mr. Room indicated that he does not believe that the regulation applies to this practice.

No action was required. No public comment was provided.

The committee recessed for a break at 10:32 a.m.

The committee reconvened at 10:41 a.m.

### Request 3: From CPhA's Long-Term Care Academy for Skilled Nursing Facilities

Stan Goldenberg, Scott Huhn, Greg Light, and Art Whitney, representing the California Pharmacists Association (CPhA), provided a presentation to explain how patient safety in long-term care facilities can be ensured without patient-centered labels.

Mr. Goldenberg provided an overview of the long-term care industry which consists of two areas including skilled nursing facilities (SNFs) and assisted/independent living. He indicated that SNFs are regulated by state and federal regulations that prohibit patient access to medications. Mr. Goldenberg stated that the medications provided to SNFs are intended to be administered by licensed nurses.

Mr. Goldenberg provided that SNFs operate according to systems that have been developed to follow the regulations to ensure efficiency, reduction of errors, and patient safety.

Mr. Goldenberg discussed a new regulation proposed by the federal government that will require a seven-day bubble pack versus the current 30-day supply.

Mr. Goldenberg provided that Business and Professions Code section 4076.5(d) allows the board to exempt from the labeling requirements prescriptions dispensed to patients in SNFs.

Mr. Room provided that at the February 2011 Board Meeting, CPhA requested an exemption from the labeling requirements prescriptions that will go home with patients upon discharge. He sought clarification regarding this request.

Mr. Whitney provided comment regarding possession versus ownership. He stated that while the patient is in the SNF, the patient has ownership of the medication but the

facility has possession. Mr. Whitney indicated that the medications are not being dispensed to the patient; instead, they are dispensed in the patient's name.

Ms. Shellans clarified that the drugs are being provided directly to the patient by a healthcare professional.

Mr. Whitney presented the committee with a sample bubble pack and a drawer from a nurse's cart that is used in SNFs. He stated that the packs are secured in a nurse's cart and are not given directly to the patient.

Ms. Shellans stated that under current law, "dispense" refers to the furnishing of drugs directly to a patient by a healthcare professional including a nurse. She stated that the key component to the patient-centered prescription label requirements is dispensing. Ms. Shellans indicated that the law does not distinguish between ownership.

Mr. Room confirmed with the presenters that the exemption is being sought for the initial transaction in which the dispensing pharmacy originally fills the prescription and delivers it to the facility, and not upon discharge. He stated that the pharmacy dispenses medication to a patient in a SNF. Mr. Room discussed that the board needs to determine if an exemption is appropriate given the chance that the medication may go home with the patient upon discharge. He indicated that Section 4076.5 (d) does not permit the board to exempt drugs that may go home with the patient.

Mr. Huhn discussed that Section 4052.7 allows the patient to take the medications to a pharmacy for repackaging.

Chair Kajioka indicated that this is not a viable solution. He discussed the efforts of other pharmacies to comply with the regulation. Chair Kajioka asked why compliance cannot be achieved in this situation.

Mr. Huhn discussed that a second or third label would be needed to fit all of the required information on the label.

Mr. Light discussed the challenges with labeling other containers of varying sizes and presented samples to the committee. He discussed that Title 22 requires that drugs in SNFs be kept in the originally received containers.

Mr. Whitney discussed post consumption via automated dispensing machines located in SNFs to dispense daily doses. He stated that under this scenario, no meds will go home with the patient and the facility is only charged for what is used.

Mr. Goldenberg discussed that this machine provides efficient filling of orders and allows patients to receive their medication in a matter of minutes instead of several hours.

Ms. Badlani asked whether a patient-specific label is attached to the medication dispensed in these machines.

Mr. Whitney indicated that the medication is dispensed with a patient-specific label.

Discussion continued regarding the use of automated dispensing machines in SNFs. It was clarified that use of these machines is becoming more common and the machines can only provide solid or oral doses.

Chair Kajioka reiterated that an exemption is not permissible if there is any chance that the medication will go home with the patient.

Ms. Herold discussed the difference between a daily dose and a 30-day supply in a bubble pack. She stated that the daily doses can qualify for the exemption as they will not go home with the patient.

Mr. Goldenberg asked whether the patient can request that medication be relabeled from a 10-point font to a 12-point font upon discharge.

Chair Kajioka provided that as the medication has already been dispensed in the 10-point font, he believes that the patient can request a 12-point font from the new pharmacy at the next refill.

Discussion continued. It was clarified that Business and Professions Code section 4119.1 allows for the use of automated dispensing machines in SNFs. It was also clarified that an exemption is not authorized if medications may go home with the patient; but can be considered for daily doses.

Chair Kajioka discussed that labels in a 10-point font comply with the regulation. He reiterated that discharged patients can request a 12-point font for refills.

Mr. Room discussed the possible exemption for daily doses dispensed by an automated dispensing machine. He indicated that a regulation is needed for this exemption.

Ms. Herold provided that the board will decide whether or not to pursue a rulemaking at the May 2011 Board Meeting. She clarified that 10-point font is the requirement and 12-point font is an option. Ms. Herold indicated that a patient cannot request a font size smaller than a 10-point font.

Mr. Lippe offered a proposal to pursue an exemption to the patient-centered label requirements for daily dose medication dispensed via an automated dispensing machine.

No public comment was provided.

**MOTION:** Recommend an exemption to the patient-centered label requirements for unit dose medications dispensed via an automated dispensing machine in skilled nursing facilities as appropriate under Business and Professions Code section 4076.5(d).

M/S: Lippe/Badlani

Support: 3 Abstain: 0 Oppose: 0

**2. Discussion to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2011), as Board of Pharmacy Regulations**

Chair Report

Chair Kajioka provided that in 2008, SB 1441 (Ridley-Thomas, Chapter 548) directed that the Department of Consumer Affairs (DCA) establish standardized parameters for substance abusing licensees on probation or those in monitoring programs such as the board's Pharmacists Recovery Program (PRP). He stated that these standards were developed in January 2010, and have been discussed at several board meetings.

Chair Kajioka discussed that to place the standards into effect, the board needs to adopt the standards as regulations.

Chair Kajioka provided that after the February 2011 Board Meeting, President Weisser appointed himself and Tappan Zee to a subcommittee to work on developing the proposed regulations to implement the SB 1441 standards. He stated that the subcommittee met on March 11, and developed language for the board's regulations.

Discussion

The committee discussed uniform standards #1 and #2 with regards to the required timeframe for completing a clinical diagnostic evaluation as well as requiring a licensee to cease practice and undergo drug testing pending the results of the evaluation.

It was clarified that the board will need to conform its disciplinary guidelines to meet the standards or any deviations from the standards.

Ms. Herold discussed the thorough work completed by the subcommittee and the requirement to thoroughly vet any deviation from the standards. She suggested that the committee direct staff to develop modifications to the disciplinary guidelines to implement the standards for review by the board.

Mr. Room volunteered to write the regulatory language.

No public comment was provided.

**MOTION:** Direct staff to develop regulatory language to modify the disciplinary guidelines to implement the SB 1441 standards.

M/S: Lippe/Kajioka

Support: 3    Oppose: 0    Abstain: 0

**3.    Questions and Answers from the Public 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**

Chair Report

Chair Kajioka provided that at the June 2010 Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July 2010.

Chair Kajioka provided that since June, the answers to these and other submitted questions have been compiled into a document and are available on the board's Web site. He stated that the board is responding to these questions to aid pharmacies in complying with the new requirements.

Chair Kajioka provided that the questions and concerns voiced with the regulations have not occurred really since last summer. He stated that during this portion of the meeting, Supervising Inspector Ratcliff will accept and answer additional questions if they are posed.

Discussion

Supervising Inspector Robert Ratcliff indicated that the board has not received additional questions but understands that items are forthcoming.

Chair Kajioka sought clarification regarding the reporting requirements for the one time use preparation of an IV solution.

Dr. Ratcliff indicated that in this case, all recording requirements apply with exception to the manufacturer and lot number.

Ms. Herold provided that the board received one comment from a large hospital requesting that the board restart the regulation process. She stated that President Weisser has declined this request. Ms. Herold indicated that the board will reevaluate this at some point in the future.

Public Comment

Steve Gray, representing Kaiser Permanente, spoke in support of the request to the board to reevaluate the compounding regulations and encouraged the board to engage

the hospitals in this process. Dr. Gray also discussed that there has been confusion expressed regarding the intent behind the requirement that the lot number be recorded on two separate records.

Chair Kajioka stated that he has also received comments regarding this recording requirement. He suggested that this requirement be evaluated in the future.

Mr. Badlani provided comment on available software that maintains individual drug lot numbers and compounding logs. He indicated that not all facilities have implemented this software.

Dr. Gray discussed the marketing of kits in typical outpatient pharmacies for products such as mouthwash. He stated that there is confusion as to whether this is considered compounding.

Dr. Ratcliff requested that Dr. Gray provide an example of these kits.

Ms. Herold discussed the large number of recalls at the pharmacy level and the impact this has on the ability of the supply chain, wholesalers, and pharmacies to locate products without the tracking of lot numbers.

Chair Kajioka provided that the board will continue to field questions as they are submitted.

#### **4. Review and Discussion of Enforcement Statistics and Performance Standards of the Board**

##### Discussion

Ms. Herold provided corrected enforcement statistics to the committee and the members of the public in attendance to replace the information provided in the meeting materials. (A copy of this document is attached, following this meeting summary.)

Ms. Herold reviewed the enforcement statistics for the 2010/2011 fiscal year. She emphasized that the number of cases at the Attorney General's (AG) Office, currently 516 cases, continues to remain high.

Mr. Room indicated that all of the AG's 40 client agencies have seen a significant increase in the number of cases that are referred to the AG's office without an increase in the number of deputy attorney generals to prosecute these cases.

Ms. Herold advised that the Office of Administrative Hearings is behind in scheduling cases.

### Public Comment

Dr. Gray asked whether the board will continue to provide statistics regarding the category of cases as it has in the past. He discussed that this information is used to educate pharmacy students.

Ms. Herold indicated that a report will be provided to the board at an upcoming board meeting.

Ms. Sodergren indicated that the board's annual report to the Legislature also provides information compiled by the department regarding case categories.

Dr. Gray asked when the next edition of the *Script* will be released.

Ms. Herold indicated that the next edition is still pending review.

Dr. Gray provided comment regarding licensees who have a criminal conviction but are still licensed by the board.

Mr. Room discussed the active caseload in this area and the role of the board's Criminal Conviction Unit. He advised that there is often a six month delay between the time of a conviction and when the board is notified. Mr. Room suggested that employers file a complaint with the board when they learn of the arrest of a licensee.

Dr. Gray provided that consumer groups have been asking whether the board is moving forward with enforcement action with respect to patient consultation.

Ms. Herold provided that failure to provide consultation will result in a citation and fine. She indicated that the president's message in the *Script* will speak to this issue.

Mr. Room provided that consultation is also part of inspection by the board.

### **5. Public Comment for Items Not on the Agenda**

No public comment was provided.

The meeting was adjourned at 12:32 p.m.

# **Attachment 5**

# Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; FDA Public Workshop Summary

***THIS IS A SUMMARY OF MAIN COMMENTS SHARED BY PUBLIC WORKSHOP PARTICIPANTS. IT IS NOT COMPREHENSIVE BUT REFLECTS THE RECURRING THEMES HEARD. THIS SUMMARY SHOULD NOT BE INTERPRETED AS A FINAL DECISION OR POSITION OF THE FDA.***

## OVERVIEW OF THE PUBLIC WORKSHOP

The Track and Trace Public Workshop took place on February 15-16, 2011. Approximately 120 participants attended, representing a broad mix of stakeholders and perspectives. The Public Workshop took a dynamic and innovative approach to gathering public input in two aspects: content-sharing and discussion sessions.

The workshop began with an overview of system goals, potential attributes, and a review of track and trace concepts and terminology by FDA staff. Virginia Herold, Executive Director of the California State Board of Pharmacy, described California's e-Pedigree requirements. Discussion sessions followed the presentations and were carried out as round-table discussions of 7-9 participants, guided by a moderator. Each table consisted of a variety of supply chain stakeholders (i.e. manufacturers, distributors, pharmacies, solution providers, etc.) so that multiple perspectives were represented at each table. Each table individually discussed three topics: Interoperability, Authentication, and Data Management, and then shared comments with the entire group of workshop participants. A final discussion topic, "Workshop Outputs", gave participants an opportunity to summarize their individual perspectives and comment on system implementation.

## OVERARCHING THEMES – WHAT FDA HEARD

Over the course of two days and four discussion sessions, a number of recurring themes arose. These messages were prevalent throughout the sessions and were not necessarily associated with a particular sector of the supply chain.

### 1. FDA should focus on developing the functional requirements of the track and trace system

Overall, workshop participants were pleased that FDA shared system goals and potential system attributes as it enabled the opportunity to react to the agency's current considerations. Participants in general wanted FDA to focus on clearly defining the functional requirements of a track and trace system, including specifics requirements for data to be captured and how to authenticate packages. Participants in general did not believe that FDA should determine how the industry would meet these requirements, suggesting that this should be addressed through private sector solutions.

### 2. FDA has the opportunity to take a leadership role in standards development and implementation

Participants expressed that leadership and involvement from FDA would be beneficial in a number of areas:

- **Harmonization of track and trace standards:** Harmonization domestically would overcome any difficulties posed by the varying state requirements. Also international harmonization would help to support the global market.
- **Product scope:** Participants would look to FDA to determine the scope of products to be included in a track and trace system. Several participants suggested a risk-based approach for determining which products should be included. Some suggested that certain products (such as blood product and medical gases) be considered for exclusion from a track and trace system or whether existing practices for those products are adequate..

- **Participant validation:** Current challenges due to different levels of regulation and licensing could be avoided if a single regulatory body performed participant validation. Some participants suggested the Drug Enforcement Administration (DEA) model.<sup>1</sup>

### 3. Explain the Public Health and Public Policy Case for Track and Trace

Many participants expressed the need to better understand the public health and public policy justification and benefits of using a track and trace system, to bring about change within their companies, their plants, and their leadership. Participants suggested a variety of ways in which the public health benefits of a track and trace system might be communicated or demonstrated, including anecdotal case studies, pilots, and alignment with international efforts. Many participants felt that more data were needed to support the public health benefits, and expected the FDA to drive the development of such data.

### 4. Incentivize adoption

Many of the participants acknowledged the effort and investment it would cost organizations to implement track and trace systems. Absent a requirement to implement track and trace, many questioned whether their organization would implement track and trace initiatives. While some participants understand that some financial and brand protection benefit would be realized (e.g. potential theft reduction, inventory optimization, recall management), many felt the return on investment was low. In order to balance this, participants wanted to explore ways to manage these costs.

To expedite adoption, some approaches suggested include:

- Impose penalties for those who were non-compliant;
- Link reimbursement/payment, from Medicare and/or Medicaid for example, with authentication of packages (Some pharmacy participants expressed concern with this approach as it could further reduce pharmacy margins.); and
- Fund through public or consortium-based private groups to support pilots and/or rollout measures

In addition, participants acknowledged that once some stakeholders adopted track and trace initiatives, these actions may incentivize other stakeholders to also move towards adoption.

### 5. Need for timely action

Participants sought timely guidance from FDA to establish national standards for track and trace prior to the requirements to comply with California's legislation in 2015. While recognizing that implementation would likely take several years, participants urged FDA to act quickly to set initial guidance so that companies can avoid duplicating existing systems efforts or avoid investing in systems that may become obsolete.

## DISCUSSION TOPICS – HIGHLIGHTS

### *INTEROPERABILITY*

#### **Use and build upon current standards**

Many participants highlighted GS1 standards in existing systems, both domestically and in several European countries. Some participants suggested that Health Industry Business Communications Council (HIBCC) and other standards be considered before determining a single standard. Some representing medical gas suppliers and blood centers questioned whether they would be obligated to change the current standards used for their products.

#### **Interoperability will provide the basis of the authentication and validation of packages**

Interoperability would make it easier to create compatible systems across geographies, product lines, and/or technologies.

**Methods to ensure interoperability compliance**

Fines for lack of compliance were suggested to incentivize interoperability. Many voiced concern about the potential impact on business operations and movement of drugs if delays occurred due to the authentication and track and trace system processing. Some participants noted that interoperability in other industries has been achieved through government regulations.

**Impact on small businesses**

Due to the potential cost and implementation burden, some participants from smaller entities wanted to explore solutions for leveraging a larger entity's system or solutions whereby small entities could benefit if all participants were part of a larger system.

**Defining standard operating procedures for exceptions handling**

Some participants noted that defining standard operating procedures would help to ensure that all participants who observe the same events use the same procedures. (Examples of events include: what to do when authentication fails, how to dispose of packages deemed 'suspicious', what type of reporting and alerts would be completed if a package was flagged.) Some participants also proposed an "exceptions-based" system, which would treat flagged suspicious packages as the exception. In this system, data for all products would still be collected, but detailed information about the distribution history would only be queried for those exceptions under investigation, to minimize cost and transactions.

**AUTHENTICATION****Need for a specific definition of authentication and its requirements**

Authentication was defined for the purposes of this workshop as involving verifying that a standardized numerical identification (SNI)<sup>2</sup> is a valid number for the package with which it is associated and verifying that the package was sold, purchased, traded, delivered, handled, stored, brokered by, or otherwise transferred from legitimate supply chain participants, and confirming that there are no discrepancies in the distribution history. Participants expressed a desire for a more specific description of authentication, including more detailed information about how data transactions and databases would be utilized for these processes. Participants desired more clarity about what constitutes "authentication of the distribution history" and precisely where authentication would occur in the supply chain. The issue of who would be responsible if a product could not be authenticated (the sender, the recipient, or the system) was raised. Some participants suggested that authentication need not be performed at every step in the supply chain. Others suggested that authentication be performed only on products with the greatest risk of being counterfeited (as determined by FDA or an industry consortium).

**Identification and validation of participants to be managed centrally**

Participants were concerned about how they would recognize and validate their trading partners. Since trading partners and other supply chain participants are currently regulated at various state and federal levels, some participants suggested FDA could play a role in developing a centralized registration database, similar to the DEA model. The database could be designed to merge existing records from current licensing/registration databases. Participants acknowledged that some of the trade associations and licensing boards may see this as a challenge to their function or authority. An alternative perspective raised by other participants explained that they had trusted relationships with their suppliers and those with whom they traded, and viewed the current relationship as self-policing. Therefore, in their view, validation of trading partners may not be necessary for a track and trace system.

### **Additional direction on inference, aggregation and exceptions handling**

The following topics were raised but not discussed in detail.

- **Inference**

Some participants stated that they rely on inference to efficiently process large amounts of inventory and distribute it. They believe it minimizes the risk of security breaches, by keeping the cases or pallets sealed.

- **Aggregation**

Aggregation, involving linking of SNIs of individual packages to a unique identifier at the case and/or pallet level, was viewed by some participants as one of the greatest costs for a manufacturer, due to the costs of optimizing the process and accounting for disruptions in the aggregation process (for example, caused by damaged data carriers or damaged packages).

- **Exceptions Handling**

Some participants expressed a need for explicit directions on standard operating procedures for handling authentication failures (examples: system or database failure, valid number but mismatched product information).

### **DATA MANAGEMENT**

#### **System design**

Participants expressed that having a clear set of system requirements was far more important than FDA determining the design of the information technology (IT) infrastructure itself. While the audience appreciated having models to which to react, many felt that the design of system architecture should be left to data systems experts, and many participants stated a solution provider would be able to design a system that would meet FDA requirements.

A **centralized system** was viewed as attractive for several reasons. While concerned about confidentiality, participants recognized the value of having all data in a single database for regulatory purposes and for easily enabling interoperability. However, the fear of a single point of failure overshadowed the interoperability and regulatory benefits for some. Additionally, some people felt a single entity providing this service would lead to monopolistic behavior. Several participants raised concerns that they would be uncomfortable not having a choice as to how and where their data is stored.

A **decentralized system** was viewed as a positive option by some participants because of the ability for each player to maintain their own data. However, there was concern that if a major participant database went down (e.g., a large distributor), its effects could be similar to that of a centralized system failure. Interoperability was also a concern given the number of individual databases that would need to be able to communicate.

Most participants seemed to respond well to a **semi-centralized system**. Participants stated that such a system introduced price and service competition while maintaining many benefits of the centralized model. Participants liked having an option to choose a service provider and felt that their current provider may be able to support this effort and create continuity for their company. A balance between easy accessibility by regulators and dispersed risk of failure would need to be accomplished. Participants came up with a variety of hybrid ideas for data management, which would need to be explored by IT architects and system designers once the system requirements were clear.

### **Pilot and rollout perspectives**

The idea of piloting a track and trace data management system was viewed positively by many participants. The idea to do a test-run prior to a full-rollout was generally viewed as useful to discover and fix major issues prior to nation-wide rollout. In addition, some felt that we might learn more about the public health benefits of a track and trace system from the data captured through pilots. Several ways were proposed to do a pilot, including:

#### Start with the basics and build in complexity over time

The model would start by requiring all supply chain participants to capture their own data only, and at a later date, supply chain participants would be required to upload other data related to movement and handling of the package. Then at a subsequent date, the supply chain would be required to authenticate the number. Workshop participants felt that this model would require similar upfront investment from all supply chain participants.

#### Start with a simple set of products and a select set of participants

This model would involve working with industry volunteers throughout the supply chain with a limited scope of products to test any data capture or sharing issues, before broadening to other products.

#### Start with a 'bookend' approach and phase in remaining players

The model proposed would not provide full visibility of the supply chain initially as it would start with manufacturers and pharmacies, and bring in distributors and logistics providers over time.

Participants felt that this model would simplify data management concerns by reducing the volume of data transactions.

A few participants advocated against having a pilot. These participants felt that proof-of-concept already exists in other countries, like Belgium and Italy, and felt that a pilot would only prolong real implementation.

### **Data visibility concerns**

Many participants were concerned with maintaining business confidentiality throughout the supply chain. Some participants did not think that even FDA itself needs full visibility into the supply chain in order to serve the purposes of investigation, recall, and auditing or other public health purposes. Once FDA defined what data it needs or wants to access itself, or to have supply chain participants access for these purposes, many participants felt that their database managers and solution providers could resolve how to protect the data to permit this access while maintaining confidentiality of business transactions, rather than having all of the data fully visible to everyone in the supply chain.

### **Additional definitions needed on product status, alerts, and recalls**

The participants expressed a desire for greater clarity on several aspects of data management. There were requests for anecdotal or case-study highlights on how alerts and recalls would function in a track and trace system. Other comments included:

#### Product status

The ability to have a 'live' field instead of static fields was considered useful, but questions were raised about how the field would be updated and by whom.

#### Alerts

The ability to flag SNIs based on batch number, date, or site produced was viewed as potentially helpful. Many suggested simple solutions, such as a coloring system in a pharmacy database (e.g. yellow for a product alert, black for a black label warning, etc).

#### Recalls

Having the capacity to facilitate recalls was seen as a considerable benefit. It was suggested that only manufacturers and FDA have access to this ability, given that the manufacturers handle their own recalls. However, more guidance was requested on how FDA would work with participants in recall situations.

### **Leadership in systems harmonization and participant needs**

Participants expressed the need for a single unified standard to avoid having to comply with different state systems or requirements, and the preference to have harmonization with international systems if possible. Many felt that only through an overarching entity (like FDA) could a single standardized system be supported by supply chain stakeholders.

## **WORKSHOP OUTPUT**

The topics discussed during the Workshop Output session were often continuations of earlier topics. Below is a summary of Workshop Output comments, including some that may also be mentioned in the above sections.

### **Ideas to ensure faster acceptance and implementation**

- Use and build on existing standards being used in other systems
- Set a specific timeline
- Link reimbursement with adoption
- Encourage compliance through a combination of incentives and penalties
- Build consensus with foreign regulators
- Build stronger public health case
- Jointly fund a pilot or establish an industry consortium to support phase-ins or pilots
- Build an industry consortium to encourage constant innovation and evaluation of system
- Develop business opportunities for smaller players that may experience negative impact
- Explore an “exceptions-based” system to minimize system demands for data transactions
- Create alignment and involvement with state boards of pharmacy
- Maintain momentum with future workshops/meetings

### **Reasonable timeframe and rollout**

Two comments were heard related to timeframe and rollout:

- the need to address timeframe prior to when California’s legislation is implemented in 2015
- interest in FDA leadership on requirements that would be the foundation of the system in order for companies to start adoption

Participants expressed differing views on how to determine the appropriate timeframe and develop a rollout plan. Some participants wanting a pilot felt comfortable with a shortened trial provided it was relatively successful and the major concerns were corrected prior to full roll-out. Time frames suggested for a pilot ranged from 6 months to 3 years.

With regards to full-scale rollout, several people referenced European programs that had run for many years prior to working smoothly. Others felt that with a good pilot and the use of clear standards, it could require less time to perfect (e.g. 2-5 years). Participants reflected on the individual challenges specific to their role in the supply chain, such as taking a line off of production to install serialization technology (manufacturing) or re-designing the sorting process (distribution).

Some participants thought a pilot was unnecessary and argued that proof-of-concept already exists. Some people thought it might take significantly longer to have a full system up and running given the complexity of these databases and transactions (e.g. upwards of 10 years).

### **Common concerns**

The workshop also served as an opportunity for participants to express their other concerns (in no particular order) about:

- Costs to, and resources needed by, companies to establish a track and trace system
- Ensuring that all supply chain participants fully implement a track and trace system
- Ensuring the ability to incorporate future needs
- Loss of company efficiency during initial implementation
- Ensuring security of system data
- Ensuring reliability and accuracy of the system
- Ability of the system to solve some issues with counterfeits, rogue pharmacies and Internet operations

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<sup>1</sup> The DEA model requires that all parties handling a controlled substance register with the DEA. Upon registration they receive a license to handle controlled substances. This license can be revoked at any time by the DEA. This system helps track participants involved in these systems.

<sup>2</sup> The SNI has been described in FDA Guidance for Industry: Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages (2010). Available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM206075.pdf>



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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
EDMUND G. BROWN, JR., GOVERNOR

April 15, 2011

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: COMMENTS OF THE CALIFORNIA STATE BOARD OF PHARMACY  
**Docket No. FDA-2010-N-0633**  
*Determination of System Attributes for the Tracking and Tracing of Prescription Drugs*

To Whom It May Concern:

I write on behalf of the California State Board of Pharmacy (Board). We are pleased to have this opportunity to respond to the Request for Comments made in Docket No. FDA-2010-N-0633, titled "Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; Public Workshop." As you know, our Executive Officer, Virginia Herold, participated in the public workshop on February 15 and 16, 2011. We offer these written comments to reinforce and supplement some of the themes of Ms. Herold's presentation. We continue to encourage and support expeditious action by the FDA in this vital standards-setting endeavor.<sup>1</sup>

Over the last several years, California and this Board have taken a leading role in setting standards for securing the prescription drug supply through deployment of our pedigree law(s). Inspired in part by a vision of a universal electronic pedigree/track-and-trace infrastructure laid out in FDA Counterfeit Drug Task Force reports in 2003, 2004, 2005, and 2006, between 2003 and 2008 the Board worked with the California Legislature to enact and amend California law(s) requiring adoption of such an infrastructure. The most recent amendments to the law(s), in 2008, were the outcome of careful and protracted legislative negotiations involving many stakeholders. Our legislative record includes statements of support from many of the most important players in all segments of the industry, reflecting a rough consensus that the California approach is the best way forward. As you are aware, the basic elements of the California approach call for staggered implementation between 2015 and 2017 of a pedigree/track-and-trace infrastructure including:

- An electronic pedigree record showing each change in ownership, from original manufacturer (and/or subsequent repackager), through all drug distributor(s), to final dispenser/furnisher/administerer(s) of the dangerous drug;
- Exchanged in an interoperable electronic system incorporating track and trace infrastructure, based on a unique identifier established at point of manufacture;
- That tracks the smallest package or immediate container (saleable unit); and
- That is universally passed and authenticated by all supply chain participants.

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<sup>1</sup> We have been actively engaged with the FDA in this endeavor for some time. Among other things, we previously submitted written comments on FDA Docket Nos. FDA-2008-N-0120, FDA-2008-N-0121, and FDA-2009-D-001.

In our view, deployment of such an infrastructure promises significant benefits. It was originally designed to prevent or diminish introduction of counterfeit, misbranded, or adulterated drugs into the secure supply chain. It clearly serves this purpose, while also providing tools for investigation and enforcement of any such intrusions, promoting accountability. Counterfeiting remains a real and potentially growing threat to the security of our drug supply.<sup>2</sup>

A universal electronic pedigree/track-and-trace infrastructure also has great potential to address other significant threats to our drug supply. For instance, our experience in California with the Heparin recall(s) in 2008, and with more recent drug and device recalls, has convinced us that there are large gaps and deficiencies in our nation's current recall practices. Problems include the sheer number of recalls that are initiated each year, resulting confusion over whether any recall notice that is received is new or duplicate information, confusion and debate over the "voluntary" nature of most recalls, and the fact that recalls are initiated by the manufacturer(s) using lot number, whereas the rest of the supply chain does not track or invoice by lot number. As the Heparin example demonstrated, it is unlikely that most recalls result in the desired effect of removing all doses of a drug (or a given lot of a drug) from the market. Universal electronic pedigree/track-and-trace infrastructure could vastly improve the operation, specificity, reliability and accountability of recall processes. Recalls could be targeted, and their accuracy tracked.

Likewise, the historical problem of "shrinkage" and loss of inventory control via theft and/or diversion seems to be growing dramatically in scale, as more and more drugs disappear on a daily basis for resale and/or are taken in large cargo thefts or warehouse burglaries.<sup>3</sup> There is very likely growing involvement by organized crime in theft and resale of pharmaceuticals. The obvious motivators include lesser exposure to criminal penalties and a ready market for resale of those drugs into the supply chain. A universal electronic pedigree/track-and-trace infrastructure could significantly diminish if not eliminate the market for stolen and diverted products, since a stolen or diverted drug would not have the requisite electronic documentation for such resale.

Because of California's size and share of the market for prescription drugs, the California model for a universal electronic pedigree/track-and-trace infrastructure has been driving industry action for the last several years. All segments of the supply chain appear to be actively preparing for the negotiated 2015-2017 deadlines in California law. We believe in that model, and will be ready to enforce its provisions should it become necessary to do so. We are excited about what it will mean for the supply chain to have full compliance with the infrastructure requirements. We fully expect a more dynamic, secure, and accountable supply chain to be the result.

We also know, however, that to be most effective the universal electronic pedigree/track-and-trace infrastructure ought to be deployed and enforced at the federal level.<sup>4</sup> We are therefore pleased to see that the FDA is making real strides toward this goal. We are doubly pleased to see so many commonalities between the California model and the "System Attributes" distributed by the FDA for discussion in the public workshop. We hope you will continue to

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<sup>2</sup> See, e.g., Dr. Sanjay Gupta's report on counterfeit prescription drugs for "60 Minutes," aired March 13, 2011.

<sup>3</sup> See, e.g., Katherine Eban, "Drug Theft Goes Big," *Fortune*, March 31, 2011.

<sup>4</sup> The 2008 amendment(s) to the California pedigree law(s) also contemplated federal action in this arena, providing that any enactment of federal statutes or regulations addressing pedigree or serialization of drugs would render the California law(s) inoperative, and that any provision inconsistent with subsequent FDA rulemaking is likewise void.

look to California for an effective model, and one for which the industry is already actively preparing.

In conclusion, we commend the FDA for taking action to define system attributes for the necessary universal electronic pedigree/track-and-trace infrastructure. We hope those attributes will continue to take their cues from California, and that the FDA will assist in developing any necessary legislation and/or regulations to require unit-level tracking/e-pedigree transmission at the federal level. The Board looks forward to continuing its historical cooperation with the FDA as it continues its work in this area. The Board is hopeful that the FDA can move very quickly to establish national standards, as the FDA has indicated is its intent.

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

Sincerely,

STANLEY C. WEISSER, R.Ph.  
President, California State Board of Pharmacy

# **Attachment 6**

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# Report to the Legislature

## Recommendations for Home-Generated Pharmaceutical Collection Programs in California



California Department of Resources Recycling and Recovery

**December 2010**

This report can be found on the Internet at:  
[www.calrecycle.ca.gov/Publications/General/2011008.pdf](http://www.calrecycle.ca.gov/Publications/General/2011008.pdf)

Publication # DRRR-2011-008

For more information, contact the CalRecycle Publications Clearinghouse at:  
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# Executive Summary

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Pharmaceutical wastes are a societal problem because they show up in the environment, particularly in our precious waterways, and because some are “controlled substances” that can be illegally diverted and abused. Accidental prescription overdoses, teen and adult abuse of prescription drugs, along with impacts to surface waters and groundwater when drugs are flushed down the toilet, all highlight the need for safe pharmaceutical waste collection programs.

Enacted in 2007, Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) addresses improper disposal of pharmaceutical waste. In addition to tasking the California Department of Resources Recycling and Recovery (CalRecycle) with establishing criteria and procedures for model pharmaceutical collection programs, the department was also charged with preparing this report. The report evaluates California’s current pharmaceutical waste collection programs and provides recommendations to the Legislature for the potential implementation of a statewide program and statutory changes.

Based on the analysis described in detail in this report, CalRecycle recommends that the Legislature adopt a combination of two options related to pharmaceutical waste collection programs: 1) statutory changes to establish clear state roles and responsibilities, provide direction to resolve several implementation challenges, and direct that the [\*Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs\*](#)<sup>1</sup> (Model Guidelines) be refined and converted into regulations; and 2) statutory direction to address funding barriers by providing financing through a private sector approach with government oversight, commonly referred to as product stewardship.

SB 966 was a major step forward in development of a consistent approach to handle home-generated pharmaceutical wastes. The law directed CalRecycle, working with several other state, local, and federal agencies, to: 1) establish criteria and procedures for model collection programs for home-generated pharmaceutical waste; 2) evaluate the model programs for efficacy, safety, statewide accessibility, and cost-effectiveness; 3) consider the incidence, if any, of diversion of drugs for unlawful sale and use; and 4) provide the Legislature with recommendations for statutory changes and the potential implementation of a statewide program.

After numerous meetings with state agencies and stakeholders, in February 2009 CalRecycle adopted voluntary Model Guidelines. CalRecycle then surveyed collection programs around the state, some of which were in existence prior to this time, to see whether they met the voluntary Model Guidelines, and conducted additional stakeholder meetings and a workshop in 2010 to discuss survey findings and potential options.

CalRecycle found that only about one-third of existing programs in California meet the voluntary Model Guidelines. Of the major types of programs (law enforcement collection, pharmacy collection, household hazardous waste collection, periodic collection “events,” and mail-back programs), each has advantages and barriers in being able to meet the voluntary Model Guidelines. For example, law enforcement programs can readily meet requirements for collecting controlled substances, but the public may not be willing to bring pharmaceutical wastes to police stations. Further, law enforcement agencies themselves have higher resource allocation priorities. Pharmacies are widespread and accessible, but they typically do not meet all of the safety protocols (e.g., regarding collection bins and security) delineated in the voluntary Model Guidelines. Household Hazardous Waste facilities also face similar issues as pharmacies, particularly relative to safety, and are dependent on local government funding support. Periodic collection

events are somewhat easier to implement for local governments and can accommodate large amounts of materials in a short time, but are not as cost-effective as continuous collection programs, often do not have safety protocols, and are subject to local government budgetary constraints. Mail-back programs can be convenient and safety is not a major concern, but there are only three such programs in the state and a high return rate is necessary for the method to be cost-effective.

Several key barriers have made the voluntary Model Guidelines difficult to meet:

- Federal law. The federal Controlled Substances Act requires strict protocols for the collection of controlled substances to prevent their illegal diversion and abuse. Although controlled substances represent only about 10 percent of home-generated pharmaceutical wastes, the requirements for their safe management (e.g., requiring only law enforcement officials to handle them) means most collection programs are costly. CalRecycle is not aware of similar requirements in other countries with pharmaceutical collection programs. The Controlled Substances Act has been amended by the *Secure and Responsible Drug Disposal Act of 2010* (United States Senate, S. 3397, 111th Congress), which should make it easier to collect controlled substances once implementing regulations are promulgated.
- California’s complicated statutory and regulatory framework. There is no clear statutory definition of home-generated pharmaceutical wastes, nor is there an identified agency or department that has sole or ultimate authority for home-generated pharmaceutical waste collection, consolidation, management, and disposal. Instead, the federal Drug Enforcement Administration and several California state agencies (Department of Public Health, Board of Pharmacy, and Department of Toxic Substances Control) exercise varying degrees of authority or policies, making it challenging for local jurisdictions to develop and maintain effective collection and management programs they know conform to legal requirements. These conflicting authorities and policies are manifested in the Model Guidelines in the form of safety requirements included to satisfy differing agency requirements and policies but are costly to implement and caused some stakeholders to feel they were unnecessary (e.g., two-key locking collection bins in pharmacies, use of secure containers at household hazardous waste sites, and registered haulers).
- Lack of funding. Based on survey results, CalRecycle found that local governments currently fund more than 80 percent of collection programs and pharmacies fund another 15 percent. CalRecycle is not aware of funding support from pharmaceutical manufacturers for collection programs in California; this contrasts significantly with the level of private sector funding in Canada and several European countries.

Based on these findings and to meet the key tenets of SB 966, in particular to provide convenient collection opportunities for home-generated pharmaceuticals wastes, CalRecycle considered four options, which are described in detail in Section V. CalRecycle recommends the Legislature adopt a combination of two options:

- “Establish Clear State Agency Roles and Responsibilities, Improve Model Guidelines and Enforcement, and Convert Guidelines to Regulation” (Option 2) and
- “Implement Product Stewardship” (Option 3)

Option 2 would entail statutory changes to establish clear state roles and responsibilities, provide direction to resolve several implementation challenges, and direct that the Model Guidelines be refined and converted into state regulations. Option 3 would address the key funding barrier by providing program

financing through a private sector approach with government oversight, commonly referred to as product stewardship. Manufacturers or drug brand owners would design, manage, and finance a statewide program, while state government would oversee program implementation and enforcement.

Implementing these two options, each of which is described in detail in Section V, would address key barriers and provide for a sustainable system of collection programs by:

- Providing clear state agency roles and responsibilities;
- Clearly defining home-generated pharmaceutical wastes, consolidated home-generated pharmaceutical wastes, and acceptable management practices;
- Supporting safe collection, transport and management of home-generated pharmaceuticals;
- Offering flexibility and allowing multiple types of collection systems;
- Providing sustainable program funding; and
- Encouraging cost-efficiency

Since regulating controlled substances is under federal authority, fully instituting these two options to allow for cost-effective collection programs will not be totally feasible until regulations are in place to implement the newly signed [\*Secure and Responsible Drug Disposal Act of 2010\*](#). In addition, these two options would likely take at least a few years to implement (i.e., to enact state legislation and develop the required regulations and stewardship program), yet unwanted drugs need to be removed from households now. For this reason, the Legislature may also wish to consider that in the short-term, public safety may be best served by encouraging landfill disposal options in communities where no other options currently exist. For example, Option 1 (i.e., promote use of the California Model Guidelines for existing collection programs and use of the federal guidelines regarding proper disposal where collection programs do not exist) could be implemented as a short-term solution, while efforts to implement Options 2 and 3 proceed. While this option would not address existing statutory and regulatory barriers or address the lack of funding for sustainable collection programs, as an interim measure it would provide for convenient, low-cost disposal, would not require new legislation, and would support some key tenets of SB 966.

# 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, which 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 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 (DTSC), the State Water Resources Control Board (SWRCB), and the California State Board of Pharmacy (CBOP), and considered stakeholder input to develop criteria and procedures for model pharmaceutical waste collection programs. CalRecycle adopted Model Guidelines in November 2008, with a subsequent revision in February 2009. Programs are not required to follow these Model Guidelines but they must be consistent with them in order to be considered 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 report presents the results of these surveys.

3. Report to the Legislature, by December 2010

As required by SB 966, CalRecycle prepared this report to 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 Legislative Report

The main purpose of this report is to offer recommendations to the Legislature on options for implementing a statewide collection program for home-generated pharmaceuticals, as directed in SB 966 (Public Resources Code Sections 47120 Et Seq.).

To develop recommendations, CalRecycle reviewed laws and policies that impact collection programs, analyzed collection programs elsewhere in the world and in other states, evaluated collection programs in California, in particular those that are consistent with the Model Guidelines, and considered comments from stakeholders and affected parties after this information was presented in a July 20, 2010 workshop.

This report includes the following sections:

- **Overview of Programs Outside of California (Section II):** Covers a range of programs in other countries and states;
- **Challenges and Barriers (Section III):** Outlines some of the challenges to program implementation;
- **Program Surveys and Results (Section IV):** Identifies the types and number of home-generated pharmaceutical waste collection programs in California, the number that meet the Model 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); and
- **Potential Options and Recommendations for Further State Action (Section V):** Discusses potential options for state action along with recommendations.

Several topics not within the direct scope of this analysis but related to the topic are listed below. While some topics are discussed when necessary as they relate to the collection programs, the report does not discuss all topics in detail:

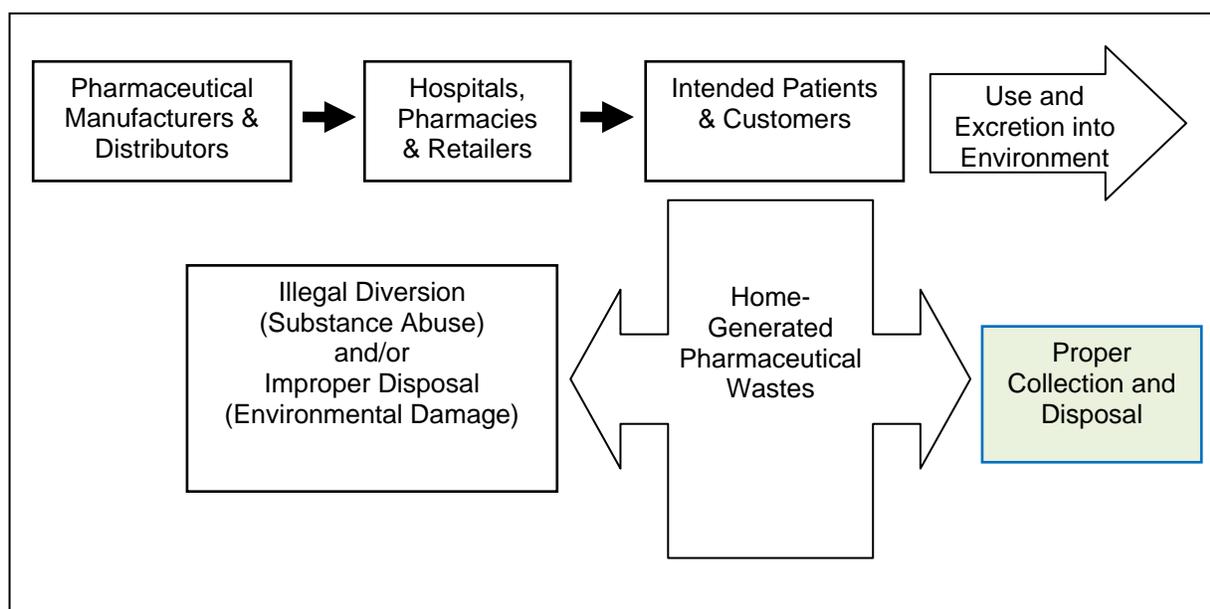
- Excretion. While human excretion is a major pathway for pharmaceuticals to reach the environment, it is a separate problem from unused pharmaceuticals that become home-generated waste. The latter issue, home-generated waste, is the focus of this report.
- Drug Distribution Solutions. While fewer prescriptions, 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 waste.
- 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 waste. In addition, several concerns exist regarding applying this concept to home-generated wastes.\*

Figure 1 shows a simplified view of the flow of pharmaceuticals, including both prescription medications and non-prescription (over-the-counter) medications.

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\* 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 and may not have sufficient safety standards to prevent illegal drug diversion.

**Figure 1. Simplified Flow of Pharmaceuticals**



This report 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 report 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).

### **3. Home-Generated Pharmaceuticals in California**

Based on information available to CalRecycle, collection programs in California collect approximately 200,000 pounds of home-generated pharmaceutical waste per year. These collection programs appear to be quite safe with very low illegal diversion. Out of 256 collection sites or programs representing 86 percent of all known programs operating in California, a CalRecycle survey found that in the past 15 years there were no reported signs of illegal drug diversion (see Section III, *1. High Cost of Safe Collection*).

However, these programs likely collect a small percentage of all home-generated pharmaceutical waste, although there is not a definitive estimate of the amount of home-generated pharmaceutical waste in the state. 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.<sup>2</sup>
- The Associated Press estimated that Americans generate at least 250 million pounds of pharmaceuticals and contaminated packaging in medical facilities each year.<sup>3</sup> Relative to California population, that would be approximately 30 million pounds in California hospitals alone.

- Some estimates suggest that 10 percent to 33 percent of all pharmaceuticals go unused.<sup>4</sup> There is not universal agreement on these percentages, with some studies reporting as little as 3 percent unused while others report that 50 percent or more are unused.<sup>5</sup>
- In addition, the number of prescriptions per 100 people has increased between 1995 and 2008 from 0.8 to 1.2 nationwide.<sup>6</sup> Considering our aging population, this trend is likely to continue.

Meanwhile, there is growing concern about illegal diversion of pharmaceuticals from homes. Collection programs provide a safe, legal, and environmentally preferable means to managing unwanted drugs from residences where they can be abused. This is a driving force for establishing home-generated pharmaceutical collection programs.

## ***4. Current Status of Regulations, Statutes and Policy***

In California, current statutory and regulatory authority to govern collection and disposal of home-generated pharmaceutical waste is divided amongst several state and federal entities. This division leads to confusing roles, responsibilities and program requirements, and is an underlying issue that challenges collection program administrators. For example:

- The U.S. Drug Enforcement Administration (DEA) governs the collection and disposal of controlled substances, a subset of home-generated pharmaceuticals, which requires law enforcement to oversee these activities;
- The California Board of Pharmacy (CBOP) licenses pharmacies, but currently does not explicitly authorize pharmacies to accept the return of home-generated pharmaceuticals, yet it supports Model Guidelines that allow collection following certain practices;
- The California Department of Toxic Substances Control (DTSC) regulates hazardous waste, which may include some pharmaceutical waste, while exempting home-generated pharmaceutical waste from classification as hazardous waste;
- The California Department of Public Health (CDPH), through the Medical Waste Management Act (MWMA), regulates collection and disposal of medical waste in California. However, it does not have statutory authority to regulate collection and disposal of home-generated pharmaceutical waste, which is excluded from the definition of medical waste. Instead, it applies a best management policy for collecting this waste. CDPH interprets this policy as follows: if home-generated pharmaceutical waste is consolidated with other home-generated pharmaceutical waste from different residences or is handled by a third party, then it is no longer considered home-generated but rather consolidated medical waste and the MWMA regulations apply, requiring the waste to be handled as medical waste.

Many stakeholders identified possible alternatives for revising the current statutes, regulations and policies to address confusion about roles and responsibilities and facilitate new take-back programs. These are explored in Appendix A: *Recommended Stakeholder Changes to Legislation, Regulations and Policies*, which contains a matrix of the current statutes, regulations and policies overseeing management of home-generated pharmaceuticals. It should be noted there is no consensus among stakeholders on roles and responsibilities and without clear legislative direction and state agency authority over certain tasks, confusion will continue.

## II. Overview of Programs Outside of California

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Other countries and states face similar challenges with managing unwanted pharmaceuticals. CalRecycle found examples of pharmaceutical collection programs in a number of other countries and states and analyzed them for their approach, costs, and effectiveness, where information was available.

Below are several programs that stand out for reasons noted. Much of the information on programs outside of the United States comes from the Health Canada report, [Pharmaceutical Disposal Programs for the Public: A Canadian Perspective](#),<sup>7</sup> which serves as a reference for readers seeking more detailed information.

Basic information about many of these international and state programs is captured in the table in Appendix B: [Overview of Pharmaceutical Collection Programs Outside of California](#).<sup>8</sup> While the descriptions below include cost information as it is reported, cost comparisons should not be used to draw firm conclusions about programs because data may compare different program attributes. This is a common problem that arises when comparing programs, especially across countries. CalRecycle still included the information as it is the best information available to suggest expected costs and encourage efforts to establish common metrics.

CalRecycle observed some common themes among the programs researched. All programs reviewed seek to provide a secure system for pharmaceuticals and programs in other countries use pharmacies as collection points. 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). This means that outside of the United States, pharmacies can serve as convenient consumer drop-off locations for all types of pharmaceuticals. This may change once regulations are promulgated as part of the recently passed *Secure and Responsible Drug Disposal Act of 2010*, (also see Section II, 2. *National Programs*, Federal Legislation and Regulations below). 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 nonprofit, state-run pharmacies. Additionally, Australia has a primarily government-funded program.

When the private sector funds and manages collection and safe disposal of drugs, such a program is referred to as a product stewardship program. Product stewardship programs offer a private sector approach to waste management. Appendix B offers cost information on various pharmaceutical programs and this preliminary information suggests a generally 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.

### 1. International Guidelines and Programs

#### WORLD HEALTH ORGANIZATION

- The **World Health Organization**<sup>9</sup> issues guidelines for pharmaceuticals management during 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.<sup>10</sup> Immobilization refers to either encapsulation or inertization (removing the packaging materials from the pharmaceuticals, grinding pharmaceuticals, and mixing them with water, cement, and lime).

## AUSTRALIA

- **Australia: Return Unwanted Medicines Project.** This national program allows consumers to return pharmaceuticals to any pharmacy across Australia. Most costs are covered by the Department of Health and Aging with limited support from the pharmaceutical industry. Preliminary information on costs per capita suggest the project is on par with other international programs, however it has a fairly low per capita collection rate in comparison. This program collects and makes available information on commonly returned medicines, reasons for return, and conducts targeted education campaigns. Consumers do not have to distinguish which drugs are controlled substances because pharmacies accept all types and then pharmacies follow specific disposal instructions for controlled substances or “Schedule 8 medicines.” The protocols for pharmacies, which must use approved collection bins, are available online at [www.returnmed.com.au/](http://www.returnmed.com.au/).

## EUROPEAN UNION

The European Union Directive 2004/27/EC, Article 127b requires that, “Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.”<sup>†</sup> As a result, numerous programs exist and several have data available as indicated below.<sup>†</sup> Additionally, Article 54j of this same directive has labeling requirements so information about collection programs appears on pharmaceutical packaging.

- **France: Cyclamed Program.** This national program allows consumers to return pharmaceuticals to local pharmacies for safe disposal. The program is funded and managed by the private sector (industry, pharmacies, and wholesalers). It stands out for having relatively high per capita collection and participation rates as noted in Appendix B. Also, the amount of pharmaceuticals collected, reported in terms of with and without packaging, indicates that it is very important to understand the extent to which 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. It is funded by members of pharmaceutical associations, including local pharmacies, manufacturers, distributors and chemical and pharmaceutical importers. This particular product stewardship program places an eco-fee of one cent on each package placed in the market. The program stands out as having a fairly high per capita collection as compared

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<sup>†</sup> The report, *Pharmaceuticals in the environment — Result of an EEA workshop, 2009* (available: [www.eea.europa.eu/publications/pharmaceuticals-in-the-environment-result-of-an-eea-workshop](http://www.eea.europa.eu/publications/pharmaceuticals-in-the-environment-result-of-an-eea-workshop)) includes a summary of European programs and says the return rate in Switzerland is very high, followed by Ireland, Luxembourg, Sweden, and France. However, the report does not provide specific information to include in this legislative report.

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. It is managed by SIGRE, a nonprofit funded by members of the pharmaceutical industry based on volume of sales. 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 and to what extent the collection metrics include packaging.
- **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, nonprofit retail pharmaceutical chain. The program stands out for being government managed and financed, and for having higher reported costs and higher 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

Health Canada reports on pharmaceutical programs in 13 provinces and territories. It specifically mentions four of these programs as achieving relatively high collection rates in either total amounts collected or on a per capita basis. These are noted below, along with the program in Ontario that started in July 2010, and offers some of the latest thinking on program design:

- **[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. 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. The program is managed by a stewardship organization called the Post Consumer Pharmaceutical Stewardship Association (PCPSA) and is funded by industry. 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.
- **[Nova Scotia Medication Disposal Program](#).** This province-wide program allows consumers to return pharmaceuticals to local pharmacies for safe disposal. The program is administered by the Pharmacy Association of Nova Scotia (PANS) and funded by industry. Pharmacies have the option of participation and, according to PANS, all choose to participate. Because the program is voluntary and does not have reporting requirements, minimal information is publicly available. However, Health Canada reports that it has a relatively high per capita collection as compared to other Canadian programs.
- **[Ontario Orange Drop Program](#).** This province-wide program covering 22 hazardous and special wastes, including household pharmaceuticals started in July 2010. New regulations defined the term “used consumer pharmaceuticals” to cover pharmaceuticals sold by retail establishments and returned by consumers. Only these pharmaceuticals can be returned to pharmacies. Pharmacies follow newly

created rules for used consumer pharmaceuticals that are less stringent than rules established for pharmaceuticals that are returned to suppliers in a reverse distribution process; the latter requiring complex tracking of ownership. Consumers push pharmaceutical waste into a one-way collection container at their local pharmacy. The waste is picked up on a regular schedule or upon request when the bin is full. The program has been administered by Stewardship Ontario and funded by industry; however, starting in fall 2010, the province will begin to provide funding to municipalities for management of this and several other programs. Ninety percent of pharmacies participate and accept unused/out-of-date pharmaceuticals from consumers. Additionally, the program holds hundreds of collection events for multiple products and uses household hazardous waste depots as collection sites. The program has established a baseline and targets initially call for collecting 47 percent of available pharmaceuticals, increasing to 74 percent in 5 years.<sup>12</sup>

- **[Saskatchewan Waste Disposal Program](#)**. This province-wide program allows consumers to return pharmaceuticals to participating local pharmacies for safe disposal. The program is managed by the Pharmacists' Association of Saskatchewan and funded by community pharmacies. This program is voluntary and does not have reporting requirements so minimal information is publicly available, but Health Canada reports that it has a relatively high per capita collection as compared to other Canadian programs.

## 2. National Programs

In addition to California laws and policies (see Section I, 4. *Current status of regulations, statutes, and policy*), there are several national efforts to address safe management of unwanted home-generated pharmaceuticals. These are found in federal policies, laws, and regulations, along with nationally-based efforts by nonprofits, including those identified below. As noted, there are no nationwide home-generated pharmaceutical waste collection programs in the United States; waste collection is a state and local managed program.

### FEDERAL GUIDELINES

- The **White House Office of National Drug Control Policy** issued in October 2009 new guidelines, *Proper Disposal of Prescription Drugs* (federal guidelines), to educate consumers about safe methods of pharmaceutical disposal.<sup>13</sup> These guidelines first recommend participating in take-back programs, if available. When that option does not exist, it is recommended that drugs be removed from original containers and mixed with undesirable substances (like coffee grounds or cat litter), and then sealed in an impermeable container before throwing the unused drugs in the trash.

These federal guidelines address the concern of removing unwanted pharmaceuticals from households to minimize drug abuse. When the policy is followed, unwanted pharmaceuticals are placed in containers and are undistinguishable from other containers in household trash, making it more difficult for someone to find and abuse them. Furthermore, disposal in household trash is convenient and removes pharmaceuticals from homes at no additional cost to consumers. Several states actively promote the federal guidelines in their programs and provide information to consumers about how to hide and disguise unwanted pharmaceuticals in household trash, when local collection programs are not available (see Section II, 3. *State Programs* below). Additionally, the U.S. Food and Drug Administration developed [educational materials for consumers](#) on these guidelines.<sup>14</sup>

By recommending disposal in household trash, the federal guidelines alleviate the concerns of improper disposal of pharmaceutical waste into sewer systems that results in pharmaceuticals entering waterways and drinking water. On the other hand, a main drawback with the federal guidelines is that pharmaceuticals can then be deposited in landfills where they may eventually be able to leach into ground and surface waters. However, CalRecycle received numerous comments about this issue and reports to date (several of which are funded by industry) indicate this is a minor impact (see Appendix C: *Overview of Reports on Pharmaceuticals in Landfill Leachate*).

## 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, it is subject to at least four national laws.

- The **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. Controlled substances must be collected by sworn law enforcement officers (pharmacies may only take back uncontrolled substances).

Program managers in California and in other states have viewed 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 collection programs at local pharmacies. Consumers often times do not know and cannot easily determine if a drug is a controlled substance. Finally, in some regions of California, local jurisdictions report that law enforcement has placed higher priority on other responsibilities and has been unwilling to participate in collection activities. Additionally, residents are not as familiar with, and in some cases are reluctant to visit, law enforcement locations.

- In October 2010, President Obama signed into law the **Secure and Responsible Drug Disposal Act of 2010** (United States Senate, S. 3397, 111th Congress). This law gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act, which will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. This law is intended to make it easier to collect and dispose of controlled substances while preventing illegal diversion of drugs. The process to develop new regulations could take a few years and, until that time, it is not completely known what the outcome will be. These new regulations are expected to impact collection programs in California since more program types could potentially begin collecting controlled substances.
- The **Resource Conservation and Recovery Act (RCRA)** governs the management of hazardous wastes at the federal and state levels, including some waste drugs. RCRA excludes from regulation pharmaceutical waste produced by individuals in their homes. States can choose to be more stringent, as California has (California Code of Regulations Title 22, Section 66261.101). However in this case, if a home-generated pharmaceutical is not a RCRA-regulated hazardous waste, it is not subject to California hazardous waste control laws. Thus, home-generated pharmaceutical waste is not regulated as hazardous waste in California unless it is comingled with other hazardous waste. This often occurs at household hazardous waste facilities where it is a general practice to comingle these wastes.

- **Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180)** determine how to classify and transport chemotherapeutic and some pharmaceutical wastes. However, household waste, which includes home-generated pharmaceutical waste, is excluded from these requirements and the HMR would apply only if home-generated pharmaceutical waste is comingled with hazardous waste.
- The **Health Insurance Portability and Accountability Act (HIPAA)** provides a federal floor of privacy protections for an individual's health information when that information is held by a covered entity or by a business associate of the covered entity. With respect to home-generated pharmaceuticals, HIPAA concerns are associated with patient information that may be contained on any packaging that is returned along with the waste.

## NATIONWIDE EFFORTS

- The **American Medicine Chest Challenge** is a nationwide take-back event that occurred on Nov. 13, 2010.<sup>15</sup>
- The **Drug Take-Back Network** provides a clearinghouse of information on pharmaceutical take-back programs across the United States covering national, state and local programs. More information is available at: [www.takebacknetwork.com](http://www.takebacknetwork.com)
- The **National Prescription Drug Take-Back Campaign** was coordinated by the DEA to remove potentially dangerous controlled substances from medicine cabinets across the nation. State and local law enforcement agencies collected more than 242,000 lbs of drugs from more than 4,000 sites in all 50 states at this first-ever nationwide program held Sept. 25, 2010.<sup>16</sup>
- The **U.S. Postal Service (USPS) Prescription Mail Back Pilot Program** is intended to provide an estimated 780,000 veterans in Baltimore, Md., Washington, D.C., and West Virginia the opportunity to safely dispose of expired and unused prescriptions and help the environment. The program is being administered by the USPS and the U.S. Department of Veterans Affairs and allows veterans to mail outdated, unwanted medicine to federally-approved facilities where it is safely destroyed. Veterans receive specially designed, postage-paid envelopes and instructions with their prescription fulfillment. Expired and unused pharmaceuticals placed in the special packaging can be dropped in familiar blue USPS collection boxes or at post offices. The envelopes are delivered to facilities regulated and approved by the U.S. Environmental Protection Agency (EPA) and DEA. Pharmaceuticals from this and other similar mail-back initiatives are destroyed in accordance with EPA and DEA standards, including cataloging and use of incineration, chemical or thermal processes.<sup>17</sup>
- The **Product Stewardship Institute (PSI)** works with stakeholders nationwide to develop product stewardship approaches for the end-of-life management for many difficult-to-manage unwanted/waste 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 unwanted/waste pharmaceuticals.<sup>18</sup>

### 3. State Programs

At this point, several states have undertaken pilot programs to test methods for collecting home-generated pharmaceuticals. Washington and Maine's pilot programs stand out, for example, for being complete and

provide fairly detailed information about costs and collections rates. Overall, among all pilot programs researched, there is 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
- Amendment to the Controlled Substances Act to allow for the collection of prescribed controlled substances at pharmacies.

In addition to pilot programs, some states promote the National Drug Control Policy (see “federal guidelines” in Section II, 2. *National Programs* above) and also allow home-generated pharmaceuticals to be incinerated at waste-to-energy facilities with other municipal solid waste.

Several state 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 have 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 federal, state and local government agencies (e.g., public health, water and environmental agencies), and pharmaceutical and nonprofit organizations.<sup>19</sup>
- **Florida:** The Florida Department of Environmental Protection promotes the National Drug Control Policy guidelines through educational materials. Brochures in English and Spanish inform Florida residents not to flush unused pharmaceuticals down the drain and explain how to dispose of unwanted pharmaceuticals in household trash. The state distributes information to consumers through pharmacies and through its website on medications management: [www.dep.state.fl.us/waste/categories/medications/default.htm](http://www.dep.state.fl.us/waste/categories/medications/default.htm). This website includes research papers, presentations and disposal guidelines. All household-generated pharmaceutical waste, including waste from collection programs, and pharmaceuticals that are evidence or confiscated by law enforcement, are allowed to be burned in Waste-to-Energy (WTE) facilities whether or not they would otherwise be hazardous waste. WTE permit conditions allow for pharmaceuticals to be burned so long as they do not exceed 3 percent of total throughput.<sup>20</sup>
- **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 a disposal facility. Funding was provided through Iowa Department of Natural Resources grants to the Iowa Board of Pharmacy, which 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).<sup>21, 22</sup>
- **Maine:** The Safe Medicine Disposal for ME Program is a statewide pilot program for the disposal of unused household medications using a mail-back return envelope system.<sup>23</sup> The program was

established through state legislation and implemented in 2007 with a \$150,000 grant from the EPA'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, the 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.<sup>24</sup> (Also see Appendix C)

- **Massachusetts:** The Massachusetts Department of Environmental Protection has a comprehensive program to study and monitor pharmaceuticals in state waters. Department personnel are working with related agencies and stakeholders to reduce the amount of medications going to wastewater treatment plants, and to keep the public informed about the issues. Additionally, Massachusetts also promotes National Drug Control Policy guidelines, calling for participation in local collection programs, and if none are available then disposing of pharmaceuticals in household trash using the federal guidelines. More information is available at: [www.mass.gov/dep/toxics/stypes/ppcpedc.htm](http://www.mass.gov/dep/toxics/stypes/ppcpedc.htm).<sup>25</sup>
- **New York:** The New York Drug Management and Disposal Act (2008) requires stores that sell pharmaceuticals, vitamins, supplements, and over-the-counter medications to display posters about how to properly dispose of drugs as part of the "Don't Flush Your Drugs" public awareness campaign. Instead of flushing medicines, households are encouraged to take advantage of community drug take-back programs that collect drugs at a central location for proper disposal. Collection event organizers must develop a collection plan, work with local law enforcement to secure the drugs at the collection event and obtain a variance, which allows the collected pharmaceuticals to be incinerated at waste-to-energy facilities within the state. Collection events to collect controlled substances must be approved by the New York State Department of Health, Bureau of Narcotic Enforcement. Households that are not able to take unwanted pharmaceuticals to collection events are advised to place their unused, unwanted, or expired drugs in the trash, taking care to destroy or disguise them to avoid misuse or misdirection with the suggestion of adding water, salt, ashes, or coffee grounds to unused medications before placing them in the trash. Detailed instructions and suggestions are available on the New York Department of Environmental Conservation website [www.dontflushyourdrugs.net](http://www.dontflushyourdrugs.net).<sup>26</sup>
- **Texas:** To help ensure unused pharmaceuticals do not enter a wastewater system, the Texas Commission on Environmental Quality is conducting a study and submitting recommendations to the Texas Legislature on the methods currently used in the state to safely handle and dispose of pharmaceuticals, medical sharps, and other potentially dangerous waste. The recommendations also suggest alternative methods used for that purpose, including the methods used in other states; and the effects of the various methods on public health and the environment. The report is due in December 2010.<sup>27</sup>
- **Washington:** To address the need for a safe way to dispose of unwanted medicines, excluding controlled substances, a coalition of government, nonprofit, and business partners began a 2006 Washington state pilot program called Pharmaceuticals from Households: A Return Mechanism (PH:ARM). The program took place 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.<sup>28</sup>
- 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 groups of states host collection events. For example, in Maryland, seven counties collect pharmaceuticals and a regional program is under way with the EPA and four states that focus on the Potomac River watershed.<sup>29</sup>

## **PROPOSED AND ENACTED STATE-LEVEL LEGISLATION**

Several states (Florida, Maine, Maryland, Minnesota, Oregon, Rhode Island, and Washington) have proposed product stewardship legislation for pharmaceuticals, but as of September 2010, none have passed as such. Minnesota enacted House File 1217 that enables various parties including licensed HHW facilities and county collection programs to have possession of prescription drugs for the purpose of disposal.

PSI tracks pharmaceutical take-back legislation and is a source for more current information. See: [www.productstewardship.us/](http://www.productstewardship.us/) (select: products, pharmaceuticals).

# III. Challenges and Barriers to Implementing a Model Collection Program in California

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CalRecycle worked closely with numerous agencies to develop the Model Guidelines<sup>30</sup> that were formally adopted by the department in November 2008, with a subsequent revision in February 2009. Agencies participating included the California Department of Public Health (CDPH), the Department of Toxic Substances Control (DTSC), the State Water Resources Control Board (SWRCB), and the California State Board of Pharmacy (CBOP), and as well as other stakeholders. The Model Guidelines contain criteria and procedures for model pharmaceutical waste collection programs by type of program. Programs are not required to follow the Model Guidelines but they must be consistent with them to be considered a “model program” under SB 966.

This section discusses the following five challenges and barriers common among California home-generated pharmaceutical collection programs:

1. High Cost of Safe Collection;
2. Lack of Public Awareness and Participation;
3. Lack of Sustainable Funding;
4. Lack of Goals; and
5. Complexity of Current Requirements, Policies and Authority.

Through survey information presented and discussed in Section IV, CalRecycle identified these challenges and barriers for current programs. The surveys focused on implementation of the Model Guidelines (see Appendix D: *Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs*) and for this reason, the explanations below reference the Model Guidelines.

## 1. High Cost of Safe Collection

Certain requirements in the Model Guidelines present unique challenges to some collection programs. Safety (security) issues are usually the primary reason why existing programs do not qualify as model programs. Meeting the requirements often 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 considerations are implemented (separate handling, weighing, and record keeping). Treating home-generated pharmaceutical waste as medical or hazardous waste either through transportation or disposal (e.g., incineration vs. hazardous waste landfills) can also be costly. 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 percent of all

drugs returned. Given that 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 Substances 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 (see Section II, 1. *International Guidelines and Programs*).

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 as may occur when regulations are promulgated as part of the recently passed S. 3397 (also see Section II, 2. *National Programs, Federal Legislation and Regulations*).

## **HAULING CONSOLIDATED WASTE**

If home-generated pharmaceutical waste is consolidated, CDPH considers it medical waste, which must be transported by a registered medical waste hauler. Transporting collected home-generated pharmaceutical waste using only haulers registered with CDPH may be more expensive than other options. At least nine pharmacies in the state used the larger cardboard “mail-back” boxes but this method does not use a registered waste hauler.

## **INCINERATION USED MORE THAN LANDFILLS**

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.

### **BUSINESSES**

Businesses tend to prefer the least expensive disposal option, which could be at in-state landfills. However, shipping home-generated pharmaceutical waste with existing larger volumes of medical or hazardous waste that are sent out of state for incineration may be more efficient than in-state landfill disposal. For instance, a relatively small amount of home-generated pharmaceutical waste could be sent in a small truck to an in-state hazardous waste landfill. However, that truck would be taken out of circulation from local hauling collection routes. In contrast, larger volumes of medical or hazardous waste are already sent out of state for incineration so combining all of these wastes may be less expensive overall.<sup>31</sup> Shipping pharmaceutical waste to landfills in California may also be more expensive depending upon the infrastructure of the company collecting the waste. Some companies haul waste and operate incinerators out of state and may find that their overall internal costs are lower to ship to their incinerator than to use an in-state landfill.<sup>32</sup>

## LAW ENFORCEMENT

If controlled substances are collected, they must be incinerated (i.e., “destruction”) according to federal law.<sup>‡</sup> California law enforcement agencies that collect controlled and/or non-controlled substances generally use two in-state waste-to-energy incinerators, which are permitted to accept this waste, but not medical waste, hazardous waste, or liquids.<sup>33</sup> Commercial medical or hazardous waste haulers that cannot use these in-state waste-to-energy incinerators for their medical or hazardous waste, also collect non-controlled substances at some law enforcement sites and send it out of state for incineration because of the lower internal costs.

## HHWs

Generally, HHW collection programs comingle home-generated pharmaceutical waste with other household hazardous wastes such as pesticides. The standard practice is for local governments to send out a Request for Proposals, select a commercial hauler with the winning bid, and the hauler usually chooses the disposal facility location. Because there are no known commercially-available medical waste or hazardous waste incinerators in California, the hazardous waste hauler generally ships it out of state for incineration.<sup>34,35</sup>

As described above, businesses, law enforcement and HHW programs may choose incineration more often because it allows controlled substances to be handled correctly and because the overall cost/benefits may be greater for incineration over in-state hazardous waste landfill disposal. In the future, if larger collection volumes could be managed at in-state disposal facilities, cost efficiencies could improve.

## TWO-KEY LOCKING COLLECTION BINS

To meet the Model 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. In addition, 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. The two-key security system complicates pharmacies’ attempts to minimize waste hauler trips and consolidate waste when bins are full. For example, 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. Also, based on written stakeholder comments after the July 20, 2010 workshop, if three specific pharmacy programs (representing 17 pharmacies) switched to the two-key system it would increase their annual costs by 141 percent (from \$30,700 to an estimated \$73,900, with an additional one-time cost of \$15,360 for bin purchases).<sup>36</sup>

## USE OF SECURE CONTAINERS AT HHW SITES

The majority of HHW facilities comingle drug waste with other HHW—often in open 55-gallon drums to allow room for other waste to be deposited easily. Unfortunately, this also allows much easier access to deposited pharmaceuticals. To meet the Model Guidelines, an additional bin may be needed (at a cost of approximately \$600 each) so materials are not comingled and remain secure. However, the relatively small amounts of pharmaceutical waste compared to other waste collected at HHW sites makes it somewhat

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<sup>‡</sup> Controlled Substances Act, Section 881 (f)(2) and Code of Federal Regulations, Section 1307.21 (b)(3)

impractical for pharmaceuticals to be managed separately from other HHW; it could lead to prolonged storage times 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 other HHW, which may make it more difficult to weigh, log and track pharmaceuticals separately. As discussed above, if HHW sites must treat other waste 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 rates. Local governments facing significant budget shortfalls fund most collection programs. Given that program costs increase with more collection, 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 percent of all California collection programs. Of that percentage, most funding comes from counties, local waste and water agencies, and to a lesser extent, cities. Pharmacies provide funding for 15 percent of collection programs. The remainder comes from various other sources, such as nonprofit organizations 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. However, there is public support for pharmaceutical companies assuming this responsibility. According to a recent survey of consumers in Washington and Oregon, 64 percent 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 II. 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.<sup>37</sup> 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***

There are two basic reasons for implementing pharmaceutical collection programs that address improper disposal. The first is to reduce the amount of pharmaceuticals that enter the environment, particularly in surface and groundwater. The second reason is to reduce illegal diversion of pharmaceuticals and prevent drug abuse. Goals set for the collection of unwanted household pharmaceuticals must address both reasons.

SB 966 does not provide any performance goals to measure success. Performance goals similar to CalRecycle’s goal of 50 percent waste diversion in California by the year 2000 could drive the creation of programs and help set realistic standards for pharmaceutical waste collection throughout the state. Goals accompanied with incentives (e.g., limiting long-term corporate liability<sup>38</sup>) can be particularly effective in driving program activity. To be effective, measures must take into account information about the amounts of pharmaceuticals sold/prescribed in California, the amounts unused, and the amounts that are eventually collected.

Additionally, a subset of measures could help track program effectiveness and guide program improvements. For example, some studies indicate that pharmaceuticals enter surface and groundwater largely due to human excretion (see Appendix C: *Overview of Reports on Pharmaceuticals in Landfill Leachate*). This suggests that collection programs may not make a large reduction on pharmaceuticals water emissions, even if programs collect all unwanted drugs. However, the studies are industry-sponsored and few in number, making it difficult to draw firm conclusions. Tracking pharmaceutical impacts on water quality could provide a deeper understanding of pollution sources and aid in finding effective solutions.

Even if goals are established, an entity must have the authority to gather necessary data from participants in order to measure progress toward meeting these goals. Otherwise, based on CalRecycle’s experience with other collection streams and based on staff knowledge of pharmaceutical collection programs outside of California, there will not be data available to determine whether goals are met or if the program is successful.

Regardless, however, there is agreement that substance abuse is a growing concern among families and communities; and providing convenient collection, supported with public education, could help address this issue. In addition to establishing collection goals, programs could also establish convenience goals and track educational efforts to better ensure adequate public participation.

## **5. Complexity of Requirements, Policies and Authority**

The Model 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. For example, Waste Management, Inc., reports that California’s regulation of pharmaceutical waste is “extremely complex and these wastes may be regulated as a hazardous waste, a medical waste, or a solid waste under California law.”<sup>39</sup> 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. Through statute, regulation, or policy, each of the following federal and state departments affects the collection and disposal of home-generated pharmaceutical waste to some degree (also see Section I, 4. *Current status of regulations, statutes, and policy*).

- **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 the 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. The Secure and Responsible Drug Disposal Act

of 2010 (S 3397) (See Section II. Overview of Programs Outside of California), amends the Controlled Substances Act to allow for the safe and effective collection and disposal of controlled substances. The specific changes will be forthcoming through a rulemaking process to start in late 2010, at the earliest.

- **CALIFORNIA BOARD OF PHARMACY**

Pharmacies lack statutory provisions for pharmaceutical collection, unlike the recently granted provisions for sharps collection. California law currently does not authorize pharmacies to accept the return of home-generated pharmaceutical waste. SB 966 states programs consistent with the Model Guidelines are "...in compliance with state law and regulation..." but SB 966 did not amend the Business and Professions Code to specifically authorize pharmacies to accept home-generated pharmaceuticals, which creates some confusion about how to interpret the legalities of pharmacy participation. Regardless, the California Board of Pharmacy's February 2010 newsletter stated, "The Board expects all pharmacies to use the [CalRecycle] Guidelines for any 'Take Back' program they offer the public."<sup>40</sup>

Likewise, California law did not authorize pharmacies to accept the return of sharps from the public until Senate Bill 821 (Committee on Business, Professions and Economic Development, Chapter 307, Statutes of 2009) 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 approximately 5 percent of all pharmaceutical waste<sup>41</sup> (e.g., nitroglycerin, warfarin, and some chemotherapy agents dispensed from hospitals), 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."<sup>42</sup>

- **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.

As noted, there is an absence in current statute of a specific definition of home-generated pharmaceutical waste and which agency has authority regardless of how it is collected, consolidated, managed and disposed. Instead, various federal and state departments (DEA, Board of Pharmacy, DTSC, CDPH) exercise statutory authority, regulatory authority or have current policies over home-generated pharmaceutical collection, management, and disposal with different levels of consistency and clarity. In turn, the separate statutes, regulations and policies can make it challenging for local jurisdictions to develop and maintain effective collection and disposal programs that they know conform to legal requirements. Clear statutory definition of which department or agency has sole authority over defining home-generated pharmaceutical waste and determining issues related to collection, consolidation, management, and disposal is essential to providing for a successful program that safely manages collection and disposal of home-generated pharmaceutical waste.

## IV. Program Surveys and Results

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### 1. Nearly All Programs Returned Surveys

During April and May 2010, CalRecycle sent surveys to 67 program managers representing 297 known home-generated pharmaceutical collection programs.<sup>§</sup> This report includes results based on the surveys returned to the department by June 10, 2010.

Many program managers represented more than one program and often more than one type of program. A one-page survey covered each 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 listed at the [SB966 Pharmaceutical Drug Waste Disposal Program Workshop](http://tinyurl.com/July2010PharmaWrkshop) web page (<http://tinyurl.com/July2010PharmaWrkshop>) varied by program type and included up to 25 questions that requested information on operations, funding, costs, collection amounts and security practices related to the standards in the Model Guidelines, over an eight-month period. Not all of the surveys were complete and some appeared to contain contradictory, unsupported, or unexplained responses. This is expected 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.

- **Continuous collection programs** are defined as drop-off locations that have scheduled collection hours at least weekly throughout the year.<sup>\*\*</sup>
- **Collection events** are defined as programs that provide:
  - Periodic drop-off opportunities at different locations, or
  - 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 USPS to an appropriate disposal location.<sup>††</sup>

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<sup>§</sup> CalRecycle became aware of these programs through workshops, discussions and other communications. Additional programs may exist.

<sup>\*\*</sup> 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.

<sup>††</sup> 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.

Overall, CalRecycle identified 297 collection programs and program managers returned surveys for 256 programs (86 percent 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%
- Law Enforcement	65	63	97%
- Household Hazardous Waste Facilities	26	18	69%
- All Other	38	24	63%
Collection Events	53	46 <sup>††</sup>	87%
Mail-back	3	3	100%
<b>Total</b>	<b>297</b>	<b>256</b>	<b>86%</b>

Based on the survey responses, the primary locations for continuous collection programs are pharmacies (102), law enforcement sites (63), and HHW collection sites (18). Ten other location types<sup>§§</sup> 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 report focuses on the top three continuous collection location types (pharmacies, law enforcement, and HHW), as well as collection events and mail-back programs.

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 HHW facilities.

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<sup>††</sup> 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 Oct. 4-11, 2008. This campaign was not included because it predated the survey period. As a result, this paper reflects 46 survey respondents.

<sup>§§</sup> 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 three mail-back programs all began in the Bay Area in 2009: the City of San Francisco, Teleosis (a nonprofit organization in the Bay Area), and Santa Cruz County. While only a few mail-back programs currently operate in California, other states utilize mail-back collection programs (as discussed in Section II. Overview of Programs Outside of California).

The number of surveys used in different analyses within this report may vary because not all surveys included all the necessary information to complete the calculations or determinations for each question or topic.

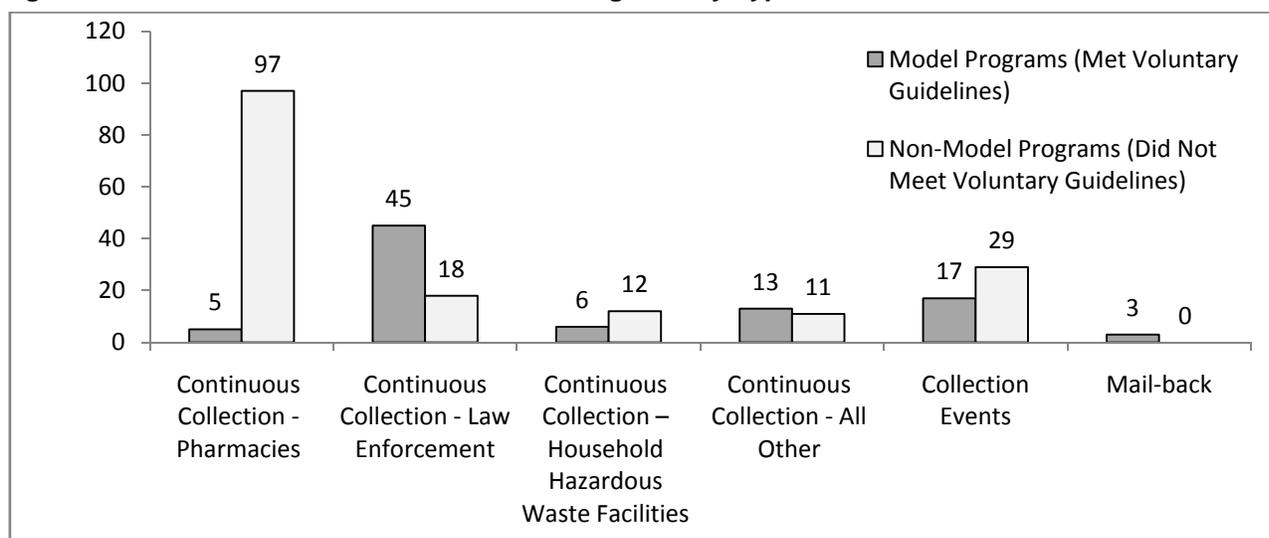
The analyses in the remainder of this report are based only on the survey responses, which do not include all programs in the “known universe,” because the survey responses are considered “confirmed” programs and have data associated with them.

## ***2. Approximately One-Third of Programs Meet the Voluntary Model Guidelines And So Are “Model” Programs***

The Model Guidelines emphasize the secure management of home-generated pharmaceutical wastes. To be a model program, a program must meet each of the criteria in the guidelines. The Model Guidelines are not mandatory or regulatory, so program managers can choose whether or not to follow them. While the Model Guidelines were designed to improve the consistency and quality of collection programs in California, programs that do not meet these voluntary Model Guidelines can still produce good results. However, for the purposes of this report, a program that does not adequately meet all the criteria in the Model Guidelines is not considered a “model program.”

Based on responses on the 256 programs surveyed, CalRecycle determined that 89 (35 percent) met all the standards in the voluntary Model Guidelines and were therefore model programs while 167 did not meet at least one criterion. Some criteria in the Model Guidelines, certain survey questions, and several survey responses contained ambiguity, so CalRecycle’s 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 (Met Voluntary Model Guidelines)	Number of Non-Model Programs (Did Not Meet Voluntary Model Guidelines)	Percentage of Model Programs Within Program Type
Continuous Collection			
- Pharmacies	5	97	5%
- Law Enforcement	45	18	71%
- Household Hazardous Waste Facilities	6	12	33%
- All Other	13	11	54%
Collection Events	17	29	37%
Mail-back	3	0	100%
<b>Total</b>	<b>89</b>	<b>167</b>	<b>35%</b>

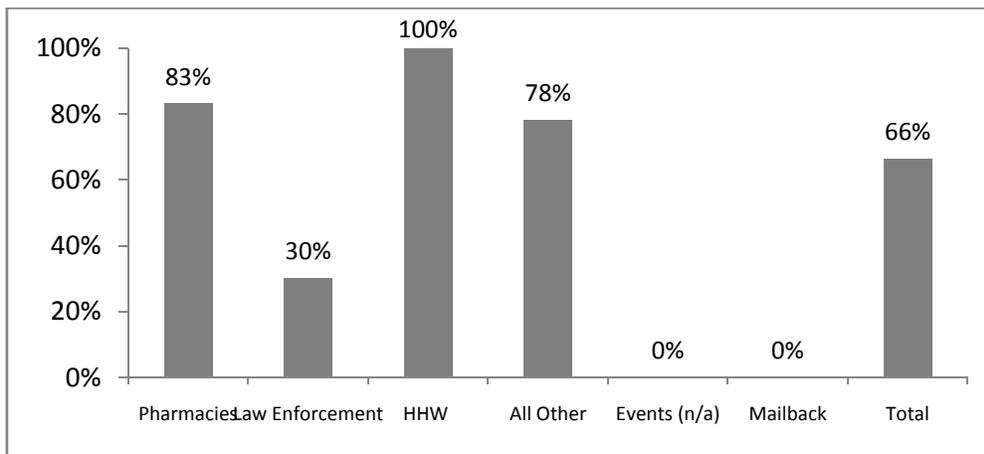
Of the 207 continuous collection programs, 69 adequately met the voluntary Model Guidelines and are model programs. Specifically, five pharmacy collection programs are models (5 percent), 45 law enforcement collection programs are models (71 percent), and 6 HHW collection programs are models (33 percent). Of the 46 collection events, 17 adequately met the voluntary Model Guidelines and are model programs (37 percent). Of the three mail-back collection programs, three adequately met the voluntary Model Guidelines and are model programs (100 percent). In general, mail-back and law enforcement programs most frequently met the Model Guidelines while pharmacies least frequently met them, but these conclusions need to be placed in context as discussed further below.

Some programs that existed prior to the adoption of the voluntary Model Guidelines have features that conflict with the guidelines. Figure 5 shows that most programs (136 out of 205 with data) were already operating at the time the voluntary Model Guidelines were approved in November 2008. Program managers had already invested significant time and/or resources to develop these existing programs, and changing them to meet the voluntary Model Guidelines prior to the survey period (approximately 18 months later) proved to be challenging for some. Changes that required additional infrastructure, resources or major changes to business procedures likely contributed to many programs not qualifying as model programs. As shown in Figures 5 and 6, nearly all of the pharmacy programs (83 percent) and all of the HHW (100 percent) were in place before the Model Guidelines were approved, which may help explain the lower rates of model programs in those two program types.

**Figure 5. Number and Percentage of Programs Started Before Voluntary Model Guidelines Approved**

	Programs that Predate Model Guidelines	Programs with known start dates	Percentage of Programs that Predate Model Guidelines <sup>***</sup>
Continuous Collection			
- Pharmacies	84	101	83%
- Law Enforcement	19	63	30%
- HHW	15	15	100%
- All Other	18	23	78%
Events	n/a	n/a	n/a
Mailback	0	3	0%
Total	136	205	66%

**Figure 6. Percentage of Programs Started Before Voluntary Model Guidelines Approved**



<sup>\*\*\*</sup> The percent of start dates reported out of the total survey responses were: pharmacies (99 percent), law enforcement (100 percent), HHW (88 percent), all other (96 percent), and mailback (100 percent) or 98 percent for all program types.

### **3. Different Programs Excel in Different Evaluation Areas: Safety, Accessibility, Cost-Effectiveness and Efficacy**

This section evaluates five program types (Pharmacies, Law Enforcement, HHW, Collection Events, and Mail-Back) using the four factors specified 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.

This section first presents the following two introductory subsections:

- **Definitions and Limitations.** CalRecycle presents definitions of the four evaluation factors for the purposes of this report, along with the major limitations associated with the analysis of each factor.
- **Program Evaluation Criteria Groupings.** CalRecycle groups the breaking points for each evaluation criterion into high, medium, and low categories.

CalRecycle then summarizes the results of the analysis and highlights the strengths and weaknesses of each of the following program types:

- **Pharmacy Program Evaluation**
- **Law Enforcement Program Evaluation**
- **HHW Program Evaluation**
- **Collection Event Program Evaluation**
- **Mail-Back Program Evaluation**

#### **DEFINITIONS AND LIMITATIONS**

Based on comments from numerous stakeholders, it is apparent that each of the following evaluation factors could be defined differently with different metrics. CalRecycle acknowledges this and, for the purposes of this report, uses the definitions provided below.

CalRecycle also acknowledges that there are analytical limitations associated with each evaluation factor. While the response rate was high, the non-respondents may have been able to provide critical data different from those program managers that responded. As with any survey, different program managers may have interpreted the questions differently. Additionally, ambiguity in some of the survey questions may have caused confusion or resulted in incorrect responses. Incomplete surveys caused voids in the analysis, regardless of what the answer might have been had the response been provided. None of these analytical limitations renders the analysis fatally flawed, but did result in a more subjective and qualitative analysis.

CalRecycle also cautions readers about trying to compare the different program types. First, the data varied significantly within each program type as well as between program types; when this type of variability exists, one must use caution when comparing averages. Second, the program types vary

tremendously in whom they serve and how they provide their services. By way of example, grocery stores, fast food chains and high-end restaurants all provide food but do so very differently and each type excels in different situations. Similarly, the fundamental differences in service delivery models in different pharmaceutical collection program types make comparisons fruitless.

### **SAFETY (SECURITY)**

Safety pertains to the security of pharmaceutical waste collection to prevent illegal diversion. The voluntary Model 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. One unmet criterion disqualifies a program from being considered a model. Also note that it may be possible to develop alternatives to the existing safety criteria in the Model Guidelines if collection system improvements can be identified in the future (e.g., more advanced practices become feasible such as shredding drug waste within each collection bin, automatically counting/tracking each pill, or tracking each pill bottle by automatically scanning barcodes or using RFID [Radio-frequency identification] tags).

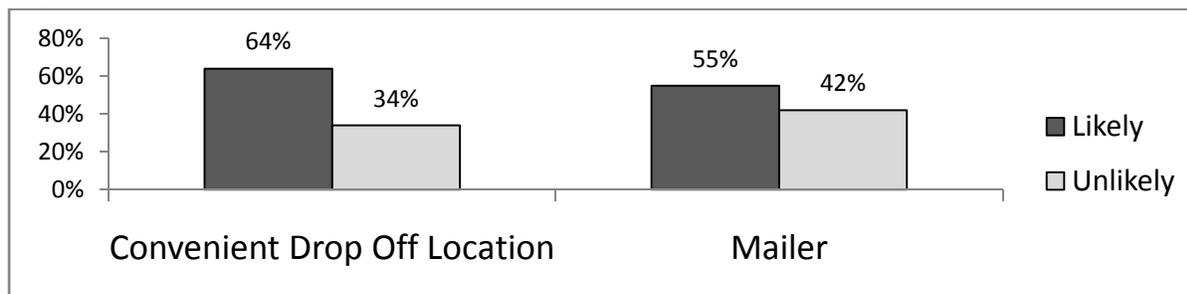
### **STATEWIDE ACCESSIBILITY (ACCESSIBILITY)**

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.

It is important to realize that 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.

Accessibility is a very subjective measure. If tailored correctly to a target population, any or all of the 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 nearly 800 consumers in Washington and Oregon, 64 percent of those surveyed would be somewhat or very likely to take their home-generated pharmaceutical waste to a “convenient” drop-off location, while 55 percent of those surveyed would be somewhat or very likely to use a mail-back program for their home-generated pharmaceutical waste (see Figure 7 below).<sup>43</sup>

**Figure 7. Washington/Oregon Residents’ Medication Disposal Preferences**



Hours of operation varied significantly within program type as well as between program types; readers should use caution when using or 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 three times the effective access or triple the collection amounts compared to access during the “right” eight 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.

### **COST-EFFECTIVENESS**

Cost-effectiveness pertains to the amount of pharmaceuticals collected in comparison to the cost of the program used to collect them. CalRecycle’s survey included questions about quantities collected and costs incurred. For this analysis, this metric is the average cost per pound for each program type.

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 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); and 3) administrative/staff time. Survey respondents could choose to provide costs for any or all of these categories. This analysis uses the cost data that program managers 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. In addition, in many cases, staff time was not tracked and was not provided. Out of all survey responses, 51 percent of the programs and sites representing a cross section of all program types did not have associated staff costs. Because all costs were not included, the results presented here 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, readers need to use caution when comparing averages.

CalRecycle did not adjust the reported amount of pharmaceutical waste collected to compensate for packaging discarded with the pharmaceuticals. While some programs encourage participants to remove packaging more than other programs, CalRecycle could not quantify the effect of this encouragement due to lack of accurate data. As a result, the cost effectiveness and efficacy relate to the combined weight of pharmaceuticals and associated packaging.

Most HHW programs do not track pharmaceutical weights separately from other household wastes they collect; most reported estimated weights. CalRecycle excluded one HHW program from the analysis because it reported a combined weight of household wastes and pharmaceuticals.

### **EFFICACY (COLLECTION RATE)**

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).

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. CalRecycle did not adjust the reported amount of pharmaceutical waste collected to compensate for packaging discarded with pharmaceuticals. As a result, efficacy relates to the combined weight of pharmaceuticals and associated packaging.

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 reporting period. For mail-back programs, the amount collected per day of operation equates to the amount collected from all mailers per program divided by the entire eight-month reporting 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 continuous collection program, a single envelope, a single event, all continuous collection programs, all envelopes, or the entire series of events).

## PROGRAM EVALUATION CRITERIA GROUPINGS

Each program type can be effective in different situations and with different target populations. CalRecycle evaluated each program type based on the four criteria (safety, accessibility, cost effectiveness and efficacy) to determine current practices and results. This report represents a snapshot of pharmaceutical collection programs -- that is, as they were in late 2009 and early 2010. As programs continue to develop, they will evolve and may expand to fill new niches. Given the dynamic nature of this policy area, changes in statutes, regulations, and/or policy may dramatically change the way in which these services are delivered.

This section contains a factor-by-factor review of the information gathered during the survey, followed by a qualitative summary of each program type. As part of the qualitative summary, CalRecycle prepared a chart for each program type that visually illustrates the overall/average performance within each evaluation area (see Figure 8 for a blank sample). As noted above, it is difficult at best to compare results **across** programs, and CalRecycle has not done so in this analysis.

**Figure 8. Relative Strengths of \_\_\_\_\_ Collection Programs**

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/Day	Possible Sites	Dollars/Pound	Pounds/Day	Current Pounds	Pounds/Program
Strongest										
Medium										
Weakest										

CalRecycle has highlighted the appropriate box for each criterion examined in each program type to show relative strengths and weaknesses. When possible, CalRecycle used natural break points in the data for separating the program types into the “strongest,” “medium” and “weakest” categories; however, the groupings are by nature somewhat subjective; selecting different break points would show different summary results. Figure 9 below shows the break points used to evaluate each program type. Those break points are described further below.

**Figure 9. Evaluation Criteria Break Points**

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/Day	Possible Sites	Dollars/Pound	Pounds/Day	Current Pounds	Pounds/Program
Strongest	>30	0-2	>70%	>70	>10	>1,000	<\$3	>10	>10,000	>1,500
Medium	10-30	3-5	30%-70%	30-70	5-10	500-1,000	\$3-\$7	5-10	1,000-10,000	150-1,500
Weakest	<10	>5	<30%	<30	<5	<500	>\$7	<5	<1,000	<150

- Safety:
  - “Number Models” = total number of existing programs in California that are model programs (meet voluntary Model Guidelines).
    - Strongest: more than 30 programs
    - Medium: 10 to 30 programs
    - Weakest: fewer than 10 programs
  - “Criteria Match” = how well existing programs were able to meet the individual criteria in the voluntary Model Guidelines.
    - Strongest: 0 to 2 guideline criteria not met by program
    - Medium: 3 to 5 guideline criteria not met by program
    - Weakest: more than 5 guideline criteria not met by program
  - “% Models” = percentage of existing programs in California that are model programs (meet voluntary Model Guidelines).
    - Strongest: more than 70 percent of programs
    - Medium: 30 percent to 70 percent of programs
    - Weakest: fewer than 30 percent of programs
- Accessibility:
  - “Current sites” = total number of existing programs in California.
    - Strongest: more than 70 programs
    - Medium: 30 to 70 programs
    - Weakest: fewer than 30 programs
  - “Hours/Day” = the average number of hours programs are available per day.
    - Strongest: more than 10 hours per day
    - Medium: 5 to 10 hours per day
    - Weakest: fewer than 5 hours per day
  - “Possible Sites” = total number of potential sites in California.
    - Strongest: more than 1,000 potential sites
    - Medium: 500 to 1,000 potential sites

- Weakest: fewer than 500 potential sites
- Cost Effectiveness:
  - “Dollars/Pound” = the average dollars spent per pound of pharmaceuticals collected.
    - Strongest: less than \$3.00 per pound
    - Medium: \$3.00 to \$7.00 per pound
    - Weakest: more than \$7.00 per pound
- Efficacy:
  - “Pounds/Day” = the average number of pounds collected per day of operation.
    - Strongest: more than 10 pounds per day
    - Medium: 5 to 10 pounds per day
    - Weakest: less than 5 pounds per day
  - “Current pounds” = total amount collected by all existing programs in California.
    - Strongest: more than 10,000 pounds
    - Medium: 1,000 to 10,000 pounds
    - Weakest: less than 1,000 pounds
  - “Pounds/Program” = the average pounds collected by each program type.
    - Strongest: more than 1,500 pounds
    - Medium: 150 to 1,500 pounds
    - Weakest: less than 150 pounds

## PHARMACY PROGRAM EVALUATION

### SAFETY (SECURITY)

#### Program Safety (Security)

While 60 percent of the 102 responding pharmacy programs indicated that they were consistent with the Model Guidelines, CalRecycle determined that only 5 percent (5 programs) actually qualified as model programs. Pharmacy programs had issues with nine safety-related criteria; however, several of the criteria overlap and may artificially inflate this count. Three issues related to collection bin access and handling caused most disqualifications: two-key<sup>†††</sup> bins (93 percent), locking full bins (84 percent), and public access to bins (65 percent)<sup>‡‡‡</sup>.

As discussed above, most pharmacy programs predated the voluntary Model Guidelines so they may have more trouble converting over to the new criteria. Additionally, some pharmacies may not have been aware of the voluntary Model Guidelines or all the specific provisions until the Board of Pharmacy officially notified them in a newsletter just before the survey period (approximately March 2010).

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<sup>†††</sup> California’s Model Guidelines require that, “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.”

<sup>‡‡‡</sup> The guideline requirements were designed to prevent pharmacy employees from individually accessing collected pharmaceutical waste and “public access to bins” indicates the pharmacy employees must handle collected pharmaceutical waste if the public does not have access to the collection bins.

## Illegal Diversion Incidences

Any program's safety or security standards should be considered in the context of existing diversion incidences. Out of 256 collection sites or programs (including 102 pharmacies) representing 86 percent of all known programs operating in California any time in the last 15 years, no survey respondents reported any signs of illegal drug diversion. Washington state's "PH:ARM Pilot" program (using a less costly two-key collection process in pharmacies than California's Model Guidelines<sup>§§§</sup>) also reported no diversion incidences in the 3½ years that 39 pharmacies in their original program have been operating collection programs.<sup>44</sup>

However, outside of these programs, one Northern California pharmacy stopped its collection program after a young woman's drug overdose death was suspected to be linked to drug diversion from the pharmacy's collection program.<sup>45</sup> Also, a Lynnwood, Wash., "pharmacist of the year" collected expired and unexpired drugs from doctors, hospices, clinics, and pharmacy customers to allegedly distribute to less developed countries. Instead, he filled his pharmacy's regular supply pill bottles.<sup>46</sup> However, this may not be considered a true "collection program" since the drug store employing the pharmacist may not have known he was collecting home-generated pharmaceutical waste from customers.<sup>47</sup> No other home-generated pharmaceutical waste collection program in the world is known to have illegally diverted its collected pharmaceutical waste.

### **STATEWIDE ACCESSIBILITY (ACCESSIBILITY)**

Pharmacy program access hours ranged from five to 12 hours per day (average of nine hours per day). With approximately 6,100 pharmacies throughout California,<sup>48</sup> there are a very large number of possible locations for future pharmacy programs. As was shown previously in Figure 7, "Washington/Oregon Residents' Medication Disposal Preferences," 64 percent of nearly 800 consumers in Washington and Oregon would be somewhat or very likely to take their home-generated pharmaceutical waste to a "convenient" drop-off location. Nine out of 10 calls that the City of San Francisco's Toxics Reduction program receives regarding home-generated pharmaceutical waste disposal are from customers wanting to drop off their waste at pharmacies.<sup>49</sup> Anecdotaly, people seem to prefer the point of sale such as a pharmacy as a convenient drop-off location as opposed to household hazardous waste facilities or law enforcement stations.<sup>\*\*\*\*</sup>

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§§§ The PH:ARM Pilot report [Grasso, Cheri, et al., (2009) Secure Medicine Return in Washington State, The PH:ARM Pilot. [www.medicinereturn.com/resources](http://www.medicinereturn.com/resources)] describes a two-key system following a less costly process: "Full boxes are removed from the container by two pharmacy staff using separate keys. After the box is taped shut, a tamper-evident seal is placed across the seams and a fax is sent to the central pharmacy warehouse notifying staff that a box of medicines will be arriving. Sealed boxes are shipped back to Bartell's central pharmacy warehouse, on the regular pharmacy route trucks. The unique numbers assigned to the boxes allow the custody and transportation to be tracked on a shipping notification form. At the central pharmacy warehouse, boxes are stored in a caged section of the warehouse until enough boxes accumulate for transportation to the disposal facility."

\*\*\*\* For instance, Melody LaBella with the Central Contra Costa Sanitary District and Karin North with the City of Palo Alto and current chair of the Bay Area Pollution Prevention Group have worked on home-generated pharmaceutical waste disposal issues for more than nine years each, including working with a variety of collection program types. In an Aug. 12, 2010 meeting with CalRecycle staff, each stated that people prefer point-of-sale disposal options.

## COST-EFFECTIVENESS

Statewide, 75 pharmacies provided sufficient cost information to calculate the costs per pound collected. Pharmacy program costs ranged from \$1.00 to \$16.67 per pound (average of \$5.60 per pound). However, as noted above, almost all of these were not considered “model” programs. If pharmacy programs change their practices to meet the voluntary Model Guidelines, the costs could increase significantly. For example, based on written stakeholder comments after a July 20, 2010, workshop, if three specific pharmacy programs (representing 17 pharmacies) switched to the two-key system it would increase the annual costs by 141 percent (from \$30,700 to an estimated \$73,900, with an additional one-time cost of \$15,360 for bin purchases).<sup>50</sup>

## EFFICACY (COLLECTION RATE)

Statewide, 75 pharmacy programs provided sufficient information to calculate the pounds of pharmaceuticals collected. Pharmacy programs collected a total of 18,120 pounds during the survey period, corresponding to an average of 242 pounds collected per program. Pharmacy programs collected from 0.3 to 12.3 pounds per day of operation (average of 2.0 pounds per day).

## QUALITATIVE SUMMARY

As presented in Figure 10, pharmacy programs:

- Excel in **accessibility** because of the large number of pharmacies in California;
- Have moderate **cost-effectiveness**;
- Have variable **efficacy** depending on the metric used; and
- Lag in **safety** because of the number of voluntary Model Guidelines criteria not met by the pharmacies.

**Figure 10. Relative Strengths of Pharmacy Collection Programs**

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/Day	Possible Sites	Dollars/Pound	Pounds/Day	Current Pounds	Pounds/Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of pharmacy programs:
  - a. They are the point-of-sale for pharmaceuticals, so residents are familiar and comfortable with these locations.
  - b. Pharmacies are designed for public access with thousands of convenient locations throughout California, sufficient parking, and handicap-accessibility, so the expansion and convenience potentials are high.
  - c. Compared to any other program type, pharmacies have the greatest incentive to attract customers with collection programs since customers are more likely to purchase other items while there.

- d. Professionals familiar with pharmaceuticals staff the programs, so the learning curve for new programs should not be as steep.
- 2. The biggest challenges for pharmacy programs:
  - a. Each has its own unique business practices, so a one-size-fits-all model (such as the voluntary Model Guidelines) may be challenging to implement.
  - b. People associate pharmacies with drugs, so meeting some level of safety standards is even more important to prevent illegal diversion.
  - c. The public typically cannot distinguish a controlled substance from a non-controlled substance, so as long as pharmacies are not allowed to collect controlled substances without law enforcement present, this will continue to complicate pharmacy programs.
  - d. Adapting to the voluntary Model Guidelines will be difficult and expensive (especially for pre-existing programs), so acceptance and adoption of the guidelines may not be common or universal.
  - e. Collection programs may not be seen as profitable or “good for business,” so pharmacies may not commit the necessary resources and/or may be reluctant to set pharmaceutical collection as a priority.
  - f. The voluntary Model Guidelines include prescriptive security requirements for pharmacies to meet Board of Pharmacy concerns about illegal diversion. These security requirements include a costly two-key collection bin and other requirements that make it difficult for pharmacies to comply with the voluntary Model Guidelines.

## LAW ENFORCEMENT PROGRAM EVALUATION

### SAFETY (SECURITY)

#### Program Safety (Security)

While 100 percent of the 63 law enforcement programs surveyed responded that they were consistent with the Model Guidelines, CalRecycle determined that only 71 percent actually qualified as model programs. Law enforcement programs had issues with five safety-related criteria. Three issues caused most disqualifications: controlled substances (29 percent), storage times (22 percent) and hauler registration (29 percent).

#### Illegal Diversion Incidences

No known incidences of illegal drug diversion have occurred in any law enforcement programs. At least one diversion incident outside of a collection program was reported.<sup>51</sup>

### STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, 63 existing law enforcement programs responded to the survey. Law enforcement program access hours ranged from 3 to 24 hours per day (average of 19 hours per day). Anecdotally, people may not be as familiar with the locations or accessibility of law enforcement stations and have expressed concerns about taking their pharmaceuticals to them. With approximately 900 law enforcement locations throughout California,<sup>††††</sup> there are many possible sites for future law enforcement programs.

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<sup>††††</sup> Based on CalRecycle staff estimates from samplings of number of stations referenced here: [www.road-police.com/police/california/california\\_police.html](http://www.road-police.com/police/california/california_police.html).

## COST-EFFECTIVENESS

Statewide, each of the 63 law enforcement programs surveyed provided sufficient cost information to calculate the costs per pound collected. Law enforcement program costs ranged from \$0.38 to \$13.89 per pound (average of \$4.56 per pound).

## EFFICACY (COLLECTION RATE)

Statewide, 63 law enforcement programs provided sufficient information to calculate the pounds of pharmaceuticals collected. Law enforcement programs collected a total of 194,522 pounds during the survey period, corresponding to an average of 3,088 pounds collected per program. Law enforcement programs collected from 0.1 to 34.7 pounds per day of operation (average of 7.1 pounds per day).

Law enforcement programs often have a 24-hour presence and often locate drop boxes outdoors. Some law enforcement programs reported that small businesses deposit their pharmaceutical waste, which is not considered home-generated, in these drop boxes. This inflates the amounts, increases the program disposal costs, would contradict the disposal requirements for any business generating that waste<sup>++++</sup>, and constitutes unfair competition for any business using this free disposal method intended only for resident use.<sup>§§§§</sup>

The largest law enforcement program reported that during its initial six-month startup period (which corresponded with the CalRecycle survey period), the program suspected a large amount of business waste disposal was occurring. Additionally, the amount of pharmaceuticals collected during the six-month startup period was much higher than subsequent periods. Residents may have disposed of a large amount of stockpiled pharmaceuticals. As a result, the representativeness of the data for that program may be questionable, which could have resulted in somewhat inflated collection rates compared to long-term collection rates.

## QUALITATIVE SUMMARY

As presented in Figure 11, law enforcement programs:

- Excel in **safety** by having a large percentage of model programs;
- Have moderate **accessibility** and **cost-effectiveness**; and
- Excel in program **efficacy** (although this may be due in part to suspect data).

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<sup>++++</sup> According to the California Medical Waste Management Act.

<sup>§§§§</sup> According to Section 17200 of the California Business and Profession Code.

**Figure 11. Relative Strengths of Law Enforcement Collection Programs**

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/Day	Possible Sites	Dollars/Pound	Pounds/Day	Current Pounds	Pounds/Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of law enforcement programs:
  - a. They are secure locations, so residents should be safe and illegal diversion should be rare.
  - b. There are nearly 1,000 locations currently in the state, so the expansion and convenience potentials are good.
  - c. Most existing programs conformed well to the voluntary Model Guidelines, so additional programs should be able to conform, too.
  - d. They can more easily meet the requirements for collecting controlled substances, so they could be convenient one-stop locations.
2. The biggest challenges for law enforcement programs:
  - a. People either think of these locations as dangerous or are unaware of their whereabouts, so getting full public participation may be difficult.
  - b. Many are facing severe budgetary and funding shortfalls, so they may not have the resources and/or may be reluctant to set pharmaceutical collection as a priority.

## HHW PROGRAM EVALUATION

### SAFETY (SECURITY)

#### Program Safety (Security)

While 78 percent of the 18 HHW programs responded that they were consistent with the Model Guidelines, CalRecycle determined that only 33 percent actually qualified as model programs. As discussed above, all of the HHW programs predated the voluntary Model Guidelines so they may have more trouble converting over to the new requirements. HHW programs had issues with three safety-related criteria. Issues related to documentation (50 percent) and storage times (44 percent) caused most disqualifications.

#### Illegal Diversion Incidences

No known incidences of illegal drug diversion have occurred at any household waste facilities.

### STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, 18 existing HHW programs responded to the survey. HHW program access hours ranged from one to nine hours per day (average of three hours per day). With approximately 140 HHW sites throughout California, there are some additional possible locations for future HHW collection programs.

## COST-EFFECTIVENESS

Statewide, 15 HHW programs provided sufficient cost information to calculate the costs per pound collected. HHW program costs ranged from \$0.13 to \$6.38 per pound (average of \$2.86 per pound). This average is considerably lower than the average costs of other programs; however, the weights of pharmaceuticals at HHW programs are more likely to be estimated rather than measured, which could impact the cost-effectiveness results (e.g., if the estimated amounts are twice the actual weight, the cost per pound will be half what it should be).

## EFFICACY (COLLECTION RATE)

Statewide, 16 HHW programs provided sufficient information to calculate the pounds of pharmaceuticals collected. HHW programs collected a total of 9,349 pounds during the survey period, corresponding to an average of 584 pounds collected per program. HHW programs collected from 0.4 to 10.3 pounds per day of operation (average of 2.0 pounds per day).

## QUALITATIVE SUMMARY

As presented in Figure 12, HHW programs:

- Excel in **cost-effectiveness** (although this may be due in part to suspect data);
- Have moderate **safety** and **efficacy**; and
- Lag in **accessibility** due to relatively few existing programs, few potential sites, and limited hours.

**Figure 12. Relative Strengths of HHW Collection Programs**

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/Day	Possible Sites	Dollars/Pound	Pounds/Day	Current Pounds	Pounds/Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of HHW programs:
  - a. They are existing programs that can handle a variety of toxic materials, so they can function as one-stop locations.
  - b. Pharmaceuticals comingled with HHW represent a relatively small amount compared to all HHW and can be collected and disposed together with relative efficiency following existing practices.
2. The biggest challenges for HHW programs:
  - a. There are fewer than 150 total HHW sites in the state, so convenience and the potential for expansion is low.
  - b. Many people staff and visit HHW sites, so meeting safety standards is important to prevent illegal diversion.

- c. Many local governments that run HHW programs are facing severe budgetary and funding shortfalls, so they may not have the resources and/or be reluctant to set pharmaceutical collection as a priority.

## **COLLECTION EVENT EVALUATION**

### **SAFETY (SECURITY)**

#### Program Safety (Security)

While 76 percent of the 46 collection events responded that they were consistent with the Model Guidelines, CalRecycle determined that only 37 percent actually qualified as model programs. Collection events had issues with three safety-related criteria. Issues related to documentation (46 percent) caused most disqualifications.

#### Illegal Diversion Incidences

No known incidences of illegal drug diversion have occurred at any collection events.

### **STATEWIDE ACCESSIBILITY (ACCESSIBILITY)**

Statewide, 46 existing collection events responded to the survey. Event access hours ranged from three to 12 hours per day (average of seven hours per day) when events were held. Events can be held at numerous types of locations, so there are numerous possible locations for future collection events.

### **COST-EFFECTIVENESS**

Statewide, 36 collection events provided sufficient cost information to calculate the costs per pound collected. HHW program costs ranged from \$0.87 to \$16.67 per pound (average of \$6.06 per pound). It appears that jurisdictions with limited resources are more likely to use collection events. If costs to open and/or operate a continuous collection program are prohibitive, a jurisdiction may operate collection events to reach all residents with some level of collection service. Collection events appear to be more common in areas with large dense populations such as the City of Los Angeles or the Bay Area, and in rural jurisdictions where they provide at least some level of service to a diffuse population.

### **EFFICACY (COLLECTION RATE)**

Statewide, 36 collection events provided sufficient information to calculate the pounds of pharmaceuticals collected. Events collected a total of 5,040 pounds during the survey period, corresponding to an average of 140 pounds collected per program. Collection events collected from 2.5 to 482.0 pounds per day of operation (average of 163.1 pounds per day). Again, these large quantities represent the amounts collected on only the days that events occurred, rather than on a daily, continuous basis.

Although events appear effective in terms of pounds collected per day, the final report for the California “No Drugs Down The Drain! Statewide Campaign, October 4-11, 2008” concluded, “While they can be successful in educating residents, event-based disposal is not a long-term solution. Some residents are not able to attend events, and stockpiling medication until a future event is not an option for many who are concerned about accidental poisoning, misuse, abuse, or diversion.”<sup>52</sup>

## QUALITATIVE SUMMARY

As presented in Figure 13, collection events:

- Have moderate **safety**, **accessibility**, and **cost-effectiveness**; and
- Have variable **efficacy** depending on the metric used, which should be expected for an approach that may be best at addressing specific needs in certain situations.

**Figure 13. Relative Strengths of Collection Events**

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/Day	Possible Sites	Dollars/Pound	Pounds/Day	Current Pounds	Pounds/Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of collection events:
  - a. They are flexible and can happen in a variety of locations, so residents have reasonable access to some level of service.
  - b. They can handle large volumes of materials in a short amount of time, so they may be more effective at dealing with existing stockpiles.
  - c. Relative to other law enforcement duties, law enforcement officers may be more likely to staff a one-time event in order to collect controlled substances rather than run a full-time collection program.
  - d. They can be effective by increasing public awareness and giving stakeholders initial experience with collection issues, which may make events a potentially effective first step toward starting a continuous collection program.
2. The biggest challenges for collection events:
  - a. People may not hear about events, so without adequate publicity they may not reach the intended audiences or get full public participation.
  - b. Staffing commitments for events can be onerous and costly for the amount of pharmaceutical waste collected.
  - c. Many people staff and visit collection events, so meeting some level of safety standards may be difficult.
  - d. Many local governments that run collection events are facing severe budgetary and funding shortfalls, so they may not have the resources and/or may be reluctant to set pharmaceutical collection as a priority.

# MAIL-BACK PROGRAM EVALUATION

## SAFETY (SECURITY)

### Program Safety (Security)

All three mail-back programs responded that they were consistent with the Model Guidelines, and CalRecycle confirmed that they all qualified as model programs. Mail-back programs had no issues with safety-related criteria. In mail-back programs, only the generator (i.e., the resident) handles pharmaceuticals and then the USPS takes custody of the envelopes, so there are very few opportunities for security issues to arise.

### Illegal Drug Diversion

The following mail-back-related example of potential illegal drug diversion was not part of any official collection program. However, it does indicate the security concerns surrounding such programs even though the USPS boasts a 94 percent conviction rate for crimes that range far afield from stolen mail or forged money orders.<sup>53</sup> The USPS investigated multiple reports of prescription medication mailed to veterans from the Veterans Administration that disappeared from a South Sacramento post office.<sup>54</sup>

## STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, three existing mail-back programs responded to the survey. Mail-back access hours ranged from six to 10 hours per day (average of 8 hours per day) for mailer pickup. Mailboxes are always available, so drop-off access is essentially 24 hours per day. Pharmacies, government offices, or a variety of other locations could distribute mailers, so there are a very large number of possible distribution locations. Drop-off locations are even more plentiful with approximately 1,850 post offices and approximately 21,310 mailboxes in California.<sup>55</sup> Residents could even give mailers to their letter carriers. Especially for homebound residents and those in rural areas, mail-back programs allow the public to send packages at anytime at any mailbox. In terms of potential drop-off locations, mail-back programs potentially offer the greatest accessibility. Santa Cruz County's relatively small mail-back program has the highest reported return rate so far (68 percent returned/distributed), possibly because a pharmacy distributed mailers specifically to people who, for various reasons, could not use a nearby pharmaceutical drop-off site.

## COST EFFECTIVENESS

Statewide, all three mail-back programs provided sufficient cost information to calculate the costs per pound collected. Mail-back costs ranged from \$4.59 to \$8.10 per pound (average of \$6.54 per pound). Because all mail-back programs started in 2009 and are relatively new in California, CalRecycle only includes the costs and pounds collected for returned mailers. Program managers pay for mailers up-front regardless of whether they are subsequently used or not. If generators (residents) do not return some mailers, then overall cost per pound will increase (e.g., if residents returned only half of the mailers, the cost per pound would double). A mailer's \$3.65 flat rate cost per envelope may encompass more upfront costs than the reported costs from pharmacy programs (e.g., staff time, kiosk cost and maintenance, and lost retail space, etc.). Finally, if residents put more pharmaceuticals in each envelope, the cost-effectiveness increases (i.e., a lower cost per pound) because the current mail-back programs use flat rate shipping arrangements. However, encouraging residents to hold onto materials longer and send fewer, fuller envelopes may increase illegal diversion opportunities. In addition, Walgreens has made postage-paid mailers available in its stores nationwide for \$2.99 each,<sup>56</sup> and at least 200 Kaiser Permanente

Hospitals in California are offering the same mailers for \$4.95 each.<sup>57</sup> Anecdotally, Kaiser has had considerable customer demand.

### EFFICACY (COLLECTION RATE)

Statewide, all three mail-back programs provided sufficient information to calculate the pounds of pharmaceuticals collected. Mail-back programs collected a total of 898 pounds during the survey period, corresponding to an average of 299 pounds collected per program. Mail-back programs collected from 0.1 to 3.2 pounds per day of operation (average of 2.1 pounds per day).

### QUALITATIVE SUMMARY

As presented in Figure 14, mail-back programs:

- Excel in **safety** by having 100 percent model programs;
- Have variable **accessibility** with low current accessibility but great potential accessibility;
- Have moderate **cost-effectiveness** (although this is dependent on high mailer return rates); and
- Lag in **efficacy** due to relatively few existing programs.

**Figure 14. Relative Strengths of Mail-Back Collection Programs**

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/Day	Possible Sites	Dollars/Pound	Pounds/Day	Current Pounds	Pounds/Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of mail-back programs:
  - a. They do not require any expertise, so mailers can be distributed in a variety of ways at almost any location.
  - b. There are convenient USPS drop-off locations across California, so the potential for convenience and expansion is very high.
  - c. The costs are all paid up-front, so there are no hidden or unexpected costs to contend with.
  - d. No intermediary handles the pharmaceuticals (other than the USPS), so safety is not as much of a concern.
  - e. Fewer regulations are necessary (e.g., CDPH’s policy to regulate consolidated home-generated pharmaceutical waste) since no intermediary consolidates or is considered to generate the waste.
2. The biggest challenges for mail-back programs:
  - a. There are only three programs in the state, so it may be seen by some as an unproven approach.
  - b. The costs are all paid up-front, so a very high return rate is necessary for the method to be cost-effective.

## V. Potential Options and Recommendations for Further State Action

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This section includes a range of potential options for further state action with regard to pharmaceutical collection programs. Options can be categorized into two groups -- regulatory and funding. Each of these is described briefly here and then in more detail below.

There are two regulatory options:

**Option 1. Continue Current Use of Model Guidelines** maintains the status quo and entails using voluntary federal guidelines and the current California Model Guidelines. The former teaches residents how to properly dispose of drugs in household trash if local collection programs are not available, while the California Model Guidelines address safe practices of home-generated pharmaceutical collection programs.

**Option 2. Establish Clear State Agency Roles and Responsibilities, Improve Model Guidelines and Enforcement, and Convert Guidelines to Regulation** relies on statutory changes to establish clear state roles and responsibilities and to provide direction to resolve several implementation challenges. It also would convert the Model Guidelines into state regulations.

These are followed by two funding options that address the need for long-term program funding, which is essential for establishing more collection programs and maintaining existing ones.

**Option 3. Implement Product Stewardship with Private Sector Leadership** provides program financing through a private sector approach, with government oversight. This is commonly referred to as product stewardship. Manufacturers or drug brand owners would design, manage, and finance a statewide program, while state government would oversee successful program implementation and enforcement.

**Option 4. Create State Collection Program Supported by Advanced Disposal Fee** relies on a fee paid by consumers at the point-of-purchase to support program activities (such fees typically are known as “advanced disposal fees”). The fees would be used to implement a state government program, in which a designated state agency would design, manage, and enforce the program, in addition to collecting and dispersing funds.

For each of these four options, CalRecycle describes in more detail below their potential impacts, arranged by the:

- Four evaluation factors specified in SB 966 (safety, accessibility, cost-effectiveness, and efficacy);
- Challenges and barriers discussed previously in this report (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 addressed by SB 966.

Options 2, 3, and 4 would require new legislation to be implemented. At the end of this section, CalRecycle offers its recommendations for a possible combination of regulatory and financing options. CalRecycle also recognizes that there is not agreement among stakeholders on preferable types of collection programs, nor on state agency roles and responsibilities. Some stakeholders advocate that unless

federal regulations change (see Section II, 2. *National Programs*, Federal Legislation and Regulations) so that pharmacies and mail-back programs may collect controlled substances, law enforcement should collect all home-generated pharmaceuticals. Otherwise drugs would need to be sorted to follow the law, but it is hard to distinguish between a controlled and uncontrolled substance so these programs are expensive. Other stakeholders argue that mail-back programs should be the primary program type allowed because they do not face these same restrictions and because they offer convenient collection, safety, and privacy. Others argue that all collection options should be available.

## 1. Regulatory Options

### OPTION 1. CONTINUE CURRENT USE OF MODEL GUIDELINES

Under this option the state would maintain the voluntary Model Guidelines, and where local programs do not exist, the state would encourage consumers to follow federal guidelines.

This option thus would encourage programs (such as at pharmacies and HHW facilities) to follow the Model Guidelines and allow consumers to continue to dispose of pharmaceuticals in their household trash that goes to landfills. Consequently, some pharmaceutical chemicals would likely be found in landfill leachate, although this appears to be a minor pathway for releases to the environment.\*\*\*\*\*

This option does not provide funds for public education; some other states such as New York do provide funding for education programs. If an organization (e.g., pharmaceutical manufacturers, brand owners, government) educated consumers on proper disposal, including the federal guidelines on how to dispose drugs in household trash, many of the impacts described below could be mitigated. This could be done without additional collection costs, without legislation, and result in removing unwanted drugs from households, but would not meet environmental objectives to significantly decrease pharmaceuticals released to the environment.

In contrast, if the primary concern of the Legislature is to provide convenient long-term collection opportunities for home-generated waste and to minimize illegal diversion of such waste, then other options listed in this section should be considered.

#### POTENTIAL IMPACTS:

Safety: No change from current level. Illegal diversion could still occur at waste disposal collection points (e.g., scavengers at trash bins, employees at materials recovery facilities). However, the “treatments”

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\*\*\*\*\* CalRecycle is aware of only a few studies regarding concentrations of pharmaceuticals in leachate from U.S. landfills, and few of these are peer-reviewed. In general, they indicate that most pharmaceuticals in the environment are the result of human excretion as opposed to being from home-generated pharmaceutical waste, that pharmaceuticals may be found in generally low concentrations in landfill leachate discharged to wastewater treatment plants, and the latter could be viewed as a minor pathway by which pharmaceuticals reach the environment (see Appendix C: *Overview of Reports on Pharmaceuticals in Landfill Leachate*).

described in the federal guidelines could be adequate if consumers follow them so that drugs would be rendered non-consumable and hidden in household trash.

Accessibility: No change from current level. A wide range of collection programs could continue as they currently exist, but many consumers would remain unaware of collection options or would not participate in available programs.

Cost-effectiveness: No change from current level. This option 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 unless there was significant public education; as a consequence, pharmaceuticals would continue to be stored at home, disposed of in landfills, or flushed down toilets, and would 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 Model 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. Greater confusion may arise if local governments adopt ordinances resulting in highly variable approaches across the state.

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.

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). If excretion is the main cause of water contamination, which research supports, then this suggests a different type of approach is needed (such as designing pharmaceuticals to be better metabolized by consumers, encouraging practices that reduce over-prescribing prescriptions, and other source-reduction approaches).

## **OPTION 2. ESTABLISH CLEAR ROLES AND RESPONSIBILITIES, IMPROVE MODEL GUIDELINES AND CONVERT TO REGULATIONS, AND PROVIDE ENFORCEMENT AUTHORITY**

This option focuses on strengthening the Model Guidelines by establishing clear state agency roles and responsibilities, making the Model Guidelines mandatory, and providing authority to enforce them.

A key element of this option is to provide clear legislative authority and “clean up” confusing laws and regulations. Appendix A: *Recommended Stakeholder Changes to Legislation, Regulations and Policies*

explores legislative alternatives for addressing several challenges facing collection programs. For example, one of the biggest points of confusion is that pharmaceutical discards can be classified and regulated in multiple ways depending on how and where they are collected and managed. The Legislature could define home-generated pharmaceutical waste and a level of management for home-generated pharmaceuticals that would provide needed safety but would be less stringent than requirements for managing medical waste. Further, the Legislature could define at what point, if any, consolidated home-generated pharmaceutical waste should be considered medical waste and handled as such. Providing needed safety would include remaining consistent with federal controlled substances laws such as the Controlled Substances Act. Legislation could also identify a state agency to develop regulations that codify current voluntary Model Guidelines and require collection and disposal programs to follow them. Additionally, the Model Guidelines could be modified to allow for additional practices, provided they offer equivalent safety (e.g., new technologies might offer lower-cost alternatives to the current two-key system used in pharmacies). The intent of these activities would be to establish clear state agency roles and responsibilities, and to improve enforcement and implementation of home-generated pharmaceutical collection and disposal programs.

As noted, under this option collection programs would be required to follow Model Guidelines to ensure safety. The Model Guidelines have been the officially sanctioned home-generated pharmaceutical waste collection guidelines in California since November 2008 and serve as a platform for establishing regulations. Additionally, out of 256 existing collection programs and events, there are not any reported signs of illegal drug diversion so it appears the Model Guidelines offer adequate safety. Legislation would have to delineate who is responsible for properly managing collected drugs and provide the lead state agency with sufficient authority to take enforcement action against non-complying entities.

Option 2 assumes no additional funding for individual collection programs would be made available, although the designated state agency would require additional resources to develop and implement regulations. Options for program funding are covered in Option 3 (private sector managed product stewardship) and Option 4 (state government managed advanced disposal fee).

#### **POTENTIAL IMPACTS:**

**Safety:** The percentage of programs meeting the Model Guidelines could rise if the guidelines became mandatory. However, a potential unintended result could be fewer programs, if the Model Guidelines were viewed as too onerous.

**Accessibility:** Because requirements will be clearer, the number of collection programs may increase to provide consumers with greater accessibility. However, the overall number of programs may not increase if the costs associated with meeting the Model Guidelines are too high. In addition, if restricted to law enforcement, accessibility would depend on the willingness of law enforcement entities to participate.

**Cost-Effectiveness:** Mandatory implementation of the Model Guidelines could result in higher costs and lower cost-effectiveness. If clarification of the Model Guidelines identified additional options or flexibility, costs could be reduced.

**Efficacy:** Some increase in collection is possible, but as long as programs are voluntary, 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 Model 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 the issue of insufficient funding or lack of a sustainable funding source. Local governments would need to continue to find ways to fund these collection programs.

Lack of Goals: No change from current challenge.

Unclear Requirements, Policies and Authorities: Would provide an opportunity to update the Model Guidelines and set clear, consistent and enforceable standards. Could better define state agency roles and responsibilities through legislation or regulation and avoid on-going debate among state entities.

Environmental impacts: Since this option assumes no additional funding would be made available and the number of collection sites would not increase significantly, pharmaceuticals would continue to be stored at home, disposed of in landfills or flushed down toilets, and eventually enter streams and groundwater.

## **2. Funding Options**

### **OPTION 3. IMPLEMENT PRODUCT STEWARDSHIP WITH PRIVATE SECTOR LEADERSHIP**

Under this option, legislation would mandate a private-sector designed and managed producer responsibility approach for pharmaceuticals. This also would provide the authority for state oversight to ensure a level playing field, and address issues of state agency roles and responsibilities so that pharmaceutical collection is less confusing and more streamlined.

Because this approach is not yet used widely in California, it bears additional explanation here. Product stewardship programs use a private-sector approach to managing discards.<sup>58</sup> 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. In California 100 local jurisdictions have already adopted product stewardship resolutions for a variety of products, indicating growing interest and support.<sup>59</sup> CalRecycle has adopted a Strategic Directive on producer responsibility and adopted an Extended Producer Responsibility Framework Document in January 2008.<sup>60</sup> Additionally, two product stewardship laws were enacted in 2010 to establish private-sector managed and funded recycling programs for carpet (AB 2398, Perez, Chapter 681, Statutes of 2010) and architectural paint (AB 1343, Huffman, Chapter 420, Statutes of 2010).

Conceptually, this approach appropriately places the primary responsibility for pharmaceutical management with the pharmaceutical manufacturer and the consumers who use them, rather than ratepayers and local governments, which currently spend more than \$600,000 per year on what is likely a small percentage of all home-generated pharmaceutical waste.<sup>††††</sup> In other words, those who benefit from pharmaceuticals pay for pharmaceutical waste management costs. Using less material in the design of products, often called source reduction, prevents waste and can provide a great environmental benefit. A

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<sup>††††</sup> A cost of \$600,000 per year is based on CalRecycle survey results from local governments (including mailback, events, and 206 continuous collection programs). Since 51 percent of all programs did not report staff time, and if current programs address only 5 percent of home-generated pharmaceuticals, then costs for collection throughout California would be much higher.

potential source reduction benefit could emerge from the closer involvement of pharmaceutical manufacturers with drug waste. Manufacturers could gain insights they currently lack regarding the extent, scope, and magnitude of drug waste and to reduce costs and negative impacts they may change their manufacturing, packaging, and prescribing/dispensing practices. For instance, pharmaceutical manufacturers may learn that certain medications intended to be taken completely are typically returned with portions unused. In this case, education practices while prescribing/dispensing may be improved in order to reduce industry-funded disposal costs. Likewise, insurers could use information gleaned from collection programs to determine optimal dispensing practices.<sup>61</sup>

Full product stewardship programs are industry-led, giving producers or manufacturers the flexibility to design and implement their own programs, with the state or federal governments' role focused on 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. Product stewardship programs are financed by the private sector and government does not collect any taxes. Rather, managing materials becomes another business cost that is incorporated into product price, similar to any other costs.

Producers (or their product stewardship organization) plan and implement collection programs, and later provide for an independent audit and submit progress reports to the lead state agency. 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. As long as goals and laws are met, state government would not be involved, except in an oversight capacity and to ensure all producers participate.

#### **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 Model 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. The option creates a new role for pharmaceutical manufacturers, who may resist additional responsibility and additional costs. It would provide sustainable funding for all program activities and could reduce financial burdens on local governments. Additional requirements on state government for oversight activities would be funded by industry through the product stewardship organization.

Lack of Goals: This option would likely have goals to work toward as part of its framework.

Unclear Requirements, Policies and Authorities: Requires new legislation that may be difficult to enact. Would minimize government bureaucracy and 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. If a product stewardship program provides incentives to reduce releases into the environment, then it could help drive the creation of new and less environmentally harmful drugs. For instance, a manufacturer's share of disposal fees could be reduced proportionate to their production of pharmaceuticals that are metabolized the most and cause the least environmental impact.

## **OPTION 4. CREATE STATE COLLECTION PROGRAM USING 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. Funds from this account are used to finance a collection program as well as to support the state agency resources needed to collect fees and implement the program. CalRecycle, or another 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. This option 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. The approach could also 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.

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\*\*\*\* For example, California's electronic waste (e-waste) program requires approximately 75 staff across state government. Among the 20 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.

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: This option would provide sustainable funding for all program activities and place significant additional costs on state government for regulatory, fiscal, and enforcement activities funded by the ADF. It could greatly reduce burden on local governments, which currently spend more than \$600,000 per year, and would create a visible fee on consumers which may be misinterpreted as a tax. Given a fee would be tied to a specific service, it would not be a tax.

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. This option would not provide an incentive to redesign pharmaceuticals to reduce their environmental impact.

### **3. Recommendations**

Per the Legislature's direction via SB 966 that home-generated pharmaceutical programs address the safety, accessibility, cost-effectiveness, and efficacy issues, CalRecycle provides the following recommendations.

#### **OVERALL RECOMMENDATION**

To provide convenient collection opportunities for home-generated pharmaceuticals and to keep these chemicals out of landfills, CalRecycle recommends a combination of **Option 2** ("*Establish Clear State Agency Roles and Responsibilities, Improve Model Guidelines and Enforcement, and Convert Guidelines to Regulation*"), and **Option 3** ("*Implement Product Stewardship with Private Sector Leadership*") for the following reasons:

- **Provides clear state agency roles and responsibilities.** Legislation is needed to sort out roles and responsibilities because state agencies are not in a position to make these determinations on their own.
- **Clearly defines home-generated pharmaceuticals, consolidated home-generated pharmaceuticals, and acceptable management practices.** Stakeholders are confused by the various laws, regulations, and policies that may or may not exempt home-generated pharmaceuticals from requirements for medical or hazardous wastes, especially once these pharmaceuticals are consolidated. Legislation would clearly define *home-generated pharmaceutical waste* and how it shall be managed, even after it is consolidated at a collection site (e.g., as a type of medical or hazardous waste, or as its own category of waste with its own safety and transportation requirements that are more flexible than

medical waste requirements). Providing this direction and incorporating the Model Guidelines into regulations would clearly establish which practices are legal.

- **Supports safe collection, transport and management of home-generated pharmaceuticals.** These options would ensure collection programs are safe and accessible because: 1) the Model Guidelines provide for adequate safety; and 2) the product stewardship approach would provide long-term funding that encourages refining existing collection programs and establishing new ones. CalRecycle recommends that authorizing legislation should address key issues identified elsewhere in this report (see *III. Challenges and Barriers to Implementing a Model Collection Program in California*) and that the Legislature designate the state agency that develops regulations as being the same as the agency responsible for enforcement. Additionally, the Model Guidelines may become outdated over time, so the legislation should define a process for updating them, including who will make important determinations on what constitutes adequate safety for any new management practices.
- **Offers flexibility in a complex regulatory environment.** A product stewardship approach provides maximum flexibility so a program can be modified to accommodate changing laws and regulations.
- **Provides sustainable program funding.** Product stewardship provides for long-term funding using a private-sector approach without significantly growing state government.
- **Allows multiple collection systems.** Under a product stewardship approach, the producers (brand owners) would design a program to best achieve defined goals. This could include a combination of collection systems such as collection at pharmacies, law enforcement agencies, HHW facilities, events, or using mail-back or other systems that conform to public and environmental safety requirements.
- **Encourages cost-efficiency.** Because a program would be designed, managed, and paid for by the private sector, it would encourage cost-efficiency.
- **Supports key tenets of SB 966.** Options 2 and 3 have the highest potential to provide for high efficacy (collection rates), safety, statewide accessibility, and cost-effectiveness as outlined in SB 966.

However, this recommendation cannot by itself totally overcome the key barrier related to controlled substances. Since controlled substances are an important part of the home-generated pharmaceutical waste stream and regulating them is under federal authority, instituting Options 2 and 3 will be problematic for controlled substances unless federal legislation currently under consideration, or similar legislation, is passed to address this issue. Newly signed federal legislation, the *Secure and Responsible Drug Disposal Act of 2010*, (S 3397), amends the Controlled Substances Act to make it easier to collect controlled substances. Specifically, this legislation gives the federal government more flexibility in developing regulations that would allow public and private entities to operate a variety of effective and safe collection and disposal methods for controlled substances. For example, options other than law enforcement could become more readily feasible for collecting and reducing potential diversion of controlled substances. Thus, it has the potential to positively impact the ability to effectively implement Options 2 and 3, depending on the resulting regulations.

## ALTERNATIVE INTERIM RECOMMENDATION

The recommendation discussed above would likely take at least a few years to implement under the best-case scenario (i.e., to enact legislation and develop the required regulations and stewardship program), yet unwanted drugs need to be removed from households now. For this reason CalRecycle offers an alternative interim recommendation. Specifically, in order to provide convenient and immediate disposal opportunities for home-generated pharmaceuticals where collection programs do not currently exist and to make these drugs less available to potential abusers, **Option 1** (“*Continue Current Use of Model Guidelines*”) could be considered for the following reasons:

- **Provides convenient, low-cost disposal.** The federal guidelines developed by the White House Office of National Drug Policy and the federal Food and Drug Administration recommend that if local collection programs are not available, expired drugs should be disposed by mixing them with an undesirable substance (e.g., coffee grounds or kitty litter), putting this mixture in an impermeable, nondescript container, and throwing the container in household trash. In basic terms this amounts to hiding the drugs in household trash. Trash disposal is available statewide, at no additional cost, making this approach convenient and low-cost disposal for consumers. This approach would accept landfills as an environmentally reasonable disposal alternative during this interim period.
- **Does not require new legislation.** Following the federal guidelines and voluntary state Model Guidelines does not require new state legislation.
- **Supports key tenets of SB 966.** While this option allows for convenient and low-cost disposal, it may fall short with respect to safety, but perhaps not more so than other options. CalRecycle is not aware of programs that offer perfect safety standards and complete protection from illegal diversion. In this case, mixing drugs with coffee grounds, for example, still renders them potentially consumable, but by placing the mixture in a nondescript container, it would be difficult for a person to know which container among thousands might have drugs. In this regard, this approach offers some safety and may be more effective than leaving expired or unwanted drugs at home or consolidating them at facilities where they can be abused or stolen. A concern to this approach is that pharmaceuticals in landfills may eventually end up in landfill leachate and enter surface and groundwater. However, available (though limited) research indicates that pharmaceutical emissions to water from landfills are generally low (see Appendix C: *Overview of Reports on Pharmaceuticals in Landfill Leachate*). This suggests that landfill disposal may be a viable alternative from an environmental benefit perspective.

The Legislature may consider that, in the short-term, public safety may be best served by encouraging landfill disposal in communities where no other options currently exist. For example, Option 1 could be implemented as a short-term solution, while efforts to implement Options 2 and 3 proceed, given that it would take time to enact authorizing legislation and develop and implement regulations. If this approach is used, it should be re-evaluated periodically because new laws and regulations may allow for easier collection of home-generated pharmaceuticals and this may allow other options to be implemented at a lower cost and more quickly.

## V. Source Reference Notes

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- <sup>32</sup> Ibid.
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Stanislaus, Inc. (50-AA-0009) available: <http://www.calrecycle.ca.gov/SWFacilities/Directory/50-AA-0009/Documents/Permit/752.PDF>

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- <sup>38</sup> "Prescription for Peril" Coalition Against Insurance Fraud, Available: <http://www.insurancefraud.org/drugDiversion.htm>
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- <sup>42</sup> California Department of Toxic Substances Control, website accessed on October 6 2010. [http://www.dtsc.ca.gov/AssessingRisk/PPCP/Pharmaceutical\\_Regulatory.cfm](http://www.dtsc.ca.gov/AssessingRisk/PPCP/Pharmaceutical_Regulatory.cfm)
- <sup>43</sup> Grasso, Cheri, et al., (2009) Secure Medicine Return in Washington State, The PH:ARM Pilot. Available: [www.medicinereturn.com/resources](http://www.medicinereturn.com/resources).
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- <sup>48</sup> Herold, Virginia, Executive Director, California Board of Pharmacy, SB 966 Pharmaceutical Drug Waste Disposal Program Workshop, July 20, 2010.
- <sup>49</sup> Zarrehparvar, Marjaneh, Program & Policy Coordinator, SF Environment Department Toxics Reduction Program, E-mail communication: October 6, 2010.
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- <sup>56</sup> “Walgreens Launches First Nationwide Safe Medication Disposal Program,” Walgreens, September 30, 2010, Available: [http://news.walgreens.com/article\\_display.cfm?article\\_id=5343](http://news.walgreens.com/article_display.cfm?article_id=5343).
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- <sup>58</sup> See [www.calrecycle.ca.gov/epr](http://www.calrecycle.ca.gov/epr) for more information on Product Stewardship, also known as Extended Producer Responsibility.
- <sup>59</sup> California Product Stewardship Council, Website: <http://www.calpsc.org>. Accessed on August 3, 2010.
- <sup>60</sup> CalRecycle, “Overall Framework for an Extended Producer Responsibility System in California,” <http://www.calrecycle.ca.gov/EPR/Framework/Framework.pdf>
- <sup>61</sup> Daughton, CG “[Drugs and the Environment: Stewardship & Sustainability](#),” National Exposure Research Laboratory, Environmental Sciences Division, US EPA, Las Vegas, NV; NERL-LV-ESD 10/081, EPA/600/R-10/106; September 12, 2010, 196 pp; available: <http://www.epa.gov/nerlesd1/bios/daughton/APM200-2010.pdf>.

# **Attachment 7**

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2010/2011

**Workload Statistics**                      **July-Sept**    **Oct-Dec**    **Jan-Mar**    **Apr-June**    **Total 10/11**

**Complaints/Investigations**

Received	565	592	608		1765
Closed	754	632	581		1967
Pending (at the end of quarter)	1151	1229	1290		1290

**Cases Assigned & Pending (by Team)**

Compliance Team	394	324	233		233
Drug Diversion/Fraud	98	121	141		141
Probation/PRP	85	82	67		67
Mediation/Enforcement	74	14	8		8
Criminal Conviction	475	518	479		479

**Application Investigations**

Received	181	217	151		549
Closed					
Approved	85	147	177		409
Denied	23	32	31		86
Total*	150	251	392		793
Pending (at the end of quarter)	448	432	205		205

**Letter of Admonishment (LOA) / Citation & Fine**

LOAs Issued	65	36	46		147
Citations Issued	307	293	192		792
Citations Closed	339	358	290		987
Total Fines Collected**	\$191,990.00	\$316,395.00	\$297,145.00		\$805,530.00

\* This figure includes withdrawn applications.

\*\* Fines collected (through 3/31/2011 and reports in previous fiscal year.)

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2010/2011

**Workload Statistics**                      **July-Sept**    **Oct-Dec**    **Jan-Mar**    **Apr-June**    **Total 10/11**

**Administrative Cases** (by effective date of decision)

Referred to AG's Office*	104	97	122		323
Pleadings Filed	82	65	55		202
<b>Pending</b>					
Pre-accusation	179	197	220		220
Post Accusation	254	271	242		242
Total*	508	496	516		516
<b>Closed**</b>					
<b>Revocation</b>					
Pharmacist	2	1	4		7
Pharmacy	0	0	0		0
Other	17	28	40		85
<b>Revocation, stayed; suspension/probation</b>					
Pharmacist	5	2	9		16
Pharmacy	0	0	0		0
Other	0	0	2		2
<b>Revocation, stayed; probation</b>					
Pharmacist	2	3	3		8
Pharmacy	1	2	6		9
Other	1	3	10		13
<b>Suspension, stayed; probation</b>					
Pharmacist	0	0	0		0
Pharmacy	0	0	0		0
Other	0	0	0		0
<b>Surrender/Voluntary Surrender</b>					
Pharmacist	2	1	3		6
Pharmacy	1	1	2		4
Other	12	8	8		28
<b>Public Reproval/Reprimand</b>					
Pharmacist	0	0	0		0
Pharmacy	0	0	0		0
Other	0	0	0		0
Cost Recovery Requested***	\$108,566.50	\$317,558.50	\$449,152.25		\$875,277.25
Cost Recovery Collected***	\$38,755.24	\$74,313.04	\$255,471.34		\$368,539.62

\* This figure includes Citation Appeals

\*\* This figure includes cases withdrawn

# Board of Pharmacy Enforcement Statistics Fiscal Year 2010/2011

<b>Workload Statistics</b>	<b>July-Sept</b>	<b>Oct-Dec</b>	<b>Jan-Mar</b>	<b>Apr-June</b>	<b>Total 10/11</b>
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\*\*\* This figure includes administrative penalties

# Board of Pharmacy Enforcement Statistics Fiscal Year 2010/2011

**Workload Statistics**                      **July-Sept**    **Oct-Dec**    **Jan-Mar**    **Apr-June**    **Total 10/11**

## Probation Statistics

Licenses on Probation

Pharmacist	99	103	100		100
Pharmacy	8	11	15		15
Other	27	30	33		33
Probation Office Conferences	51	26	64		64
Probation Site Inspections	36	53	55		55
Probationers Referred to AG for non-compliance	1	0	5		6

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 3/31/2011)

Program Statistics

In lieu of discipline	1	0	0		1
In addition to probation	3	3	0		6
Closed, successful	0	6	3		9
Closed, non-compliant	1	0	0		1
Closed, other	2	1	2		5
Total Board mandated Participants	45	55	45		45
Total Self-Referred Participants*	30	22	19		19
Treatment Contracts Reviewed	73	61	62		196

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 March 31, 2011

## Performance Measures

### Q3 Report (January – March 2011)

To ensure stakeholders can review the Board's progress toward meeting its enforcement goals and targets, we have developed a transparent system of performance measurement. These measures will be posted publicly on a quarterly basis.

In future reports, the Department will request additional measures, such as consumer satisfaction. These additional measures are being collected internally at this time and will be released once sufficient data is available.

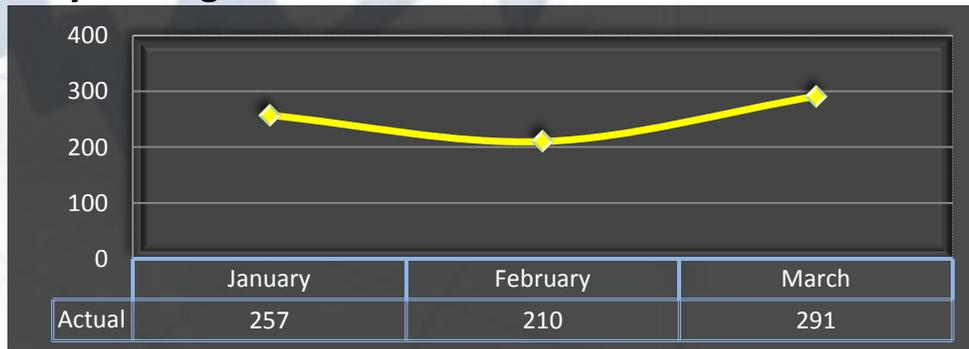
#### Volume

Number of complaints and convictions received.

**Q3 Total: 758**

*Complaints: 336 Convictions: 422*

**Q3 Monthly Average: 253**

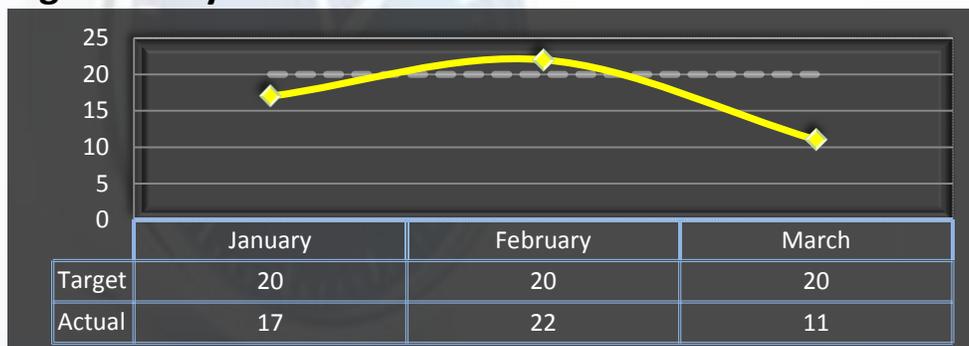


#### Intake

Average cycle time from complaint receipt, to the date the complaint was assigned to an investigator.

**Target: 20 Days**

**Q3 Average: 16 Days**

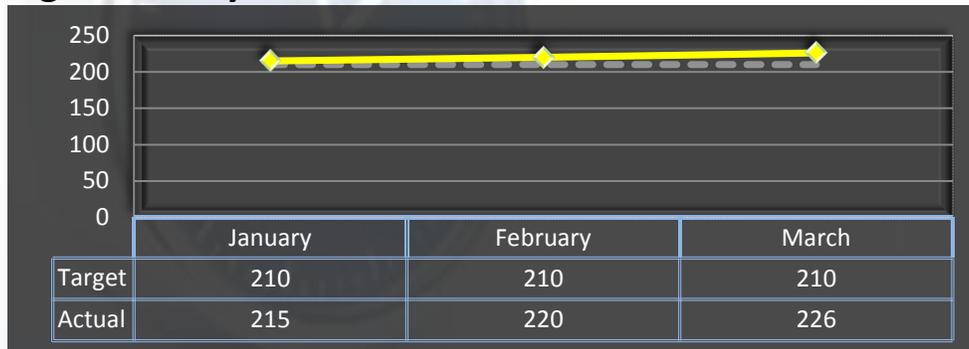


## Intake & Investigation

Average cycle time from complaint receipt to closure of the investigation process. Does not include cases sent to the Attorney General or other forms of formal discipline.

**Target: 210 Days**

**Q3 Average: 221 Days**

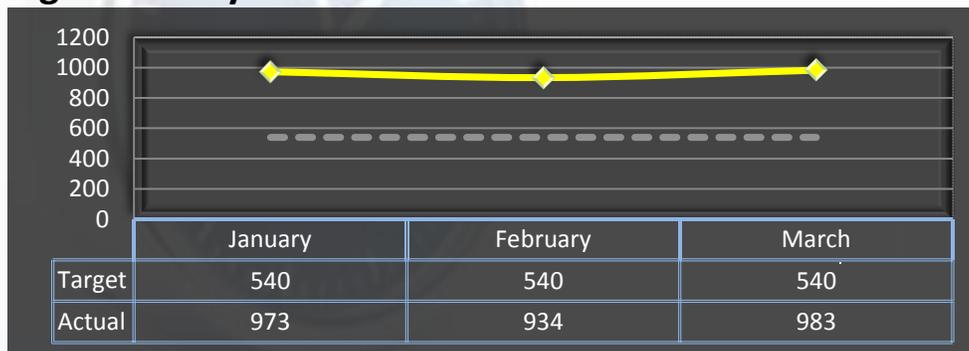


## Formal Discipline

Average number of days to complete the entire enforcement process for cases resulting in formal discipline. (Includes intake and investigation by the Board, and prosecution by the AG)

**Target: 540 Days**

**Q3 Average: 970 Days**

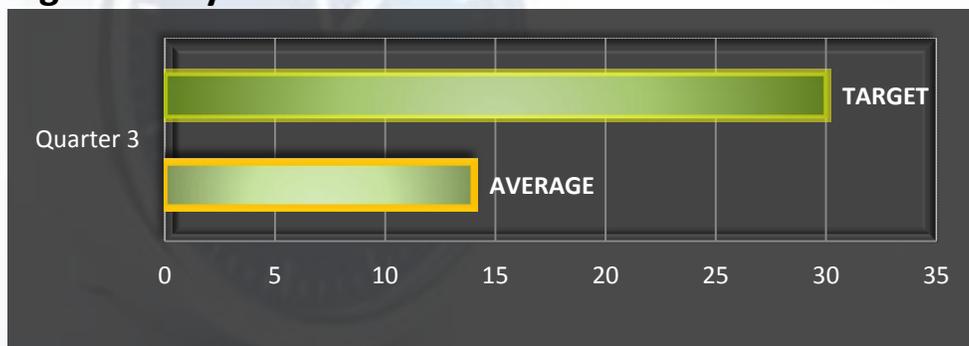


## Probation Intake

Average number of days from monitor assignment, to the date the monitor makes first contact with the probationer.

**Target: 30 Days**

**Q3 Average: 14 Days**

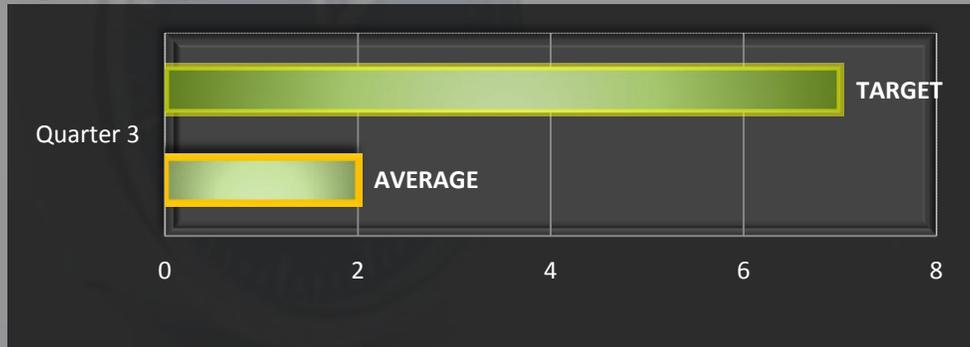


## Probation Violation Response

Average number of days from the date a violation of probation is reported, to the date the assigned monitor initiates appropriate action.

**Target: 7 Days**

**Q3 Average: 2 Days**



**Note:** Due to the budget crisis, Board of Pharmacy currently has 24 enforcement unit vacancies which cannot be filled. This has adversely affected enforcement cycle times.

# **Attachment 8**

# 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	547	145 26%	45 8%	80 15%	277 51%	276
	Qtr 2	550	177 32%	59 11%	82 15%	232 42%	202
	Qtr 3	690	166 24%	80 12%	104 15%	340 49%	209
	Qtr 4						
	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	363	140 38%	93 26%	75 21%	55 15%	195
	Qtr 2	333	113 34%	77 23%	81 24%	62 19%	181
	Qtr 3	283	125 44%	35 12%	70 25%	53 19%	165
	Qtr 4						
	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.

<b>Qtr 1</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals	407	298	45	14	50
Closed 4301 letters, license denials, withdrawn by Board	169	81	23	38	27
Cite and/or fine letter of admonishment	248	99	63	28	57
Attorney General's Office	87	25	19	13	30
<b>Qtr 2</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals	424	300	59	41	24
Closed 4301 letters, license denials, withdrawn by Board	202	95	34	35	38
Cite and/or fine letter of admonishment	161	62	44	24	31
Attorney General's Office	96	25	31	14	26
<b>Qtr 3</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals	444	298	73	37	36
Closed 4301 letters, license denials, withdrawn by Board	286	108	70	54	54
Cite and/or fine letter of admonishment	158	70	53	21	14
Attorney General's Office	85	34	16	20	15
<b>Qtr 4</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals					
Closed 4301 letters, license denials, withdrawn by Board					
Cite and/or fine letter of admonishment					
Attorney General's Office					

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><b>1. Administer the Pharmacists Recovery Program.</b></p> <table border="1" data-bbox="365 241 1511 531"> <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>30</td> <td>45</td> <td>1</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>22</td> <td>55</td> <td>0</td> <td>6</td> </tr> <tr> <td>Qtr 3</td> <td>19</td> <td>55</td> <td>0</td> <td>3</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program	Qtr 1	30	45	1	0	Qtr 2	22	55	0	6	Qtr 3	19	55	0	3	Qtr 4													
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	Qtr 2	22	55	0	6																														
	Qtr 3	19	55	0	3																														
Qtr 4																																			
<p><b>2. Administer the Probation Monitoring Program.</b></p> <table border="1" data-bbox="365 598 1235 909"> <thead> <tr> <th></th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Individuals</td> <td>122</td> <td>129</td> <td>132</td> <td></td> </tr> <tr> <td>Sites</td> <td>10</td> <td>14</td> <td>18</td> <td></td> </tr> <tr> <td>Tolled</td> <td>34</td> <td>29</td> <td>28</td> <td></td> </tr> <tr> <td>Inspections Conducted</td> <td>51</td> <td>53</td> <td>53</td> <td></td> </tr> <tr> <td>Successfully Completed</td> <td>8</td> <td>4</td> <td>4</td> <td></td> </tr> <tr> <td>Petitions to Revoke Filed</td> <td>2</td> <td>9</td> <td>1</td> <td></td> </tr> </tbody> </table>		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Individuals	122	129	132		Sites	10	14	18		Tolled	34	29	28		Inspections Conducted	51	53	53		Successfully Completed	8	4	4		Petitions to Revoke Filed	2	9	1	
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Petitions to Revoke Filed	2	9	1																																
<p><b>3. Issue all citations and fines within 30 days.</b></p> <table border="1" data-bbox="365 976 1414 1371"> <thead> <tr> <th></th> <th><u>N</u></th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th><u>Average Days</u></th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>312</td> <td>200 64%</td> <td>107 34%</td> <td>5 2%</td> <td>0 0%</td> <td>26</td> </tr> <tr> <td>Qtr 2</td> <td>263</td> <td>230 87%</td> <td>11 4%</td> <td>20 8%</td> <td>2 1%</td> <td>20</td> </tr> <tr> <td>Qtr 3</td> <td>195</td> <td>94 48%</td> <td>58 30%</td> <td>42 22%</td> <td>1 1%</td> <td>39</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	Qtr 1	312	200 64%	107 34%	5 2%	0 0%	26	Qtr 2	263	230 87%	11 4%	20 8%	2 1%	20	Qtr 3	195	94 48%	58 30%	42 22%	1 1%	39	Qtr 4						
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Qtr 4																																			

5. Obtain immediate public protection sanctions for egregious violations.

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

6. Submit petitions to revoke probation within 30 days once noncompliance with terms of probation is substantiated.

	30 days	60 days	> 60 days	<u>N</u>
Qtr 1	1	1	7	9
Qtr 2	5	0	0	5
Qtr 3	2	1	0	3
Qtr 4				

Objective 1.3	Achieve 100 percent closure on all administrative cases within 1 year.																																															
Measure:	Percentage of administrative cases closed within 1 year.																																															
Tasks:	1. File pleadings within 90 days of referral.																																															
	<table border="1" data-bbox="370 254 1430 464"> <thead> <tr> <th></th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Number of Cases Referred to Attorney General's Office</td> <td>88</td> <td>97</td> <td>89</td> <td></td> </tr> <tr> <td>Accusations Filed</td> <td>74</td> <td>46</td> <td>48</td> <td></td> </tr> <tr> <td>Statement of Issues Filed</td> <td>6</td> <td>10</td> <td>6</td> <td></td> </tr> <tr> <td>Petitions to Revoke Probation Filed</td> <td>2</td> <td>9</td> <td>1</td> <td></td> </tr> </tbody> </table>									Qtr 1	Qtr 2	Qtr 3	Qtr 4	Number of Cases Referred to Attorney General's Office	88	97	89		Accusations Filed	74	46	48		Statement of Issues Filed	6	10	6		Petitions to Revoke Probation Filed	2	9	1																
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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="370 216 1479 285">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="370 285 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>43</td> <td>499</td> <td>6%</td> </tr> <tr> <td>Qtr 2</td> <td>37</td> <td>536</td> <td>6%</td> </tr> <tr> <td>Qtr 3</td> <td>31</td> <td>567</td> <td>6%</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="370 541 1414 611">2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</p> <table border="1" data-bbox="370 611 1166 831"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>50</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>165</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td>65</td> <td>0</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="370 867 1471 905">3. Initiate investigations based upon violations discovered during routine inspections.</p> <table border="1" data-bbox="370 905 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>43</td> <td>7</td> <td>16%</td> </tr> <tr> <td>Qtr 2</td> <td>37</td> <td>9</td> <td>24%</td> </tr> <tr> <td>Qtr 3</td> <td>31</td> <td>10</td> <td>32%</td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	43	499	6%	Qtr 2	37	536	6%	Qtr 3	31	567	6%	Qtr 4					Number of Inspections	Number Inspected Late	Qtr 1	50	0	Qtr 2	165	0	Qtr 3	65	0	Qtr 4				Number of Inspections	Number of Investigations Opened	Percent Opened	Qtr 1	43	7	16%	Qtr 2	37	9	24%	Qtr 3	31	10	32%	Qtr 4			
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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 842"> <p><b>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</b></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> <p><i>Oct. 2010: Executive Officer provides information about California's requirements to a GS1 training session in San Francisco.</i></p> <p><i>Feb. 2010: Executive Officer provides presentation on California's e-pedigree requirements at FDA workshop on developing a track and trace.</i></p> </li> <li data-bbox="370 842 1487 1066"> <p><b>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.</b></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> <li data-bbox="370 1066 1487 1646"> <p><b>3. Monitor the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.</b></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> <p><i>Jan. 2011: Board prepares guidance document for pharmacies and prescribers.</i></p> <p><i>May 2011: Medical Board reviews guidance document prepared to approve portion for prescribers.</i></p> </li> </ol>

4. **Evaluate establishment of an ethics course as an enforcement option.**
  - Oct. 2008: Board holds regulation hearing on proposed requirements for the ethics class.*
  - Jan. 2009: Board adopts regulation.*
  - Sept. 2009: Regulation takes effect.*
  - 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.*
  - Oct. 2010: First course provided.*
  - March 2011: Second provider begins offering course.*
5. **Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.**
  - Dec. 2009: Executive Officer provides presentation on California's e-pedigree requirements to three national association meetings.*
  - 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).*
  - March 2011: Executive Officer participates in PEW Trust's public forum on what was learned about the 2008 heparin adulteration.*
  - April 2011: DEA and board cohost day-long conference for pharmacies of controlled substances. Due to interest and success, more conferences planned.*
6. **Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.**
  - Sep. 2007: Provided comments on proposed statutory requirements.*
  - Dec 2007: Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.*
  - Provided comments on proposed e-prescribing initiatives.*
  - Oct. 2008: Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.*
  - Nov. 2008: Board hosts conference on e-prescribing as part of department's professionals Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.*
  - Jan. 2009: Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.*
  - March 2009: Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.*
  - April 2010: Board reviews Drug Enforcement Agency proposed regulations on e-prescribing of controlled substance.*
  - Nov. 2010: Executive Officer provides presentations at annual California e-prescribing meeting.*
  - Jan. 2011: Board prepares guidance document for pharmacies on DEA's requirements.*
  - May 2011: Medical Board reviews same guidance document for prescribers.*
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.**
  - Oct. 2008: Requirements for security forms in place..*
  - 2nd Qtr 09-10: Board executive staff and several board members attend California Healthcare Foundation's annual summit to implement e-prescribing.*

- 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.*
- 2nd Qtr 10/11:** *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.*

**3rd Qtr 10/11:** 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.  
Executive staff attend joint meeting with California District Attorneys Association.

**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.

**Aug. 2010:** Executive Officer provides information regarding board policy on drug take back programs in pharmacies to CalRecycle and its draft report on model take back programs. Written comments are later provided on behalf of the board.

**Jan. 2011:** Board reviews final version of CalRecycle's report.

**May 2011:** Final report released.

**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.

**2011:** Board receives copies of drug recalls at the pharmacy level and releases them through the subscriber alert system.

**March 2011:** Board participates in international conference convened by the PEW Trust on the 2008 heparin contamination to identify ways to prevent a reoccurrence.

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.*  
*1st/2nd Qtr 10/11: Proposed changes to Board Disciplinary Guidelines drafted. Staff continue working with DCA on standards.*  
*2nd Qtr 10/11: Board staff begin incorporating standards for Board consideration.*  
*3rd Qtr 10/11: Changes to standards are approved by Substance Abuse Coordination Committee.*
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.*  
*1st/2nd Qtr 10/11: Board sponsors legislation to secure records more timely from licensees.*  
*Board conducts civil service exams for inspector and supervising inspector classifications. Hiring freeze prevents hiring of staff.*  
*2nd Qtr 10/11: Board submits freeze exemptions, all are denied.*  
*3rd Qtr 10/11: Governor Brown established a formal hiring freeze.*  
*New hiring freeze exemptions prepared for eight inspector positions.*  
*4th Qtr 10/11: Board staff secure an exemption to hire eight inspectors.*
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.*

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|  | <p>15. Complete comprehensive review of investigative and enforcement internal processing to identify process improvements.</p> <p><i>1st Qtr 09/10: Board staff implemented on-line assignment of investigations.<br/>Board staff implemented on-line review of draft pleadings.</i></p> <p><i>2nd Qtr 09/10: Board staff began drafting Default Decision and Orders.</i></p> <p><i>4th Qtr 09/10: Board staff began drafting Petition to Revoke Probation Pleadings.<br/>Board staff implemented a pilot program to provide pre-populated investigation reports to the Compliance Team.</i></p> <p><i>3rd Qtr 10/11: Board staff review citation and fine program.</i></p> <p>16. Complete review of pharmacies dispensing prescriptions for Internet web site operators.</p> <p><i>2010: Updates on disciplinary actions provided at board meetings and in <u>The Script</u>.</i></p> <p>17. Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB).</p> <p><i>1st Qtr 10/11: 656 reports submitted (includes initial and revised submissions).</i></p> <p><i>2nd Qtr 10/11: 334 reports submitted (includes initial submissions).</i></p> <p><i>3rd Qtr 10/11: 432 reports submitted.</i></p> |
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