



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Enforcement Committee Report

Randy Kajioka, PharmD, Chair
Greg Lippe, Public Board Member
Neil Badlani, Pharmacist Member
Tappan Zee, Public Board Member

ENFORCEMENT COMMITTEE REPORT AND ACTION

There was no meeting of the Enforcement Committee this quarter.

- a. **FOR INFORMATION: Presentation of an Overview of California's Pharmacists Recovery Program (PRP) as Provided in Business and Professions Code Sections 4360 et. seq**

Attachment 1

Relevant Statutes

Business and Professions Code, Chapter 9, Division 2, Article 21, Sections 4360 et seq., establishes the board's mandate to operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. This article also sets forth the general parameters for this program.

During this meeting, the board will receive a presentation on the statutory requirements for the PRP as well as the program parameters established in the contract.

Attachment 1 contains Article 21.

- b. **FOR POSSIBLE ACTION: Discussion of the Future of CURES Following Budget Reductions to the Department of Justice, Bureau of Narcotic Enforcement**

Attachment 2

Part of the Governor's 2011-12 budget included substantial reduction to the Department of Justice's Bureau of Narcotic Enforcement. This is the unit that house's California's CURES program, a prescription monitoring program for controlled substances in schedules II-IV.

This is an important program to this board and is used in drug diversion enforcement actions. For the last several months the board has received inquiries about the status of the program. Licensees have reported problems in reaching the board. Board staff also have had difficulty in contacting program staff.

At the request of board staff, a meeting is scheduled with DOJ staff for January 26, 2012 to discuss the status of the program. At this meeting, the executive officer will provide an update on the CURES program.

Attachment 2 contains a copy of Health and Safety Code Section 11165 – 11165.3, which establishes and defines the parameters and use of the CURES program.

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

Attachment 3

The board's enforcement statistics are provided in **Attachment 3** as well as the performance statistics compiled by the DCA. The reporting of the board's enforcement statistics not include some of the reporting requirements established in SB 1441 Uniform Standards.

d. **FOR INFORMATION: Second Quarterly Update of the Committee's Strategic Performance Goals 2011/12.**

Attachment 4

Attachment 4 contains the second quarter's update report on the committee's strategic plan.

Article 21. Pharmacists Recovery Program

4360. Impaired Pharmacists: Legislative Intent

The board shall operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.

4361. Definitions

(a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.

(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacists.

4362. Function of Program: Board Referrals; Voluntary, Confidential Participation

(a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

(1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.

(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on his or her entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

4364. Criteria for Participation to be Established by Board

(a) The board shall establish criteria for the participation of pharmacists and intern pharmacists in the pharmacists recovery program.

(b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.

(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

4365. Contracting with Employee Assistance Program: Selection

The board shall contract with one or more qualified contractors to administer the pharmacists recovery program.

4366. Function of the Employee Assistance Program

The functions of the contractor administering the pharmacists recovery program shall include, but not be limited to, the following:

(a) To evaluate those pharmacists and intern pharmacists who request participation in the program.

(b) To develop a treatment contract with each participant in the pharmacists recovery program.

(c) To monitor the compliance of each participant with their treatment contract.

(d) To prepare reports as required by the board.

(e) To inform each participant of the procedures followed in the program.

(f) To inform each participant of their rights and responsibilities in the program.

(g) To inform each participant of the possible consequences of noncompliance with the program.

4369. Board Referrals to Program: Written Information Provided to Licensee; Termination for Non-Compliance; Report to Board of Termination; Authority to Discipline

(a) Any failure to comply with the treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the pharmacist's or intern pharmacist's participation in the pharmacists recovery program. The name and license number of a pharmacist or intern pharmacist who is terminated from the pharmacists recovery program and the basis for the termination shall be reported to the board.

(b) Participation in the pharmacists recovery program shall not be a defense to any disciplinary action that may be taken by the board.

(c) No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program.

4371. Review of Program Activities

(a) The executive officer of the board shall designate a program manager of the pharmacists recovery program. The program manager shall have background experience in dealing with substance abuse issues.

(b) The program manager shall review the pharmacists recovery program on a quarterly basis. As part of this evaluation, the program manager shall review files of all participants in the pharmacists recovery program.

(c) The program manager shall work with the contractor administering the pharmacists recovery program to evaluate participants in the program according to established guidelines and to develop treatment contracts and evaluate participant progress in the program.

4372. Confidential Records; Exception for Disciplinary Proceeding

All board records and records of the pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery, subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code. However, board records and records of the pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

4373. Immunity from Civil Liability

No member of the board shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

Health and Safety Code Section

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The department may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the **Code** of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber

using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug **Code**) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis **code**), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may provide a notarized application developed by the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient maintained within the Department of Justice, and the department may release to that practitioner or pharmacist, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(A) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal Drug Enforcement Administration (DEA) registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(B) Any authorized subscriber shall notify the Department of Justice within 10 days of any changes to the subscriber account.

(2) To allow sufficient time for licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and a pharmacist to apply and receive access to PDMP, a written request may be made, until July 1, 2012, and the Department of Justice may release to that practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate

the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil **Code**.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the **Code** of Federal Regulations.

11165.2. (a) The Department of Justice may conduct audits of the CURES Prescription Drug Monitoring Program system and its users.

(b) The Department of Justice may establish, by regulation, a system for the issuance to a CURES Prescription Drug Monitoring Program subscriber of a citation which may contain an order of abatement, or an order to pay an administrative fine assessed by the Department of Justice if the subscriber is in violation of any provision of this chapter or any regulation adopted by the Department of Justice pursuant to this chapter.

(c) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement establishing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars (\$2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the subscribers, and the history of previous violations.

(4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the subscriber that if the subscriber desires a hearing to contest the finding of a violation, a hearing shall be requested by written notice to the CURES Prescription Drug Monitoring Program within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government **Code**.

(5) In addition to requesting a hearing, the subscriber may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied or the order of abatement which could include permanent suspension to the system, a monetary fine, or both, depending on the gravity of the violation. However, the subscriber does not waive its right to request a hearing to

contest a citation by requesting an informal conference. If the citation is affirmed, a formal hearing may be requested within 30 days of the date the citation was affirmed. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

(6) Failure of a subscriber to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action taken by the department. If a citation is not contested and a fine is not paid, the subscriber account will be terminated:

(A) A citation may be issued without the assessment of an administrative fine.

(B) Assessment of administrative fines may be limited to only particular violations of law or department regulations.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as a satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the CURES Program Special Fund, available upon appropriation by the Legislature. These special funds shall provide support for costs associated with informal and formal hearings, maintenance, and updates to the CURES Prescription Drug Monitoring Program.

(f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action may not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.

(g) Nothing in this section shall be deemed to prevent the department from serving and prosecuting an accusation to suspend or revoke a subscriber if grounds for that suspension or revocation exist.

11165.3. The theft or loss of prescription forms shall be reported immediately by the security printer or affected prescriber to the CURES Prescription Drug Monitoring Program, but no later than three days after the discovery of the theft or loss. This notification may be done in writing utilizing the Bureau of Narcotic Enforcement 1175 Reporting Theft/Loss Form or may be reported by the authorized subscriber through the CURES Prescription Drug Monitoring Program.

Board of Pharmacy Enforcement Statistics

Fiscal Year 2011/2012

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 11/12**

Complaints/Investigations

Received	611	610			1221
Closed	413	450			863
Pending (at the end of quarter)	1772	1849			1849

Cases Assigned & Pending (by Team) at end of quarter*

Compliance Team	537	584			584
Drug Diversion/Fraud	226	318			318
Probation/PRP	101	119			119
Routine Inspection	33	85			85
Mediation/Enforcement **	64	82			82
Criminal Conviction	561	661			661

Application Investigations

Received	217	379			596
Closed					
Approved	135	137			272
Denied	18	27			45
Total ***	243	224			467
Pending (at the end of quarter)	209	363			363

Letter of Admonishment (LOA) / Citation & Fine

LOAs Issued	20	21			41
Citations Issued	239	127			366
Citations Closed	273	190			463
Total Fines Collected ****	\$319,115.00	\$198,405.00			\$517,520.00

* This figure include reports submitted to the supervisor.

** This figure include reports submitted to the citation and fine unit.

*** This figure includes withdrawn applications.

****Fines collected (through 12/31/2011 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics

Fiscal Year 2011/2012

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 11/12**

Administrative Cases (by effective date of decision)

Referred to AG's Office*	85	49			134
Pleadings Filed	61	56			117
Pending					
Pre-accusation	194	175			175
Post Accusation	279	265			265
Total*	533	515			515
Closed					
Revocation					
Pharmacist	2	4			6
Intern Pharmacist	0	1			1
Pharmacy Technician	16	28			44
Designated Representative	1	0			1
Pharmacy	0	0			0
Revocation, stayed; suspension/probation					
Pharmacist	2	3			5
Intern Pharmacist	0	0			0
Pharmacy Technician	1	0			1
Designated Representative	0	0			0
Pharmacy	0	0			0
Revocation, stayed; probation					
Pharmacist	3	5			8
Intern Pharmacist	0	0			0
Pharmacy Technician	6	5			11
Designated Representative	0	0			0
Pharmacy	3	3			6
Surrender/Voluntary Surrender					
Pharmacist	0	3			3
Intern Pharmacist	0	0			0
Pharmacy Technician	7	8			15
Designated Representative	0	0			0
Pharmacy	0	1			1

Board of Pharmacy Enforcement Statistics

Fiscal Year 2011/2012

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 11/12
Public Repeval/Reprimand					
Pharmacist	0	1			0
Intern Pharmacist	0	0			0
Pharmacy Technician	0	0			0
Designated Representative	0	0			0
Pharmacy	0	0			0
Cost Recovery Requested**	\$88,205.00	\$285,189.20			\$373,394.20
Cost Recovery Collected**	\$78,117.99	\$65,379.59			\$143,497.58

* This figure includes Citation Appeals

** This figure includes administrative penalties

Probation Statistics

Licenses on Probation

Pharmacist	111	110			110
Intern Pharmacist	5	3			3
Pharmacy Technician	31	35			35
Designated Representative	2	2			2
Pharmacy	18	20			20
Wholesaler	2	3			3
Probation Office Conferences	17	40			57
Probation Site Inspections	73	66			139
Probationers Referred to AG for non-compliance	2	1			3

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.

As of December 31, 2011

SB 1441 – Program Statistics

Pharmacist Recovery Program (PRP)

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 11/12
PRP Self-Referrals	6	5			11
PRP Board Referrals	3	0			3
PRP Intakes	9	5			14
New Probationers					
New Probationers	9	9			18
Pharmacists	2	3			5
Interns	0	0			0
Technicians	7	6			13
Total PRP Participants					
Total PRP Participants	76	81			NA
Contracts Reviewed	70	76			146
					0
Total Probationers	100	95			NA
Inspections Completed	97	106			203
Referrals to Treatment					
Referrals to Treatment	4	3			7
Drug Test Ordered	967	1076			2043
Drug Tests Conducted	937	1018			1955
Relapsed					
Relapsed	5	4			9
Major Violation Actions					
Cease Practice/Suspension	8	7			15
Termination - PRP	3	2			5
Referral for Discipline	3	2			5
Exit from PRP or Probation					
Successful Completion	2	3			5
Termination - Probation	2	3			5
Voluntary Surrender	2	1			3
Surrender as a result of PTR	0	1			1
Public Risk	3	2			5
Non-compliance	19	11			30
Other	1	2			3
Number of Patients Harmed					
Number of Patients Harmed	0				0
Drug of Choice at PRP Intake or Probation					
Pharmacists	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 11/12
Alcohol	9	3			12
Opiates	3				3
Hydrocodone	2	4			6
Oxycodone		1			1
Benzodiazepines		1			1
Barbiturates	1				1
Marijuana					0
Heroin					0
Cocaine	1				1
Methamphetamine					0
Pharmaceutical Amphetamine		1			1
Phentermine					0

Methadone					0
Zolpidem Tartrate					0
Hydromorphone		1			1
Promethazine w/Codeine		1			1
Intern Pharmacists	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 11/12
Alcohol					0
Opiates					0
Hydrocodone					0
Oxycodone					0
Benzodiazepines					0
Barbiturates					0
Marijuana					0
Heroin					0
Cocaine					0
Methamphetamine					0
Pharmaceutical Amphetamine					0
Phentermine					0
Methadone					0
Zolpidem Tartrate					0
Hydromorphone		1			1
Promethazine w/Codeine		1			1
Pharmacy Technicians	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 11/12
Alcohol	3	2			5
Opiates					0
Hydrocodone	1	1			2
Oxycodone					0
Benzodiazepines	1				1
Barbiturates					0
Marijuana	3				3
Heroin					0
Cocaine					0
Methamphetamine	2	1			3
Pharmaceutical Amphetamine					0
Phentermine	1				1
Methadone		1			1
Zolpidem Tartrate	1				1
Hydromorphone					0
Promethazine w/Codeine					0
Pharmacist Recovery Program	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 11/12
Participant Files Audited		6			

Performance Measures

Q2 Report (October - December 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.

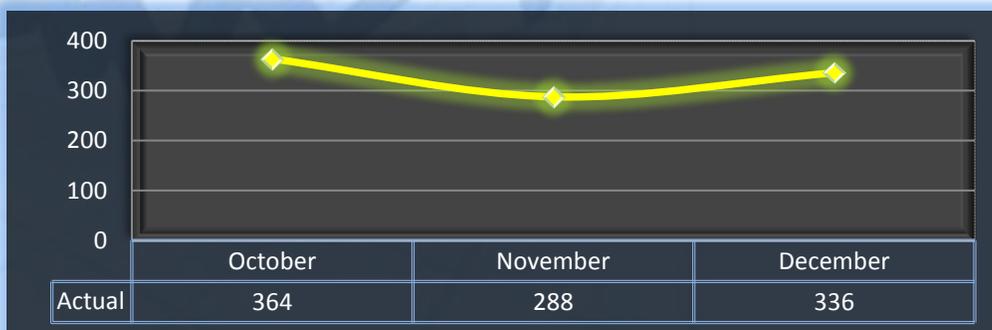
Volume

Number of complaints and convictions received.

Q2 Total: 988

Complaints: 393 Convictions: 595

Q2 Monthly Average: 329

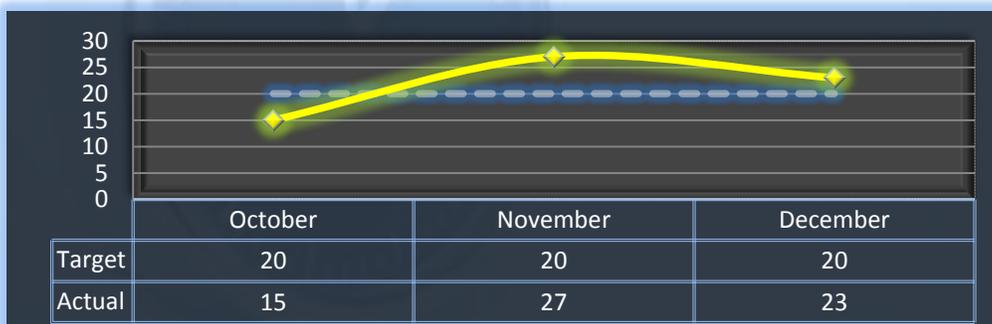


Intake

Average cycle time from complaint receipt, to the date the complaint was assigned to an investigator.

Target: 20 Days

Q2 Average: 22 Days

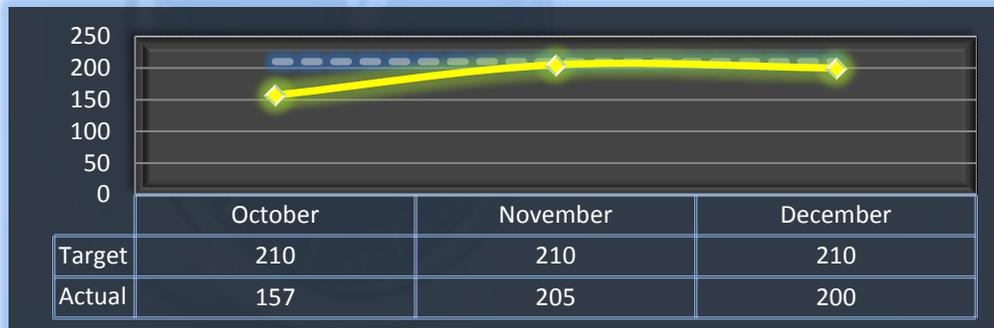


Intake & Investigation

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

Q2 Average: 192 Days

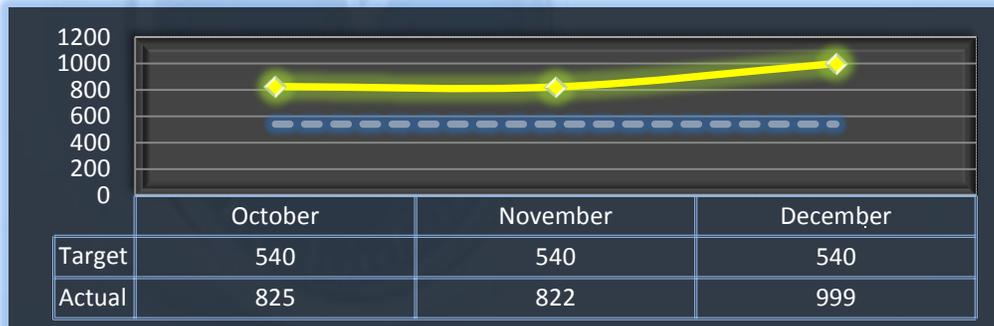


Formal Discipline

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

Q2 Average: 862 Days

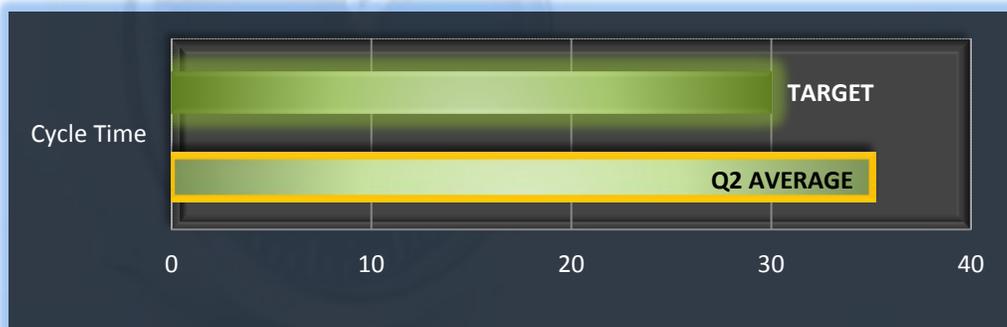


Probation Intake

Average number of days from monitor assignment, to the date the monitor makes first contact with the probationer.

Target: 30 Days

Q2 Average: 35 Days

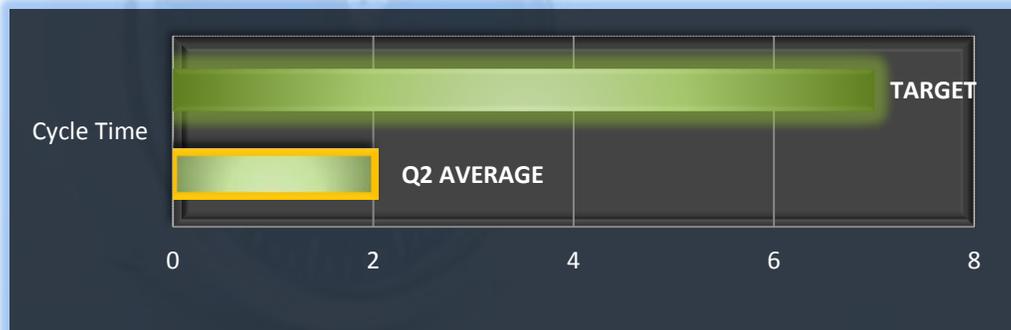


Probation Violation Response

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

Q2 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.

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	383	135	51	91	106	164
			35%	13%	24%	28%	
	Qtr 2	379	172	30	58	119	135
			45%	8%	15%	32%	
	Qtr 3						
	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	275	123	50	37	65	187
			45%	18%	13%	24%	
	Qtr 2	220	111	34	34	41	159
			51%	15%	15%	19%	
	Qtr 3						
	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.

Qtr 1	N	< 180	< 270	< 365	> 365
Closed investigations, no additional action, license approvals	298	242	25	14	17
Closed 4301 letters, license denials, withdrawn by Board	138	112	12	6	8
Cite and/or fine letter of admonishment	138	62	22	12	42
Attorney General's Office	84	34	29	6	15
Qtr 2	N	< 180	< 270	< 365	> 365
Closed investigations, no additional action, license approvals	348	273	47	20	8
Closed 4301 letters, license denials, withdrawn by Board	123	81	34	5	3
Cite and/or fine letter of admonishment	89	35	29	8	17
Attorney General's Office	39	16	12	9	2
Qtr 3	N	< 180	< 270	< 365	> 365
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					
Qtr 4	N	< 180	< 270	< 365	> 365
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:	1. Administer the Pharmacists Recovery Program.						
		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program		
	Qtr 1	25	51	3	1		
	Qtr 2	26	55	2	1		
	Qtr 3						
	Qtr 4						
	2. Administer the Probation Monitoring Program.						
		Qtr 1	Qtr 2	Qtr 3	Qtr 4		
	Individuals	151	156				
	Sites	20	24				
	Tolled	28	27				
	Inspections Conducted	67	66				
	Successfully Completed	4	4				
	Petitions to Revoke Filed	3	2				
	3. Issue all citations and fines within 30 days.						
	<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	
Qtr 1	241	141	90	9	1	31	
		59%	37%	4%	.4%		
Qtr 2	128	95	13	10	10	29	
		74%	10%	8%	8%		
Qtr 3							
Qtr 4							
4. Issue letters of admonishment within 30 days.							
	<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	
Qtr 1	15	10	5	0	0	25	
		67%	33%	0%	0%		
Qtr 2	15	12	1	2	0	24	
		80%	7%	13%	0%		
Qtr 3							
Qtr 4							

These data are actual number of citations and letters of admonishment (LOA) issued.
One investigation may have multiple licensees that are issued a citation or LOA (split cases).

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	2	0	0
Qtr 2	1	1	0
Qtr 3			
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	0	0	0	0
Qtr 2	1	1	11	4
Qtr 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.																																																															
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Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/14.																																																							
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																																																							
Tasks:	<p data-bbox="370 220 1479 289">1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.</p> <table border="1" data-bbox="370 289 1479 506"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Aggregate Inspections This Cycle</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>449</td> <td>449</td> <td>5%</td> </tr> <tr> <td>Qtr 2</td> <td>572</td> <td>884</td> <td>9%</td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="370 548 1414 617">2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</p> <table border="1" data-bbox="370 617 1166 833"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>81</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>85</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> </tr> </tbody> </table> <p data-bbox="370 875 1471 909">3. Initiate investigations based upon violations discovered during routine inspections.</p> <table border="1" data-bbox="370 909 1479 1125"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number of Investigations Opened</th> <th>Percent Opened</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>530</td> <td>60</td> <td>11%</td> </tr> <tr> <td>Qtr 2</td> <td>572</td> <td>46</td> <td>8%</td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></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	449	449	5%	Qtr 2	572	884	9%	Qtr 3				Qtr 4					Number of Inspections	Number Inspected Late	Qtr 1	81	0	Qtr 2	85	0	Qtr 3			Qtr 4				Number of Inspections	Number of Investigations Opened	Percent Opened	Qtr 1	530	60	11%	Qtr 2	572	46	8%	Qtr 3				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="365 220 1485 840"> <p>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</p> <p><i>Oct. 2009: Executive Officer provides information about California's e-pedigree requirements at a SecurePharma Conference of drug manufacturers and wholesalers in Philadelphia and at a SpecialtyPharma Conference (contract drug manufacturers) in Phoenix.</i></p> <p><i>Dec. 2009: Executive Officer provides information about California's e-pedigree requirements at the Health Care Distributors Association Trace and Track Conference in Washington D.C.</i></p> <p><i>March 2010: Executive Officer provides information about California's e-pedigree requirements via a Webinar hosted by IBS.</i></p> <p><i>April 2010: Board reviews Food and Drug Administration guidance on a unique serialized identifier released March 26.</i></p> <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 data-bbox="365 850 1485 1060"> <p>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.</p> <p><i>Sep. 2006: Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.</i></p> <p><i>Oct. 2006: Board adds Consumer friendly materials regarding sales of these drugs to its website.</i></p> <li data-bbox="365 1071 1485 1642"> <p>3. Monitor the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.</p> <p><i>Nov. 2006: Board submits letter supporting change in Drug Enforcement Administration policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.</i></p> <p><i>Sep. 2008: Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.</i></p> <p><i>Dec. 2009: Executive Officer meets with DEA officials in Washington D.C. to discuss interest in e-prescribing of controlled drugs.</i></p> <p><i>April 2010: Board reviews proposed Drug Enforcement Administration requirements for electronic prescribing of controlled substances.</i></p> <p><i>June 2010: Enforcement Committee received updates on DEA rule change.</i></p> <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>

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.*
- 4th Qtr 10/11: Board updated on progress of language development and incorporated into disciplinary guidelines for Board consideration. Board staff initiate review of reporting requirements.*
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. Board staff secure a second exemption to hire three additional inspectors. Six new staff begin. Training is limited because of travel restrictions.*

14. **Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions.**
*1st Qtr 09/10: Unit created via budget change proposal, 6.5 staff hired, trained, initiate work.
There are 1,287 rapsheet investigations under review.*
2nd Qtr 09/10: There are 1,037 rapsheet investigations under review.
3rd Qtr 09/10: There are 652 rapsheet investigations under review.
*4th Qtr 09/10: Post implementation review of Criminal Conviction Unit completed.
Enforcement Committee advised of new unit outcomes.*
15. **Complete comprehensive review of investigative and enforcement internal processing to identify process improvements.**
*1st Qtr 09/10: Board staff implemented on-line assignment of investigations.
Board staff implemented on-line review of draft pleadings.*
2nd Qtr 09/10: Board staff began drafting Default Decision and Orders.
*4th Qtr 09/10: Board staff began drafting Petition to Revoke Probation Pleadings.
Board staff implemented a pilot program to provide pre-populated investigation reports to the Compliance Team.*
3rd Qtr 10/11: Board staff review citation and fine program.
4th Qtr 10/11: Board staff evaluates complaints closed without findings to ensure integrity of the process. Some deficiencies noted. Process improvements identified and staff educated.
16. **Complete review of pharmacies dispensing prescriptions for Internet web site operators.**
2010: Updates on disciplinary actions provided at board meetings and in The Script.
17. **Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB).**
1st Qtr 10/11: 656 reports submitted (includes initial and revised submissions).
2nd Qtr 10/11: 334 reports submitted (includes initial submissions).
3rd Qtr 10/11: 432 reports submitted.
4th Qtr 10/11: 96 reports submitted. Position vacant effective September 2011 due to employee retirement. Recruitment pending with Department of Consumer Affairs Human Resources.
1st Qtr 11/12: 65 reports submitted.
2nd Qtr 11/12: 23 reports submitted.