



**California State Board of Pharmacy**

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

## **Enforcement Committee Report**

Ramón Castellblanch, PhD, Board Member  
Randy Kajioka, PharmD, Board Member  
Greg Lippe, Board Member

The Enforcement Committee met on December 8, 2009, in Sacramento. There was no Work Group on E-Pedigree Meeting held in conjunction with this meeting. Minutes of this meeting are provided in **Attachment 6**, near the back of this tab section.

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**A. FOR INFORMATION: Presentation-- Medication Error Reporting Systems in Hospitals -- Loriann De Martini, PharmD, Chief Pharmaceutical Consultant, California Department of Public Health**

Reduction of medication errors is a principal concern of those in the health care professions. Over the years, the Board of Pharmacy has made reduction of errors a major component of its licensee and consumer education efforts and its enforcement activities.

For example, this board was the first state board of pharmacy to require that a thorough quality assurance review be undertaken within two business days to ensure the error is not repeated. The requirement is applicable to pharmacies in both community and hospital settings.

In hospitals, the California Department of Public Health, which licenses hospitals, has additional requirements for the medication errors made in hospitals. For the last year, some of these errors are reported publicly on the CDPH's Web site.

During this meeting, Dr. De Martini will provide an overview of these requirements and report on data on medication errors discovered by the CDPH.

**B. FOR INFORMATION: Presentation – Online Access of Pharmacies to Data in the Controlled Substance Utilization Review and Evaluation System (CURES) Katherine Ellis, Department of Justice**

For more than 10 years, all pharmacies and health care practitioners dispensing controlled substances to patients in California have had to report information into the CURES system. CURES is a prescription monitoring program aimed at preventing diversion and inappropriate dispensing of controlled drugs.

The CURES system is actually run by the California Department of Justice. For any controlled drug listed in Schedules II, III or IV, CURES contains information on:

- Patient, address and other identifying information

- drug name, strength and quantity dispensed
- prescriber's name and identifying information
- pharmacy name and identifying information

The system has been strongly supported by the board, and the board often accesses this information as part of its investigations.

Late this summer, the CURES system made a major step forward in offering prescribers and pharmacies timely data about histories of controlled drugs dispensed to any patient. The system now allows authorized entities online access ("real time") to the dispensing histories of controlled drugs dispensed to any patient. The data is as recent as two or three weeks. By reviewing this data, prescribers and pharmacies can see the total number of controlled substances dispensed to a given patient. This information can be important as to whether a prescriber should prescribe, or a pharmacy dispense, a controlled drug while the patient is still before the prescriber or in the pharmacy.

At this meeting, Ms. Ellis will provide an overview of the new online feature and explain how pharmacies can use this information.

**C. FOR INFORMATION: Department of Consumer Affairs New Enforcement Model  
Attachment 1**

Since July 2009, the Department of Consumer Affairs has been working to upgrade the capabilities of health care boards to investigate and discipline their licensees to protect the public. The proposed changes have taken various forms, and many proposals are still being developed and finalized. The goal is to ensure the average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months. Formal discipline means those cases which are the most serious, and for which license removal or restriction is being sought.

The DCA has requested that this issue be added to the board meeting agendas of all health care boards.

The board has been discussing and implementing changes to its enforcement program all year, beginning with the approval of a criminal conviction unit effective July 1, 2009, to respond to notices of arrests and convictions of our licensees and applicants. The board has also been advised about the department's efforts to implement SB 1441, which directs the department to develop standards for "diversion" or monitoring programs for health care board licensees. The board's Pharmacists Recovery Program will be affected by these standards once in place. In November, the department released the uniform standards. The board's executive staff has been working with the board's counsel to identify how these standards can be implemented (legislation needed, regulation change needed, contract amendment needed). The Legal Office is still working through these changes, which when completed will be brought to the board at a future meeting for action.

Additionally, some of the enforcement changes relate to the need for additional staff. To this end, the department advocated creation of budget change proposals that would be added to the Governor's 2010/11 budget. In the case of this board, this will expand the board's staff by 22.5 positions.

The department is also preparing provisions that will need to be enacted as legislation. At this time, the provisions have not been released for public review. Again, these provisions will be available at a future board meeting.

Very recently, the department released its "Consumer Protection Enforcement Initiative" that provides an overview of where the department is going with the enforcement program changes. This report is provided as **Attachment 1**.

**d. Report of the Enforcement Committee Held December 8, 2009**

**1. FOR ACTION: Support the DEA's Efforts to Reclassify Carisoprodol to Federal Schedule IV of Controlled Substances**

**Attachment 2**

In November, the federal Drug Enforcement Administration released proposed rules to reclassify carisoprodol to federal Schedule IV. Currently this drug is not scheduled either at the federal or state level.

Written comments on this reclassification were due by December 17, 2009.

Board supervising inspectors strongly support this reclassification. When investigating drug diversion and misuse of drugs, carisoprodol (or Soma) is a frequently misused and diverted drug. Patients often purchase such drugs from Web sites without legitimate prescriptions. In fact a recent citation and fine issued to a California pharmacy that was dispensing drugs to California patients from Web sites in violation of CA law, involved carisoprodol in 52 percent of the more than 3,000 prescriptions identified by the board sent to California purchasers.

At the December 2009 Enforcement Meeting, the committee directed Ms. Herold to send comments on behalf of the board's staff supporting the reclassification of Carisoprodol to federal Schedule IV. A copy of this letter is provided in **Attachment 2** as is the federal Notice.

At this meeting, a request for the board to vote on whether it supports the reclassification of carisoprodol into federal Schedule IV is sought.

## 2. FOR INFORMATION: Consequences for Pharmacies Dispensing Prescriptions for Internet Web Site Operators

### Attachment 3

In recent months, the board's inspectors have investigated a number of cases where California pharmacies are filling large numbers of prescriptions from Internet Web site operators in situations where patients are in a number of states, a prescriber is writing prescriptions for the patients from a single state, and the California pharmacy is filling the prescription.

Many times these prescriptions are not valid because an appropriate exam by a prescriber has not occurred. California law allows the board to issue citations for such violations at \$25,000 per invalid prescription. Over the last 12 months, the board has issued multiple million dollar fines to California pharmacies and pharmacists for filling such false prescriptions. Often these sales are of controlled drugs, other times they are lifestyle drugs (Viagra, Xenical) or drugs like tramadol or carisoprodol. The Drug Enforcement Administration is also involved in some of these Web site investigations and has fined or disciplined California pharmacies for their participation.

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

At the Enforcement Meeting, the executive officer provided a listing of the huge fines issued in the last year to California pharmacies aiding Internet providers in distributing prescription drugs without a valid prescription.

The *July 2008 The Script* reminded pharmacies not to participate in such scams. A copy of the article is provided in **Attachment 3**.

A copy of California Business and Professions Code section 4067 is provided below.

#### **4067. Internet; Dispensing Dangerous Drugs or Devices without Prescription**

- (a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

- (b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars (\$25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars (\$25,000) per occurrence.
- (c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).
- (d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.
- (e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.
- (f) For the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242 and the requirements for a veterinarian in Section 2032.1 of Title 16 of the California Code of Regulations.

### **3. FOR INFORMATION: Reporting of Settlements to the Board as Required by California Business and Professions Code Sections 800-802**

#### **Attachment 4**

The board's staff recently learned that some insurance companies and some licensees may not be aware of their responsibilities to report settlements to the board for errors and omissions pursuant to requirements in California Business and Professions Code sections 800, 801 and 802. (**Attachment 4** contains the text of these code sections.) As a result, these reports are not being submitted to the board.

The board uses these reports to initiate investigations. In 2008-09, the board received four reports under sections 800-802. Board staff believes that this is a strong underreporting of settlements that are required to be reported to the board.

As part of the enforcement upgrades being pursued by the health care boards of the department, this underreporting will be addressed. A newsletter article will appear in a future *The Script*, and the board will begin enforcement actions against those who fail to report settlements to the boards.

### **4. FOR INFORMATION: Other Items Discussed During the December 2009 Enforcement Committee Meeting**

- Presentation by Green RX on Drug Management Programs to Use Drugs Before they Become Outdated

During the meeting, the committee heard a presentation by Green RX that advanced a proposal for drug management between pharmacies that would allow pharmacies to transfer drugs to other pharmacies to alleviate shortages and prevent drugs from becoming outdated.

The committee took no action based on this presentation.

- Update on California Drug "Take Back" Programs from Patients

The next issue of *The Script* will promote the California Integrated Waste Management Board's guidelines for model programs for the "take back" or return of unwanted prescription drugs from patients. The article will advise that the board expects pharmacies to use these guidelines if they participate in taking back drugs from patients. (The newsletter will be published at the end of January 2009.)

Staff is aware that a number of communities are establishing collection programs for unwanted prescription drugs, which under California law are considered hazardous waste. However, unlike other items for which recycling or specialty collection programs have been established (like used motor oil or plastic shopping bags), aggregations of prescription drugs have value. Few of the pharmacy programs comply with the CIWMB guidelines and many also violate the federal Drug Enforcement Administration's requirements for the appropriate take back of controlled substances.

President Ken Schell, Executive Officer Herold and Supervising Inspector Judi Nurse recently attended a conference convened by the CIWMB on various recycling and disposal issues surrounding California. Representatives from various waste collection, recycling and disposal programs from most California cities and counties attended. The board's purpose in attending this conference was to emphasize support for the CIWMB's guidelines.

Recently the board's executive officer met with staff from Sharps, Inc. This is the firm that provided a presentation on mail back options at the July 2009 Board Meeting. They left Executive Officer Herold with a modified mail-back box that incorporates many of the suggestions made during the July Board Meeting.

In December, the executive officer met with DEA policy staff in Washington DC on issues involving controlled drugs. One of the issues discussed was a take back policy that will allow patients to return unwanted drugs but prevent diversion. The DEA indicates that they expect federal legislation to be introduced on this issue early in 2010.

The committee also received statistics about the costs per pound of mail back. A summary of the two studies:

In July 2009 from Maine:

Number of envelopes received at the incinerator (7/17/09)	3,374
Total weight (pounds)	1,560
Average weight per envelope (pounds)	0.4624
Cost (\$3.49/envelope)	\$11,775

Price/weight (pounds) \$7.55

San Francisco mail-back program (through November 9, 2009)

Number of envelopes distributed (before 11/09)	1,443
Number of envelopes returned to incinerator (11/09)	558 (38.7%)
Total weight (pounds)	417.4
Average weight per envelope (pounds)	0.7480
Cost	\$1,947.42
Price/weight (pounds)	\$4.67

After publication and release of the board's newsletter promoting the guidelines, the board's inspectors will begin discussing appropriate components for take back programs with pharmacies during inspections.

- Consideration of Best Practices on How to Use CURES Data As Part of Drug Utilization Review

**Attachment 5**

In California all controlled drugs dispensed to patients by pharmacies or prescribers must be reported electronically to the Controlled Substances Utilization and Review System (CURES) each week. This is the data that is now accessible to prescribers and pharmacies via the Internet. The implementation of this feature is a major step forward in assuring that patients who are doctor shoppers are not able to obtain drugs from pharmacies or prescribers by going to multiple prescribers and pharmacies.

Earlier during this segment of the Board Meeting, the Department of Justice will present a demonstration of the new system.

At the December committee meeting, the committee reviewed an article describing a possible need for pharmacies to check the prescription monitoring programs operating in their state (such as CURES) before dispensing controlled drugs to ensure patients do not obtain duplicate prescriptions of drugs and go on to kill or injure others. A court case recently held that the pharmacy could be held responsible if it did not check this data. However, a decision rendered last week by the Nevada Supreme court reversed this decision (**Attachment 5**).

Currently in California, the board requires pharmacists to use corresponding responsibility. **Attachment 5** also contains an article from the July 2001 *The Script* that discusses corresponding responsibility.

- Ongoing Discussion on Prevention of Medication Errors

At the December meeting, the committee discussed medication errors. The board's new video tape for consumers on preventing a med error from reaching

them was shown. The talking points for the executive officer's discussions involving medication errors were also discussed.

- e. **Minutes of the December 8, 2009 Meeting: Attachment 6**
- f. **Enforcement Statistics: Attachment 7**
- g. **Strategic Plan Update of the Committee: Attachment 8**

# Attachment 1

*Department of Consumer  
Affairs*

*Consumer Protection  
Enforcement Initiative*



## **CONSUMER PROTECTION ENFORCEMENT INITIATIVE**

*"A Systematic Solution to a Systemic Problem"*

The Department of Consumer Affairs (DCA) is the umbrella agency that oversees 19 healing arts boards that protect and serve California consumers. The healing arts boards regulate a variety of professions from doctors and nurses to physical therapists and optometrists. These licensees are some of the best in the country and provide excellent care to Californians on a daily basis. However, when a licensee violates the laws that govern his or her profession, enforcement action must be taken to protect the public.

In recent years some of DCA's healing arts boards have been unable to investigate and prosecute consumer complaints in a timely manner. In fact, some boards take an average of three years to investigate and prosecute these cases; this is an unacceptable timeframe that could put consumers' safety at risk.

DCA reviewed the existing enforcement process and found systemic problems that limit the boards' abilities to investigate and act on these cases in a timely manner. These problems range from legal and procedural challenges to inadequate resources. In response, DCA launched the Consumer Protection Enforcement Initiative (CPEI) to overhaul the enforcement process at the healing arts boards. The CPEI is a systematic approach designed to address three specific areas:

- Administrative Improvements
- Staffing and IT Resources
- Legislative Changes

Once fully implemented, DCA expects the healing arts boards to reduce the average enforcement completion timeline from 36 months to between 12 and 18 months.

## **I. Administrative Improvements**

During the review of the enforcement process, DCA worked with the boards to identify areas that could be improved administratively to better coordinate broad enforcement objectives, improve the services provided to the healing arts boards, and establish streamlined enforcement processes and procedures that can be used by all boards. The following are some of the efforts that emerged from those discussions:

### ***“365 Project”***

DCA’s Division of Investigation (DOI) embarked on a project in 2009 to strategically focus on cases that were one year or older. DOI worked closely with boards to identify the cases upon which they should focus their resources. This project has produced impressive results, and in 2009 the DOI closed 50% more cases than the comparable period in 2008.

### ***Delegation of Subpoena Authority***

One of the initial administrative changes implemented by DCA was delegating subpoena authority to each executive officer as a tool to gather evidence and interview witnesses. DCA’s Legal Office conducted subpoena training for board staff, and this authority has started being exercised by boards. We expect to see increased use of subpoenas as a result of this change, and boards will be able to pursue cases that they otherwise would not have pursued.

### ***Process Improvement***

DCA and the boards are working to identify best practices for a number of enforcement processes and procedures, such as complaint intake, handling of anonymous complaints, vote by email protocols, and adjudication procedures. This effort will take advantage of the most effective practices utilized by the various boards, and entities in other states, and will ultimately shave time off all aspects of the enforcement process.

### ***Enforcement Academy***

DCA’s Strategic Organization, Leadership, & Individual Development Division is developing enhanced training programs for enforcement staff. The enforcement academy will teach investigators and other enforcement staff key skills used in complaint intake, investigation procedures, case management, database use, and other areas. Never before has DCA offered such a comprehensive enforcement training program. An initial training was offered in November 2009, and the full enforcement academy will begin its regular cycle in April 2010.

### ***Deputy Director for Enforcement and Compliance***

DCA established an executive level position that reports to the Director and is responsible for regularly examining each board’s enforcement program to monitor enforcement performance and compliance with all applicable requirements. This position monitors performance measures so that boards’ enforcement programs can be continuously assessed for improvement.

### ***Performance Expectations with Other Agencies***

DCA has been working with the Attorney General’s Office and the Office of Administrative Hearings (OAH) to establish performance agreements that will expedite the prosecution of cases. DCA and the AG’s Office are developing expectations for filing accusations, setting settlement conferences, and filing continuance requests. Further, DCA is working with OAH to establish timelines for setting cases for hearings, which, once implemented, could reduce a case timeline by months.

## II. Enhancing Enforcement Resources

There are 36 licensing entities under the DCA (of which are 19 healing arts boards) and, with a few exceptions, all of these programs share the resources of the Department, from Division of Investigations (DOI), to Personnel to IT Support. While the healing arts boards fall under the umbrella of DCA they are separate semi-autonomous groups overseen by board members appointed by the Governor and the Legislature. Additionally, all of the licensing entities under DCA are special fund agencies funded exclusively through fees collected through licensees with no general fund support.

### ***Enforcement Staff***

DCA's review of the enforcement process identified a need for more focused staff resources in the areas of investigations and complaint intake. The majority of DCA's licensing entities share the resources of DCA's overburdened DOI. Annually, DOI's 48 investigative staff members receive over 1,300 cases, in topics ranging from nurses to repossessioners to smog check stations. Having so many investigations performed by DOI has resulted in a number of problems, including loss of control over the investigation by the boards, a lack of investigators with expertise in specific licensing areas, and excessive caseloads. These problems have led to excessive turn-around times and growing backlogs. Through the 365 Project, the DOI has worked with boards to reduce the case backlog, but the current structure has revealed a need for more significant changes.

In order to increase accountability in the investigative process, DCA is working to provide boards with the authority to hire non-sworn investigators to be housed within each board. This will enhance boards' control over investigations, allow for more appropriate workload distribution, and enable investigators to develop expertise. Additionally, to coincide with process improvement efforts, some boards will increase complaint intake staff. DCA is seeking a total of approximately 140 new enforcement positions (full year equivalent) across all healing arts boards. The vast majority of these positions are investigators and investigative supervisors, and the remainder is mostly complaint intake staff. In addition to increasing staffing, DCA will ensure that staff are properly trained, monitored, and assessed so that cases are expedited as quickly as possible.

Because DCA's boards are special fund agencies, new positions will not place a drain on the General Fund and boards will pay for new staff with existing resources or with fee increases where necessary. The number of positions requested is a result of an individual assessment of each board, and assumes workload savings associated with DCA's current process improvement efforts. The Governor's Budget includes the initial phase-in of these positions beginning July 2010.

### ***Create a New Licensing and Enforcement Database***

DCA's current licensing and enforcement database systems are antiquated and impede the boards' ability to meet their program goals and objectives. Over the past 25 years, these systems have been updated and expanded, but system design and documentation have deteriorated to such an extent that it has left the systems unstable and difficult to maintain. These systems have inadequate performance measurement, data quality errors, an inability to quickly adapt to changing laws and regulations, and a lack of available public self-service options. The CPEI relies on advanced workflow capabilities and cross-entity external system communications that the aging system's technology cannot provide.

The implementation of a replacement system is needed to support enforcement monitoring, automate manual processes, streamline processes, and integrate information about licensees. DCA intends to procure a Modifiable Commercial Off-The-Shelf (or "MOTS") enterprise licensing and

enforcement case management system. DCA's research has shown various MOTS licensing and enforcement systems exist that can provide intelligent case management to reduce enforcement and licensing turnaround times, detailed performance measurements, increased data quality, advanced configurability, and robust web presences for public self-service.

The Governor's Budget authorizes DCA to redirect existing funds to begin implementation of this system in FY 2010-11.

### **III. Statutory Changes: Putting Consumers First**

Each board within DCA has a statutory mandate to hold consumer protection as its paramount objective. Over the years, boards' enforcement authorities have been slow to keep up with legal trends and changes in the professions regulated, and due process protections have grown to protect licensees above consumers. DCA believes that now is the time to re-align consumer protection laws so that they place public protection first. In 2010, the DCA will pursue legislation to help boards carry out their critical missions of protecting consumers.

#### ***Increased Suspension Authority***

One of the most important roles that professional licensing boards do to protect consumers is preventing potentially dangerous individuals from practicing. The CPEI would strengthen the boards' ability to do this in a number of ways, including authorizing the DCA Director to issue an order for a licensee to cease practice or restrict practice, upon the request of a board executive officer. This authority is necessary in the most egregious cases because the standard enforcement process can take a year to complete, at best, and even the expedited process in existing law (interim suspension order) can take months to complete. This proposal would also seek the statutory authority to revoke or deny a license to an individual for acts of sexual misconduct with a patient or conviction as a felony sex offender.

DCA is also seeking automatic suspension authority for licensees who test positive for drugs or alcohol when they are already in a diversion program or on probation for drug or alcohol related practice violations. In such instances, a board has already made a determination that a licensee presents a threat to the public; allowing the licensee to continue practicing would unacceptably place consumers in harm's way. Similarly, DCA believes that practicing under the influence of drugs or alcohol is as much a threat to public safety as driving under the influence. This proposal would make such activity a crime, and would allow law enforcement to quickly intervene when a patient's safety is at risk.

Additionally, the CPEI would provide for the automatic suspension of convicted felons for the duration of their sentence.

#### ***Increased Access to Critical Information***

The CPEI would make improvements to the information that boards receive, so they can investigate possible violations of law. Specifically, it would prohibit the use of a gag clause in a civil settlement that would prohibit consumers or their legal counsel from filing a complaint with the appropriate board. Regulatory gag clauses are explicitly prohibited in legal malpractice settlements and there have been numerous court decisions that describe a compelling public interest in voiding regulatory gag clauses in other professions. The Center for Public Interest Law notes that the inclusion of gag clauses is an alarmingly pervasive practice that thwarts the ability of boards to carry out their consumer protection mission. The CPEI would also require court officials to report to the healing arts boards convictions and felony charges filed against the boards' licensees, and expand reporting by employers and supervisors regarding individuals who were suspended or terminated for cause.

Adequate access to medical records can shave months off the process to investigate a licensee. Medical records are used by healing arts boards' to determine whether a licensee caused harm to a patient. Any delay in an investigation of a licensee may result in a potentially dangerous licensee continuing to practice. Thus, it is essential that healing arts boards have quick access to medical records. The CPEI gives all of the healing arts boards the authority to inspect and copy, as applicable, any documents and records relevant to an investigation. In cases where a licensee fails

to cooperate with an investigation, the CPEI provides boards with additional authorities to ensure compliance.

***Enforcement Process Efficiencies***

DCA proposes to remove unnecessary workload and costs from the enforcement process. This can be done by streamlining the appeal process for citations, permitting boards to contract with collection agencies to retrieve unpaid fines and fees, authorizing executive officers to sign default decisions and certain stipulated settlements, and allowing licensees to agree to stipulated settlements before a formal accusation is filed. These are relatively small changes that could result in significant workload savings.

Efficiency and accountability will also be improved by tightening deadlines on boards and establishing deadlines on other state agencies. This proposal would reduce the time allotted for a board to act on the proposed decision from an Administrative Law Judge from 100 days to 45 days. DCA also believes that establishing a deadline for the Department of Justice to notify healing arts boards of arrests and convictions of licensees would greatly improve the board's ability to pursue cases in a timely manner.

***Licensing Fees***

Lastly, DCA is seeking to tie the maximum licensing fee amounts to the Consumer Price Index to keep up with inflation and ensure the boards have the resources to adequately run their enforcement programs.

# Attachment 2

*Proposal to Move  
Carisoprodol to  
Federal Schedule IV*



**California State Board of Pharmacy**

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

December 10, 2009

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

RE: COMMENTS OF CALIFORNIA STATE BOARD OF PHARMACY STAFF  
**Docket No. DEA—333: *Placement of Carisoprodol into Schedule IV***

To Whom It May Concern:

I write on behalf of the executive and enforcement staff of the California State Board of Pharmacy (Board). We are pleased to be able to respond to a Request for Comments included in your Docket No. DEA—333, a Notice of Proposed Rulemaking titled *Schedules of Controlled Substances: Placement of Carisoprodol into Schedule IV*. We **strongly support** the decision to make carisoprodol a controlled substance, given its history of and potential for diversion/abuse.

As you may know, the Board is the agency within California primarily responsible for the enforcement of California's Pharmacy Law (Cal. Bus. & Prof. Code, § 4000 et seq.). The Board also shares in enforcement of the state's Uniform Controlled Substances Act (Cal. Health & Saf. Code, § 11000 et seq.; see Cal. Bus. & Prof. Code, § 4011). The Board staff and I are pleased to enjoy a long history of mutual cooperation between the Board and the Drug Enforcement Agency (DEA). As part of an enforcement agency, we share your interest in discouraging drug diversion and abuse, and agree that one method for doing so is by a controlled substance classification making applicable various criminal and civil sanctions.

The Board staff and I agree it is appropriate to apply this classification to carisoprodol. We often find, in investigating cases of diversion, abuse, or misuse of drugs, that carisoprodol is included among the drugs diverted, abused, or misused. We also often find that carisoprodol is among the drugs purchased from internet sites without legitimate prescriptions. For example, in one recent case involving internet procurement, our investigators discovered that more than 52 per cent of the over 3,000 prescriptions dispensed in the case included orders for carisoprodol.

Thank you for your attention to these matters, and for your willingness to hear our input. We are hopeful the DEA can move quickly on this rulemaking. Please feel free to contact me if we can help, by phone at (916) 574-7911, or by email to [Virginia\\_Herold@dca.ca.gov](mailto:Virginia_Herold@dca.ca.gov).

Sincerely,

A handwritten signature in cursive script that reads "Virginia Herold".

VIRGINIA K. HEROLD  
Executive Officer, California State Board of Pharmacy

[Federal Register: November 17, 2009 (Volume 74, Number 220)].  
[Proposed Rules]  
[Page 59108-59112]  
From the Federal Register Online via GPO Access [wais.access.gpo.gov]  
[DOCID:fr17no09-16]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-333P]

Schedules of Controlled Substances: Placement of Carisoprodol  
Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

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SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to place the substance carisoprodol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and on an evaluation of the relevant data by DEA. If finalized, this action would impose the regulatory controls and criminal sanction of schedule IV on those who handle carisoprodol and products containing carisoprodol.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before December 17, 2009. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Standard Time (EST) on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ``Docket No. DEA-333'' on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152.

Comments may be sent to DEA by sending an electronic message to [dea.diversion.policy@usdoj.gov](mailto:dea.diversion.policy@usdoj.gov). Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this

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document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight EST on the day the comment period closes because <http://www.regulations.gov> terminates the public's ability to submit comments at midnight EST on the day the comment period closes. Commenters in time zones other than EST may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone (202) 307-7183.

#### SUPPLEMENTARY INFORMATION:

Comments and Requests for Hearing: In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (5 U.S.C. 556 and 557). All persons are invited to submit their comments or objections with regard to this proposal. Requests for a hearing may be submitted by interested person and must conform to the requirements of 21 CFR 1308.44 and 1316.47. The request should state, with particularity, the issues concerning which the person desires to be heard and the requestor's interest in the proceeding. Only interested persons, defined in the regulations as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)," may request a hearing. 21 CFR 1308.42. Please note that DEA may grant a hearing only "for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment, or repeal of a rule issuable" pursuant to 21 U.S.C. 811(a). All correspondence regarding this matter should be submitted to the DEA using the address information provided above.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.)

voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ``PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ``CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the FOR FURTHER INFORMATION CONTACT paragraph.

## Background

Carisoprodol is a centrally acting muscle relaxant and is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions. Carisoprodol has been available since 1959 as a prescription drug in the United States under the trade name Soma<sup>[supreg]</sup>. It is also marketed as generic products. Carisoprodol is similar to a variety of central nervous system (CNS) depressants, including meprobamate (C-IV) and chlorthalidone (C-IV). The actual abuse data from several databases demonstrate that carisoprodol is abused in the United States. Because of growing concerns about abuse of carisoprodol, a number of states have regulated carisoprodol under their controlled substance regulations, and a number of additional states are currently considering such regulation.

Because of the evidence relating to diversion, abuse, and trafficking of carisoprodol, in March 1996, the DEA requested from the DHHS a scientific and medical evaluation and a scheduling recommendation for carisoprodol, in accordance with 21 U.S.C. 811(b).

In February 1997, the U.S. Food and Drug Administration (FDA) Drug Abuse Advisory Committee (DAAC) deliberated upon the abuse and scheduling issues and concluded that the data were insufficient to control carisoprodol under the CSA at that time. Since the FDA DAAC meeting, pharmacological studies addressing the abuse liability of carisoprodol have been conducted under the direction of the National

Institute on Drug Abuse (NIDA) and the College on Problems of Drug Dependence (CPDD). DEA acquired new carisoprodol-related data on actual abuse, law enforcement encounters and other information and sent this supplementary information to DHHS on November 14, 2005. FDA acquired new data from the Drug Abuse Warning Network (DAWN), National Survey of Drug Use and Health (NSDUH), Florida Medical Examiners Commission reports, FDA's Adverse Event Reporting System (AERS) and information from the published scientific literature and conducted a scientific and medical evaluation. These data collectively indicate that carisoprodol has abuse potential and is being diverted, trafficked, with increasing frequency and magnitude.

Carisoprodol abuse has been associated with increasing numbers of emergency department (ED) visits in recent years as indicated by DAWN. The "abuse frequency," calculated as ED visits per 10,000 prescriptions, of carisoprodol (frequency range during 2002-2007: 15.1 to 22.6 visits/10,000 prescriptions) is similar to that of a schedule IV drug, diazepam (frequency range during 2002-2007: 12.5 to 14.1 visits/10,000 prescriptions). Carisoprodol is used as either the sole drug or in combination with other substances such as opioids, benzodiazepine, alcohol, marijuana, and cocaine. Data from the AERS database show that carisoprodol is associated with adverse health events including dependence and withdrawal syndrome.

The data from National Poison Data System of the American Association of Poison Control Centers documented 8,821 carisoprodol toxic exposure cases including 3,605 cases in which it was

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the sole drug mentioned in 2007. Medical Examiners Commission Reports released by the Florida Department of Law Enforcement (FDLE) indicate that carisoprodol/meprobamate related deaths in Florida increased by 100 percent from 208 deaths in 2003 to 415 deaths in 2008.

The National Forensic Laboratory Information System (NFLIS), a DEA system that tracks analyzed drug exhibits submitted by the federal, state, and local law enforcement, documented evidence of substantial diversion of carisoprodol. For example, law enforcement submitted a total of 3,873 carisoprodol drug items to participating forensic laboratories in 2008. NFLIS consistently listed carisoprodol in the top 25 most frequently identified drugs since 2000. The 2007 NSDUH data show that 2.7 million individuals used Soma[supreg] in their lifetime (i.e., ever used) for a non-medical purpose.

The data from in vitro electrophysiological studies using the whole-cell patch clamp technique demonstrate that carisoprodol elicits barbiturate-like effects. Intravenous drug self-administration studies in rhesus monkeys show that carisoprodol has positive reinforcing effects. Meprobamate, pentobarbital, and chlordiazepoxide substitute fully for the discriminative stimulus effects of carisoprodol in rats. Bemegride, a barbiturate antagonist, antagonizes the discriminative stimulus effects of carisoprodol.

Data from an animal study indicates that carisoprodol has

dependence liability similar to barbital (schedule IV), a central nervous system depressant. Carisoprodol administered orally fully prevented the appearance of abstinence phenomena in dogs tolerant and dependent on barbital. Several published reports document evidence of tolerance and dependence to carisoprodol and indicate the occurrence of abstinence symptoms during carisoprodol withdrawal in humans.

On October 6, 2009, the Acting Assistant Secretary for Health, DHHS, sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that carisoprodol be placed into schedule IV of the CSA. Enclosed with the October 6, 2009, letter was document prepared by the FDA entitled, "Basis for the Recommendation for Control of Carisoprodol in Schedule IV of the Controlled Substance Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)). The factors considered by the Assistant Secretary of Health and DEA 21 U.S.C. 811(c) with respect to carisoprodol were:

- (1) Its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effects;
- (3) The state of current scientific knowledge regarding the drug;
- (4) Its history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) What, if any, risk there is to the public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Based on the recommendation of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

1. Carisoprodol has a low potential for abuse relative to the drug or other substances in Schedule III. Animal studies indicate that carisoprodol is similar to schedule IV drugs such as meprobamate and chlordiazepoxide in its central nervous system depressant effects. The documented data on law enforcement encounters and actual abuse of carisoprodol demonstrate that it has a potential for abuse and is being diverted and abused. Since 2000, DEA's NFLIS database consistently mentioned carisoprodol in the top 25 drugs that were most frequently identified by state and local forensic laboratories thereby indicating that carisoprodol is being diverted. Emergency department visits data from DAWN indicate that abuse frequency of carisoprodol is similar to that of diazepam, a schedule IV drug. Recent data from DAWN medical examiner reports and emergency department visits showed an increase in carisoprodol abuse.

2. Carisoprodol has a currently accepted medical use in treatment in the United States. Carisoprodol is an FDA approved drug and is used for the relief of discomfort associated with acute, painful musculoskeletal conditions.

3. Abuse of carisoprodol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in

schedule III. Carisoprodol, similar to barbital (schedule IV), prevent the abstinence syndrome in drug withdrawn barbital-dependent dogs. Published reports indicate that carisoprodol causes psychological or physical dependence and withdrawal syndrome.

Based on these findings, the Deputy Administrator of DEA concludes that carisoprodol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible warrants control in schedule IV of the CSA. (21 U.S.C. 812(b)(4))

References to the above studies and data may be found in the Health and Human Services scheduling recommendation and DEA's independent analysis, both of which are available on the electronic docket associated with this rulemaking.

#### Requirements for Handling Carisoprodol

If this rule is finalized as proposed, carisoprodol would be subject to CSA regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a schedule IV controlled substance, including the following:

**Registration.** Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with carisoprodol, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with carisoprodol, would need to be registered to conduct such activities in accordance with 21 CFR part 1301.

**Security.** Carisoprodol would be subject to schedules III-V security requirements and would need to be manufactured, distributed, and stored in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77.

**Labeling and Packaging.** All labels and labeling for commercial containers of carisoprodol which are distributed on or after finalization of this rule would need to comply with requirements of 21 CFR 1302.03-1302.07.

**Inventory.** Every registrant required to keep records and who possesses any quantity of carisoprodol would be required to keep an inventory of all stocks of carisoprodol on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who desires registration in schedule IV for carisoprodol would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

**Records.** All registrants would be required to keep records pursuant to 21

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CFR 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23.

**Prescriptions.** All prescriptions for carisoprodol or prescriptions

for products containing carisoprodol would be required to be issued pursuant to 21 CFR 1306.03-1306.06 and 1306.21, 1306.22-1306.27.

Importation and Exportation. All importation and exportation of carisoprodol would need to be in compliance with 21 CFR part 1312.

Criminal Liability. Any activity with carisoprodol not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on or after finalization of this proposed rule would be unlawful.

## Regulatory Certifications

### Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

### Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

In considering the impact on small entities, the first question is whether a substantial number of small entities are affected. In this instance, the entities affected are those now selling carisoprodol-containing products without registration. DEA has identified 22 firms manufacturing carisoprodol-containing products in 2009.\1\ Fifteen of these firms have existing DEA registrations. This leaves seven firms from this data set selling carisoprodol without registration. DEA has no information on the number of non-registrants distributing or importing carisoprodol, but there is every reason to believe that the number of such firms is well in excess of the seven already identified. The Small Business Administration size standard for a small wholesaler of drugs is 100 employees. It is clearly possible to operate a drug distributing firm with fewer than 100 employees. There can be no question that a substantial number of small entities will be affected by this rule.

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\1\ IMS Health National Prescription Audit (NPA).

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The impact on non-registrants now selling carisoprodol will occur in two forms: the cost of registration and the cost of meeting the security requirements in 21 CFR part 1301. There is also a potential

impact on firms not now selling carisoprodol who might have wished to enter the market.

The annual registration fee for a distributor, importer, or exporter is \$1,147. There is some uncertainty in estimating the cost of meeting the security requirements, because most nonregistrants already meet the security requirements, at least in part, for schedule III and IV substances. To be conservative, it is assumed that every nonregistrant will have to buy a safe to store carisoprodol. A safe with capacity of 13.5 cubic feet should be adequate. A safe of this size may be purchased for \$1,350. Annualized over 15 years at 7.0 percent, that is \$148 per year. Total annual cost of compliance with the rule, then, is \$1,295. The usual standard for a significant economic impact is 1.0 percent of revenue. For \$1,295 per year to be a significant economic impact, annual revenue of a firm would have to be under \$130,000. Any firm in the business of distributing drugs needs annual revenue well in excess of that amount to sustain itself.

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\2\ NationwideSafes.com <http://www.nationwidesafes.com/capacity-more-than-4pt0-cu-ft.html>.

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It should be acknowledged that, for a small firm, there may be some inconvenience and expense in preparing necessary forms for registration and registration renewal. These are minor costs. There are also recordkeeping requirements, but these impose little or no incremental cost for a firm that is already maintaining records needed for a wholesale business. The costs of registration and security requirement will not be a significant economic impact.

If a firm chose not to register and to drop its carisoprodol line, the cost to the firm would exceed its earnings on the carisoprodol sales. The firm might also lose some customers who do not want to buy from a vendor without carisoprodol in its product line. A competent manager will recognize this cost. In light of the very small cost of registering, he would presumably choose to drop carisoprodol from the firm's products only if the firm were earning a negligible profit from that line and he judged that dropping it would not turn away significant customers. In light of the foregoing analysis, DEA finds that this rule will not have a significant economic impact on a substantial number of small entities. DEA has no information regarding the number of persons who may distribute carisoprodol-containing products, but do not manufacture, package, repackage, or relabel those products. Therefore, DEA seeks comment on any entities that might be affected by this control action.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

## Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

## Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

## Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

## List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator

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hereby proposes that 21 CFR part 1308 be amended as follows:

### PART 1308--SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by redesignating paragraphs (c) (5) through (c) (52) as paragraphs (c) (6) through (c) (53) and adding a new paragraph (c) (5) to read as follows:

Sec. 1308.14 Schedule IV.

\* \* \* \* \*

(c) \* \* \*

(5) Carisoprodol..... 81

\* \* \* \* \*

Dated: November 10, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9-27583 Filed 11-16-09; 8:45 am]

BILLING CODE 4410-09-P

# Attachment 3

## *Fines Issued to California Pharmacies for Internet Violations*

## Illegal Internet Dispensing: A Letter

During the previous year, information was publicized warning doctors and pharmacists about unsolicited faxed and e-mailed scams that recruit pharmacists to break the law. While appearing to be legal, these scams offered pharmacists higher than usual dispensing fees for participating in Internet dispensing pursuant to prescriptions that were illegal. Unfortunately, some pharmacists have agreed to engage in these activities, resulting in severe fines and disciplinary actions by the Board of Pharmacy.

Such solicitations are continuing in what appears to be in increasing numbers, so it seems appropriate to print the following open letter that was provided by a disciplined pharmacist who learned too late the consequences of filling and mailing illegal Internet prescriptions.

### To Fellow Pharmacists:

I want to share with you things that I learned the hard way—the first being that you must live up to your obligation as a licensed professional by keeping yourself informed of the current rules regulating the practice of pharmacy. Next, you also should think very long and hard before you involve yourself or your pharmacy in dispensing Internet-generated prescriptions. The Internet is not panacea when it comes to generating pharmacy income.

The explosion of technology as an integral part of our society has presented pharmacists and pharmacies with the opportunity to fill patient prescriptions that are generated through the use of the Internet. This can seem like an enticing opportunity for increased revenue. It certainly seemed that way to me. I have practiced pharmacy for many years and consider myself to be a capable, conscientious and ethical pharmacist. As with many pharmacists practicing during this challenging time, my idea was to find a steady revenue stream of cash patients for my pharmacy. The Internet seemed like the ideal solution. It was not.

The following are some of the things I thought were true and later learned were not:

**Myth 1:** I can dispense and ship prescriptions throughout the United States without any restrictions.

**Truth 1:** Many, if not all, states require that a pharmacy be licensed as an “out-of-state” pharmacy before it may fill and mail prescriptions to residents of that state. Failure to obtain a license or registration in that state can lead to civil penalties and other sanctions. Those sanctions can then lead to disciplinary action by the California State Board of Pharmacy against your California license.

**Myth 2:** Prescriptions generated via the Internet are legal prescriptions as long as the physician has a current medical license and a valid DEA registration.

**Truth 2:** A valid medical license and DEA registration are not the only concerns. Business and Professions Code section 4067 requires a “good faith prior examination” by the physician in order to lawfully dispense or furnish dangerous drugs pursuant to a prescription, including those that are generated via the Internet. Further, the California Code of Regulations section 1761, prohibiting a pharmacist from dispensing drugs pursuant to an erroneous or uncertain prescription, also applies to prescriptions generated via the Internet.

**Myth 3:** The filling of an on-line questionnaire by a patient meets the statutory requirement of a good faith prior examination.

**Truth 3:** The Board of Pharmacy has taken a very firm position that this is not a good faith prior examination. The Board requires that there be a face-to-face encounter between the patient and prescribing physician, during which an appropriate history is obtained, a legitimate medical purpose is established, and contraindications for the drug are eliminated. This position is consistent with the position taken by the Medical Board of California.

**Myth 4:** It is OK to fill Internet prescriptions for dangerous drugs or devices, so long as the Internet prescription I fill is for a California-licensed physician, because my pharmacy and I are both licensed in California.

**Truth 4:** The locations of the physician, pharmacy or pharmacist are not germane to this issue. Effective January 1, 2001, B & P Code section 4067 prohibits the dispensing or furnishing of a dangerous drug or device thru the use of the Internet to a resident of California unless the prescription for that drug or device was issued pursuant to a good faith prior examination. The law authorizes the Board of Pharmacy to assess a fine of up to \$25,000 for each violation, e.g., each prescription filled.

## to Pharmacists and Pharmacy Owners

**Myth 5:** As long as no patient is actually harmed or injured as a result of a prescription I fill, the Board of Pharmacy will just tell me to stop and not impose any fine or sanction.

**Truth 5:** The Board of Pharmacy has also taken a very firm position that the furnishing or dispensing of a dangerous drug or device pursuant to a prescription generated via the Internet when you knew or reasonably should have known that there was no good faith prior examination by the prescriber, is a serious violation of California law. Just because you were lucky enough not to harm or injure a patient, it does not mean you didn't put the public's health at risk. Accordingly, the Board of Pharmacy will do more than just tell you to stop. It will most probably impose a substantial fine.

**Myth 6:** If I was unaware that B & P Code section 4067 became effective on January 1, 2001, I cannot be held accountable for prescriptions I filled after that date and no fine can be imposed by the Board of Pharmacy.

**Truth 6:** Ignorance in this instance is not bliss, nor is it an excuse. It is the pharmacist's responsibility and obligation as a licensed professional to stay current with all new laws and regulations affecting the practice of pharmacy. Although the Board did advise me through its publication, *The Script*, of the existence of section 4067, I did not become familiar with requirements of the law prior to my filling prescriptions via the Internet. That was a big mistake. From my own experience, I can tell you that the Board of Pharmacy and the Legislature are serious about curbing the practice of unlawfully dispensing dangerous drugs or devices through the use of the Internet. The Board ordered me to stop, but it also imposed heavy fines on my pharmacy and me.

In conclusion, believe me when I tell you that I know whereof I speak. I filled Internet-generated prescriptions for California and out-of-state residents for a period of time, and both my pharmacy and pharmacist license were assessed fines by the Board that exceeded \$1,000,000. This did not include my own legal fees. Additionally, I was fined by another state for dispensing dangerous drugs via Internet-generated prescriptions to residents of that state without being licensed there. Therefore, I advise you to look past the potential short-term financial gain, and avoid the long-term mistake that I made.

The laws and regulations that govern our profession help and protect the patients, residents, and consumers of California. We need to take the initiative by making sure that we understand and comply with those laws and regulations.

We are all in this together. I write this "open letter" so that you can benefit from what I learned.

Sincerely,

A Sadder But Wiser Pharmacist

## Future mailing of *The Script* will be limited Sign up for online delivery

The first Board of Pharmacy newsletter was published in January 1971, and copies were always sent to each pharmacist and pharmacy and other licensure groups. Because of budget constraints in 2003, the Board of Pharmacy found it could no longer provide the newsletter to pharmacists. Consequently, the Board began to mail newsletters only to pharmacies and wholesalers. The Pharmacy Foundation of California, because of their concern for assuring that the important information contained in the newsletter reached individual pharmacists, printed and mailed copies of *The Script* to all

California pharmacists. Unfortunately, the Foundation can no longer continue to do so.

**The Board of Pharmacy acknowledges the Pharmacy Foundation of California and is grateful for its long and generous support of the Board and the profession of pharmacy.**

The Board will continue to mail *The Script* twice per year (January and July) to pharmacies and wholesalers for sharing with their licensed employees. *The Script*

will always be available online, and the Board strongly urges pharmacists and other licensees to download the newsletter from the Board's Web site, [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) under "Written Information and Publications."

Additionally, the Board encourages all licensees to sign up to receive "Subscriber Alerts" from the Board when important new items and newsletters are added to the Web site. The process is fast and easy. Just go to [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) and under the "Quick Hits" menu on the left, select "Join our E-Mail List."



# Attachment 4

*CA Business and  
Professions Code Sections  
800-802*

CALIFORNIA CODES  
BUSINESS AND PROFESSIONS CODE

800. (a) The Medical Board of California, the Board of Psychology, the Dental Board of California, the Osteopathic Medical Board of California, the State Board of Chiropractic Examiners, the Board of Registered Nursing, the Board of Vocational Nursing and Psychiatric Technicians, the State Board of Optometry, the Veterinary Medical Board, the Board of Behavioral Sciences, the Physical Therapy Board of California, the California State Board of Pharmacy, and the Speech-Language Pathology and Audiology Board shall each separately create and maintain a central file of the names of all persons who hold a license, certificate, or similar authority from that board. Each central file shall be created and maintained to provide an individual historical record for each licensee with respect to the following information:

(1) Any conviction of a crime in this or any other state that constitutes unprofessional conduct pursuant to the reporting requirements of Section 803.

(2) Any judgment or settlement requiring the licensee or his or her insurer to pay any amount of damages in excess of three thousand dollars (\$3,000) for any claim that injury or death was proximately caused by the licensee's negligence, error or omission in practice, or by rendering unauthorized professional services, pursuant to the reporting requirements of Section 801 or 802.

(3) Any public complaints for which provision is made pursuant to subdivision (b).

(4) Disciplinary information reported pursuant to Section 805.

(b) Each board shall prescribe and promulgate forms on which members of the public and other licensees or certificate holders may file written complaints to the board alleging any act of misconduct in, or connected with, the performance of professional services by the licensee.

If a board, or division thereof, a committee, or a panel has failed to act upon a complaint or report within five years, or has found that the complaint or report is without merit, the central file shall be purged of information relating to the complaint or report.

Notwithstanding this subdivision, the Board of Psychology, the Board of Behavioral Sciences, and the Respiratory Care Board of California shall maintain complaints or reports as long as each board deems necessary.

(c) The contents of any central file that are not public records under any other provision of law shall be confidential except that the licensee involved, or his or her counsel or representative, shall have the right to inspect and have copies made of his or her complete file except for the provision that may disclose the identity of an information source. For the purposes of this section, a board may protect an information source by providing a copy of the material with only those deletions necessary to protect the identity of the source or by providing a comprehensive summary of the substance of the material. Whichever method is used, the board shall ensure that full disclosure is made to the subject of any personal information that could reasonably in any way reflect or convey anything detrimental, disparaging, or threatening to a licensee's reputation, rights, benefits, privileges, or qualifications, or be used by a board to make a determination that would affect a licensee's rights, benefits, privileges, or qualifications. The information required to

be disclosed pursuant to Section 803.1 shall not be considered among the contents of a central file for the purposes of this subdivision.

The licensee may, but is not required to, submit any additional exculpatory or explanatory statement or other information that the board shall include in the central file.

Each board may permit any law enforcement or regulatory agency when required for an investigation of unlawful activity or for licensing, certification, or regulatory purposes to inspect and have copies made of that licensee's file, unless the disclosure is otherwise prohibited by law.

These disclosures shall effect no change in the confidential status of these records.

801. (a) Except as provided in Section 801.01 and subdivisions (b), (c), and (d) of this section, every insurer providing professional liability insurance to a person who holds a license, certificate, or similar authority from or under any agency mentioned in subdivision (a) of Section 800 shall send a complete report to that agency as to any settlement or arbitration award over three thousand dollars (\$3,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(b) Every insurer providing professional liability insurance to a person licensed pursuant to Chapter 13 (commencing with Section 4980) or Chapter 14 (commencing with Section 4990) shall send a complete report to the Board of Behavioral Science Examiners as to any settlement or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(c) Every insurer providing professional liability insurance to a dentist licensed pursuant to Chapter 4 (commencing with Section 1600) shall send a complete report to the Dental Board of California as to any settlement or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(d) Every insurer providing liability insurance to a veterinarian licensed pursuant to Chapter 11 (commencing with Section 4800) shall send a complete report to the Veterinary Medical Board of any settlement or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or injury caused by that person's negligence, error, or omission in practice, or rendering of

unauthorized professional service. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(e) The insurer shall notify the claimant, or if the claimant is represented by counsel, the insurer shall notify the claimant's attorney, that the report required by subdivision (a), (b), or (c) has been sent to the agency. If the attorney has not received this notice within 45 days after the settlement was reduced to writing and signed by all of the parties, the arbitration award was served on the parties, or the date of entry of the civil judgment, the attorney shall make the report to the agency.

(f) Notwithstanding any other provision of law, no insurer shall enter into a settlement without the written consent of the insured, except that this prohibition shall not void any settlement entered into without that written consent. The requirement of written consent shall only be waived by both the insured and the insurer. This section shall only apply to a settlement on a policy of insurance executed or renewed on or after January 1, 1971.

801.01. (a) A complete report shall be sent to the Medical Board of California, the Osteopathic Medical Board, or the California Board of Podiatric Medicine, with respect to a licensee of the board as to the following:

(1) A settlement over thirty thousand dollars (\$30,000) or arbitration award of any amount or a civil judgment of any amount, whether or not vacated by a settlement after entry of the judgment, that was not reversed on appeal, of a claim or action for damages for death or personal injury caused by the licensee's alleged negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services.

(2) A settlement over thirty thousand dollars (\$30,000) if it is based on the licensee's alleged negligence, error, or omission in practice, or by the licensee's rendering of unauthorized professional services, and a party to the settlement is a corporation, medical group, partnership, or other corporate entity in which the licensee has an ownership interest or that employs or contracts with the licensee.

(b) The report shall be sent by the following:

(1) The insurer providing professional liability insurance to the licensee.

(2) The licensee, or his or her counsel, if the licensee does not possess professional liability insurance.

(3) A state or local governmental agency that self-insures the licensee.

(c) The entity, person, or licensee obligated to report pursuant to subdivision (b) shall send the complete report if the judgment, settlement agreement, or arbitration award is entered against or paid by the employer of the licensee and not entered against or paid by the licensee. "Employer," as used in this paragraph, means a professional corporation, a group practice, a health care facility or clinic licensed or exempt from licensure under the Health and Safety Code, a licensed health care service plan, a medical care foundation, an educational institution, a professional institution, a professional school or college, a general law corporation, a public

entity, or a nonprofit organization that employs, retains, or contracts with a licensee referred to in this section. Nothing in this paragraph shall be construed to authorize the employment of, or contracting with, any licensee in violation of Section 2400.

(d) The report shall be sent to the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine, as appropriate, within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto, within 30 days after service of the arbitration award on the parties, or within 30 days after the date of entry of the civil judgment.

(e) If an insurer is required under subdivision (b) to send the report, the insurer shall notify the claimant, or if the claimant is represented by counsel, the claimant's counsel, that the insurer has sent the report to the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine. If the claimant, or his or her counsel, has not received this notice within 45 days after the settlement was reduced to writing and signed by all of the parties or the arbitration award was served on the parties or the date of entry of the civil judgment, the claimant or the claimant's counsel shall make the report to the appropriate board.

(f) If the licensee or his or her counsel is required under subdivision (b) to send the report, the licensee or his or her counsel shall send a copy of the report to the claimant or to his or her counsel if he or she is represented by counsel. If the claimant or his or her counsel has not received a copy of the report within 45 days after the settlement was reduced to writing and signed by all of the parties or the arbitration award was served on the parties or the date of entry of the civil judgment, the claimant or the claimant's counsel shall make the report to the appropriate board.

(g) Failure of the licensee or claimant, or counsel representing the licensee or claimant, to comply with subdivision (f) is a public offense punishable by a fine of not less than fifty dollars (\$50) and not more than five hundred dollars (\$500). A knowing and intentional failure to comply with subdivision (f) or a conspiracy or collusion not to comply with subdivision (f), or to hinder or impede any other person in the compliance, is a public offense punishable by a fine of not less than five thousand dollars (\$5,000) and not more than fifty thousand dollars (\$50,000).

(h) (1) The Medical Board of California, the Osteopathic Medical Board of California, and the California Board of Podiatric Medicine may develop a prescribed form for the report.

(2) The report shall be deemed complete only if it includes the following information:

(A) The name and last known business and residential addresses of every plaintiff or claimant involved in the matter, whether or not the person received an award under the settlement, arbitration, or judgment.

(B) The name and last known business and residential address of every physician and surgeon or doctor of podiatric medicine who was alleged to have acted improperly, whether or not that person was a named defendant in the action and whether or not that person was required to pay any damages pursuant to the settlement, arbitration award, or judgment.

(C) The name, address, and principal place of business of every insurer providing professional liability insurance to any person

described in subparagraph (B), and the insured's policy number.

(D) The name of the court in which the action or any part of the action was filed, and the date of filing and case number of each action.

(E) A brief description or summary of the facts of each claim, charge, or allegation, including the date of occurrence.

(F) The name and last known business address of each attorney who represented a party in the settlement, arbitration, or civil action, including the name of the client he or she represented.

(G) The amount of the judgment and the date of its entry; the amount of the arbitration award, the date of its service on the parties, and a copy of the award document; or the amount of the settlement and the date it was reduced to writing and signed by all parties. If an otherwise reportable settlement is entered into after a reportable judgment or arbitration award is issued, the report shall include both the settlement and the judgment or award.

(H) The specialty or subspecialty of the physician and surgeon or the doctor of podiatric medicine who was the subject of the claim or action.

(I) Any other information the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine may, by regulation, require.

(3) Every professional liability insurer, self-insured governmental agency, or licensee or his or her counsel that makes a report under this section and has received a copy of any written or electronic patient medical or hospital records prepared by the treating physician and surgeon or podiatrist, or the staff of the treating physician and surgeon, podiatrist, or hospital, describing the medical condition, history, care, or treatment of the person whose death or injury is the subject of the report, or a copy of any deposition in the matter that discusses the care, treatment, or medical condition of the person, shall include with the report, copies of the records and depositions, subject to reasonable costs to be paid by the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine. If confidentiality is required by court order and, as a result, the reporter is unable to provide the records and depositions, documentation to that effect shall accompany the original report. The applicable board may, upon prior notification of the parties to the action, petition the appropriate court for modification of any protective order to permit disclosure to the board. A professional liability insurer, self-insured governmental agency, or licensee or his or her counsel shall maintain the records and depositions referred to in this paragraph for at least one year from the date of filing of the report required by this section.

(i) If the board, within 60 days of its receipt of a report filed under this section, notifies a person named in the report, that person shall maintain for the period of three years from the date of filing of the report any records he or she has as to the matter in question and shall make those records available upon request to the board to which the report was sent.

(j) Notwithstanding any other provision of law, no insurer shall enter into a settlement without the written consent of the insured, except that this prohibition shall not void any settlement entered into without that written consent. The requirement of written consent shall only be waived by both the insured and the insurer.

801.1. (a) Every state or local governmental agency that self insures a person who holds a license, certificate or similar authority from or under any agency mentioned in subdivision (a) of Section 800 (except a person licensed pursuant to Chapter 3 (commencing with Section 1200) or Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act) shall send a complete report to that agency as to any settlement or arbitration award over three thousand dollars (\$3,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error or omission in practice, or rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(b) Every state or local governmental agency that self-insures a person licensed pursuant to Chapter 13 (commencing with Section 4980) or Chapter 14 (commencing with Section 4990) shall send a complete report to the Board of Behavioral Science Examiners as to any settlement or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

802. (a) Every settlement, judgment, or arbitration award over three thousand dollars (\$3,000) of a claim or action for damages for death or personal injury caused by negligence, error or omission in practice, or by the unauthorized rendering of professional services, by a person who holds a license, certificate, or other similar authority from an agency mentioned in subdivision (a) of Section 800 (except a person licensed pursuant to Chapter 3 (commencing with Section 1200) or Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act) who does not possess professional liability insurance as to that claim shall, within 30 days after the written settlement agreement has been reduced to writing and signed by all the parties thereto or 30 days after service of the judgment or arbitration award on the parties, be reported to the agency that issued the license, certificate, or similar authority. A complete report shall be made by appropriate means by the person or his or her counsel, with a copy of the communication to be sent to the claimant through his or her counsel if the person is so represented, or directly if he or she is not. If, within 45 days of the conclusion of the written settlement agreement or service of the judgment or arbitration award on the parties, counsel for the claimant (or if the claimant is not represented by counsel, the claimant himself or herself) has not received a copy of the report, he or she shall himself or herself make the complete report. Failure of the licensee or claimant (or, if represented by counsel, their counsel) to comply with this section is a public offense punishable by a fine of not less than fifty dollars (\$50) or more than five hundred dollars

(\$500). Knowing and intentional failure to comply with this section or conspiracy or collusion not to comply with this section, or to hinder or impede any other person in the compliance, is a public offense punishable by a fine of not less than five thousand dollars (\$5,000) nor more than fifty thousand dollars (\$50,000).

(b) Every settlement, judgment, or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or personal injury caused by negligence, error, or omission in practice, or by the unauthorized rendering of professional services, by a marriage and family therapist or clinical social worker licensed pursuant to Chapter 13 (commencing with Section 4980) or Chapter 14 (commencing with Section 4990) who does not possess professional liability insurance as to that claim shall within 30 days after the written settlement agreement has been reduced to writing and signed by all the parties thereto or 30 days after service of the judgment or arbitration award on the parties be reported to the agency that issued the license, certificate, or similar authority. A complete report shall be made by appropriate means by the person or his or her counsel, with a copy of the communication to be sent to the claimant through his or her counsel if he or she is so represented, or directly if he or she is not. If, within 45 days of the conclusion of the written settlement agreement or service of the judgment or arbitration award on the parties, counsel for the claimant (or if he or she is not represented by counsel, the claimant himself or herself) has not received a copy of the report, he or she shall himself or herself make a complete report. Failure of the marriage and family therapist or clinical social worker or claimant (or, if represented by counsel, their counsel) to comply with this section is a public offense punishable by a fine of not less than fifty dollars (\$50) nor more than five hundred dollars (\$500). Knowing and intentional failure to comply with this section, or conspiracy or collusion not to comply with this section or to hinder or impede any other person in that compliance, is a public offense punishable by a fine of not less than five thousand dollars (\$5,000) nor more than fifty thousand dollars (\$50,000).

802.1. (a) (1) A physician and surgeon, osteopathic physician and surgeon, and a doctor of podiatric medicine shall report either of the following to the entity that issued his or her license:

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

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

(2) The report required by this subdivision shall be made in writing within 30 days of the date of the bringing of the indictment or information or of the conviction.

(b) Failure to make a report required by this section shall be a public offense punishable by a fine not to exceed five thousand dollars (\$5,000).

802.5. (a) When a coroner receives information that is based on findings that were reached by, or documented and approved by a

board-certified or board-eligible pathologist indicating that a death may be the result of a physician's or podiatrist's gross negligence or incompetence, a report shall be filed with the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine. The initial report shall include the name of the decedent, date and place of death, attending physicians or podiatrists, and all other relevant information available. The initial report shall be followed, within 90 days, by copies of the coroner's report, autopsy protocol, and all other relevant information.

(b) The report required by this section shall be confidential. No coroner, physician and surgeon, or medical examiner, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her acting in compliance with this section. No board-certified or board-eligible pathologist, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her providing information under subdivision (a).

803. (a) Except as provided in subdivision (b), within 10 days after a judgment by a court of this state that a person who holds a license, certificate, or other similar authority from the Board of Behavioral Science Examiners or from an agency mentioned in subdivision (a) of Section 800 (except a person licensed pursuant to Chapter 3 (commencing with Section 1200)) has committed a crime, or is liable for any death or personal injury resulting in a judgment for an amount in excess of thirty thousand dollars (\$30,000) caused by his or her negligence, error or omission in practice, or his or her rendering unauthorized professional services, the clerk of the court that rendered the judgment shall report that fact to the agency that issued the license, certificate, or other similar authority.

(b) For purposes of a physician and surgeon, osteopathic physician and surgeon, or doctor of podiatric medicine, who is liable for any death or personal injury resulting in a judgment of any amount caused by his or her negligence, error or omission in practice, or his or her rendering unauthorized professional services, the clerk of the court that rendered the judgment shall report that fact to the agency that issued the license.

# Attachment 5

## *Corresponding Responsibility and Prescription Monitoring Programs*

## **NEVADA HIGH COURT SAYS PHARMACIES CAN'T BE SUED FOR DEATH**

By AMY MERRICK  
The Wall Street Journal  
December 24, 2009, 4:50 P.M. ET

The Nevada Supreme Court, in a 5-2 decision Thursday, ruled that pharmacies cannot be held liable when a customer causes a fatal car accident.

The case, Sanchez vs. Wal-Mart Stores et al, asked whether drugstores must use information available to them to protect the public from potentially dangerous customers.

The customer, Patricia Copenig, had purchased nearly 4,500 doses of prescription painkillers in one year, attracting the attention of Nevada's controlled-substance task force. The state board sent letters to 14 pharmacies in the Las Vegas area in 2003 warning that Ms. Copenig could be abusing drugs.

A year later, Ms. Copenig was driving a Dodge Durango when she hit two delivery men who were standing on the shoulder of a highway, killing one and severely injuring the other. In Ms. Copenig's car, police found prescription bottles and loose pills. Police reports said she appeared confused, and a blood test detected the painkiller hydrocodone. Ms. Copenig pleaded guilty to two counts of reckless driving and served nine months in jail.

The men's families sued Ms. Copenig and the doctors who wrote her prescriptions. After the task-force records came to light, lawyers for Messrs. Sanchez and Martinez added Wal-Mart Stores Inc., Walgreen Co., CVS Caremark Corp. and other pharmacies as defendants. The legal action against Ms. Copenig and the doctors has been on hold while the pharmacies sought to be dismissed from the lawsuits.

The district court granted the pharmacies' request, noting that the Nevada law creating the task force doesn't specify whether any action is required by the pharmacies.

The families appealed to the state Supreme Court, which affirmed the district court's ruling. "We conclude that pharmacies do not owe a duty of care to unidentifiable third parties...[T]he pharmacies' acts of dispensing prescription drugs to Copenig did not create a legal duty," the court wrote in its majority opinion.

In a footnote, the court added that a regulation amended by the state pharmacy board in 2006, two years after the accident, could change the relationship of pharmacies to third parties. But the court declined to decide whether that regulation definitely imposed any new duty on pharmacies.

Phillip Aurbach, an attorney for the families, said he was disappointed with the decision. "It is my belief that the court should not have allowed the pharmacies to throw away the notices, but that the pharmacies should have been required to call the doctors to verify the prescriptions," he said.

Two justices dissented from the majority opinion, saying the pharmacies had a duty to review Ms. Copenig's records and consider the task-force letters before filling her next prescription.

"Generally, the relationship between a customer and pharmacist does not establish a duty in favor of third parties," the dissenting opinion said. "This case, however, includes a component that the majority ignores—notice."

A spokesman for Walgreen, reiterating a previous statement, said: "While we're sympathetic to those injured in Ms. Copening's car accident, we agree with the district judge's decision that our pharmacists fulfilled their legal duties." A Wal-Mart spokeswoman said, "This is a deep personal tragedy for the families involved." She declined to comment further.

The Nevada case, which was the subject of an Oct. 28 article on page one of The Wall Street Journal, is part of a broader movement to place more responsibility for patients' prescription-drug use on pharmacies. Prescription-tracking systems are operating in 33 states, with the goal of identifying potential addicts and referring them for treatment, or getting law enforcement involved if necessary.

Write to Amy Merrick at [amy.merrick@wsj.com](mailto:amy.merrick@wsj.com)

Karen  
Abbe/Pharmacy/DCANotes  
11/05/2009 10:14 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes  
cc Anne Sodergren/Pharmacy/DCANotes@DCANotes, Carolyn  
Klein/Pharmacy/DCANotes@DCANotes  
bcc  
Subject Wall Street Journal: Case Spurs Pharmacies' Fears of  
Lawsuits Over Drug Abuse

## **THE WALL STREET JOURNAL.**

WSJ.com

### **CASE SPURS PHARMACIES' FEARS OF LAWSUITS OVER DRUG ABUSE**

By Amy Merrick  
Wall Street Journal  
October 29, 2009

When Patricia Copenig, a petite, 35-year-old doctor's office receptionist, bought nearly 4,500 doses of prescription painkillers one year, alarm bells sounded at the Nevada controlled-substance task force. The state board sent letters to 14 pharmacies in the Las Vegas area warning that Ms. Copenig could be abusing drugs.

On the afternoon of June 4, 2004 -- a year after the letters were sent -- Ms. Copenig climbed into a gray Dodge Durango, veered onto U.S. 95 and was seen weaving erratically in and out of three-lane traffic, witnesses later said. She plowed into 21-year-old Gregory Sanchez Jr., a delivery-van driver who had pulled over to repair a flat tire on the highway's shoulder, killing him at the scene. She also hit Robert Martinez, 33, who had been helping Mr. Sanchez move packages out of his van. Mr. Martinez suffered a head injury, a broken right leg and other wounds. Ms. Copenig wasn't injured.



Pill bottles from Lam's Pharmacy in Las Vegas were found in a customer's car after a fatal car accident.

A lawsuit filed by Mr. Martinez, his family and Mr. Sanchez's family, now pending before the Nevada Supreme Court, may be the first U.S. case to address whether pharmacies can be held liable when a customer causes a fatal car accident. The case, Sanchez vs. Wal-Mart Stores et al, asks whether drugstores must use information at their disposal to protect the public from potentially dangerous customers.

The Nevada case is part of a broader movement under way to place more responsibility for patients' prescription-drug use on pharmacies.

Abuse of prescription drugs has risen dramatically over the past two decades, along with a surge in the number of controlled-substance prescriptions being written.

In 2007, U.S. retail pharmacies dispensed nearly 180 million prescriptions for opiates, such as hydrocodone and oxycodone, up from about 40 million in 1991, according to congressional testimony last year from the National Institute on Drug Abuse.

At the same time, pharmacists have much more patient information at their disposal, thanks to pharmacy computer systems and a proliferation of state online prescription-tracking databases. The availability of patient information is only expected to increase as electronic health records are adopted by more and more doctors.

As a result, consumers, government officials and pharmacies themselves are increasingly asking what a pharmacy is legally and ethically obligated to do with this newly available information.

This week, the National Association of Boards of Pharmacy is convening a task force to discuss pharmacies' roles in prescription-tracking programs. Separately, the association is considering whether to develop new guidelines about pharmacists' responsibilities to the general public. The issue "is not even an area we'd thought about until recently," says Carmen Catizone, executive director of the group.

Prescription-tracking systems are operating in 33 states, with the goal of identifying potential addicts and referring them for treatment, or getting law enforcement involved if necessary. Most have been set up since 2002. Last month, California launched the largest such database, covering 7,500 pharmacies and 158,000 prescribers.

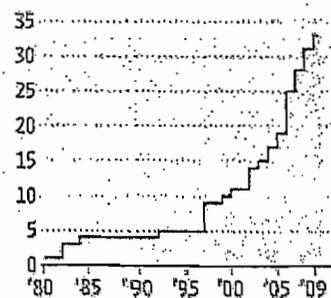
With such programs, "there's certified information coming across, and that's where pharmacies are struggling" to know exactly how to respond, Mr. Catizone says. Earlier this year, the association passed a nonbinding resolution urging pharmacists to help reduce the excessive use of controlled substances by their customers.

The pharmacy industry -- which includes big chains such as Wal-Mart Stores Inc., CVS Caremark Corp. and Walgreen Co., all parties in the Nevada case -- acknowledges the growing public pressure to curb prescription-drug abuse. At a recent conference of the National Association of Chain Drug Stores, conference materials called preventing prescription-drug abuse "the new focus in the war on drugs." It noted that "public and private initiatives are looking to the entire supply chain, including retail pharmacy, to be part of the solution."

The drugstore chains contacted for this story declined to comment on the issue. The National Association of Chain Drug Stores also declined comment.

## Rising Record

Number of states collecting data under prescription-drug monitoring programs



Note: Washington suspended data collection in September 2008  
Source: Drug Enforcement Administration

The chains are watching the Nevada case closely. Legally, it's one thing for a pharmacy to be held liable for hurting an individual customer by, say, filling a prescription with the wrong drug. But drugstores worry Sanchez could open them to broader and more ambiguous responsibility with significant consequences to the industry.

Some predict higher insurance costs and more expensive prescriptions, to absorb the costs of additional lawsuits. In court filings, Wal-Mart argued that pharmacies might decide not to stock certain regulated painkillers. Walgreen suggested that the judgment of pharmacists could be pitted against that of doctors, as pharmacists struggle to decide whether to refuse a prescription.

Michael Wall and L. Kristopher Rath, attorneys for Longs Drug, now owned by CVS Caremark, predicted a "tsunami of litigation" if the families prevail. Drugstores could be sued by their own customers if pharmacists refuse to fill valid prescriptions and customers are harmed, they said. Drugstores could also be sued by those who claim to be injured by a customer who purchased prescription drugs.

In their defense, the drugstore chains argue that they face a dilemma similar to that faced by bartenders in some states. Bartenders can be held liable for the acts of customers served too much alcohol. Similarly, doctors have been successfully sued by car-crash victims for failing to warn patients not to drive under the influence of certain medications.

Nevada was one of the first states to systematically share prescription information among doctors, pharmacists and law-enforcement officials when it set up a computer database to track potential drug abuse in 1997.

Under Nevada law, pharmacies must report their patients' controlled-substance prescription records each month. Staff members of the state's Prescription Controlled Substance Abuse Prevention Task Force filter that data for warning signs of abuse, such as purchasing drugs from multiple pharmacies. If a customer sets off enough red flags, the task force sends a form letter to the pharmacies the patient has visited.

"The focus of the task force is to get people into treatment and help them," says Larry Pinson, executive director of the state pharmacy board. "The primary option is for the pharmacist to speak with the patient."

But the law creating the task-force database isn't explicit about what pharmacies should do with the letters, he says.

## Tracking Drug Use

Status of state prescription-drug monitoring programs

■ Program in place   ■ Legislation enacted, not yet operational   □ No program



In June 2003, the task force sent letters to the 14 pharmacies in the Las Vegas area, including Wal-Mart,

Walgreen, CVS and others, warning them that Ms. Copenig had purchased during the prior year 60 prescriptions, or nearly 4,500 doses, of controlled substances. Most were for medications containing hydrocodone, a frequently abused narcotic.

"It is not the Task Force's intent to determine how you dispense prescriptions," the letter said. "Well-informed pharmacists can and will use their professional expertise to assist patients who may be abusing controlled substances."

In Ms. Copenig's case, there's no documentation of any pharmacist making a note in her customer records about the task-force letter, counseling her about drug addiction or refusing to give her prescriptions. She continued to buy large quantities of hydrocodone, as well as Soma, a muscle relaxant, from numerous pharmacies, according to her prescription records, which are part of the lawsuit. The combination of the two drugs, which is said to produce a euphoria similar to that induced by heroin, is known locally as the "Las Vegas cocktail."

That June afternoon in 2004, Ms. Copenig left the Las Vegas OB-GYN clinic where she worked as a receptionist. She drove a Durango owned by her employer, Richard M. Groom.

Witnesses reported later that Ms. Copenig was driving haphazardly, jerking her steering wheel from side to side. She appeared to be either laughing to herself or having a seizure.

Around the same time, Mr. Sanchez got a flat tire. He pulled his silver Airborne Express van onto the shoulder of U.S. 95 and sent a text message to a dispatcher: "Yo my tire blew."

Mr. Martinez, his co-worker, parked his own van behind Mr. Sanchez's vehicle, and the two men started moving freight out of the disabled vehicle. Ms. Copenig swerved off the road and hit them both. Mr. Sanchez died at the scene. The coroner discovered tire tracks across his lower back. Mr. Martinez suffered multiple injuries and was taken to the hospital.

In Ms. Copenig's car, police found prescription bottles and loose pills, 167 in total, of hydrocodone, Soma and other drugs. Police reports said Ms. Copenig appeared confused. She took off her low-heeled sandals and tried to walk barefoot in a straight line, following a patrol officer's directions, but struggled to keep her balance. When police asked, she couldn't remember the name of one of her two children.

She claimed she had taken only medicine for a migraine headache that day; a blood test detected hydrocodone. She was charged with reckless driving, driving while intoxicated and being involved in a fatal accident.

Ms. Copenig pleaded guilty to two counts of reckless driving and served nine months in jail. Through a spokeswoman, she and her attorney declined to comment. The state revoked the license of Dr. Groom's business partner, Doyle S. Steele, the doctor who wrote most of Ms. Copenig's prescriptions. A few months after the accident, the Sanchez and Martinez families sued Ms. Copenig and the doctors.

After the task-force records came to light in pretrial discovery, lawyers for Messrs. Sanchez and Martinez added seven pharmacy-chain owners -- including Wal-Mart, Walgreen, CVS Caremark and Rite Aid Corp. -- and one independent drugstore as defendants.

Individual pharmacists have been successfully prosecuted for knowingly filling controlled-substance prescriptions that weren't issued for legitimate medical needs. In guidelines to pharmacists, the federal Drug Enforcement Administration says: "The pharmacist who deliberately looks the other way when there is reason to believe that the purported prescription had not been issued for a legitimate medical purpose, may be prosecuted...." Pharmacies have said that the guidelines leave open questions about what practices are unacceptable.

In general, courts have found that doctors owe greater duties to patients when issuing prescriptions than pharmacists do when filling them.

But recent court decisions have expanded pharmacists' responsibility. In 1994, the Indiana Supreme Court ruled in *Hooks SuperRx Inc. vs. McLaughlin* that a pharmacy had a duty to stop dispensing painkillers to a patient who was refilling a prescription faster than normally would be appropriate.

In the Nevada case, Clark County district court Judge Douglas W. Herndon dismissed the pharmacies from the suit, noting that the Nevada law creating the task force doesn't specify what action, if any, is required by the pharmacies.

The families appealed to the state Supreme Court, which heard oral arguments in March.

Lawyers for the pharmacies argue that, while drugstores may choose not to sell drugs to a customer, they had no legal obligation to turn away Ms. Copening or to protect the general public from her actions.

In a statement, Walgreen said: "While we're sympathetic to those injured in Ms. Copening's car accident, we agree with the district judge's decision that our pharmacists fulfilled their legal duties." Similarly, Wal-Mart said, "This is a deep personal tragedy for the families involved." Because the court hasn't issued its decision, "we don't believe it's appropriate to say more at this time," the company said.

CVS Caremark, Rite Aid and Albertson's Inc., the parent company of Sav-On Drug, all declined to comment on the case. The parent company of Lam's Pharmacy, a Las Vegas drugstore, declined to comment.

Some regulators say that even if the drugstore chains are absolved of any legal responsibility in the Nevada case, their pharmacists still had ethical duties to respond to the task-force report. "That requirement is still there professionally, if not legally," says William Winsley, executive director of the Ohio Board of Pharmacy, which isn't involved in the Nevada case.

The Nevada Supreme Court is expected to issue its opinion by the end of the year.

Write to Amy Merrick at [amy.merrick@wsj.com](mailto:amy.merrick@wsj.com)

Printed in The Wall Street Journal, page A18

# Physicians and pharmacists have corresponding responsibility when writing and dispensing controlled substance prescriptions

*If a physician writes a controlled substance prescription that is not for a legitimate medical purpose, the pharmacist shares a corresponding responsibility or liability with that physician if he or she fills that prescription while knowing or having objective reason to know that the prescription was not issued for a legitimate medical purpose.*

A pharmacist's "objective reason to know" includes, but is not limited to, warnings or cautions or other suspicious information from a Board inspector, Board publications, the media, other pharmacy personnel, or personnel of other drug entities. These are all ways of putting a pharmacist on notice to be cautious and to use that information and his or her professional judgment to determine whether a prescription should be filled. The more the pharmacist is already on notice to be cautious, the less additional information or factors would be required to establish that he or she failed to properly consider prescriptions before filling them.

That said, how does a pharmacist evaluate a controlled substance prescription that appears—at least on its face—to have all the elements of a valid prescription? To make it easier to evaluate questionable prescriptions, the Board has developed a set of guideline questions that pharmacists may ask themselves before dispensing. However, it is important to remember that these guidelines do not cover every possibility; nor will every question apply in every case.

## Questions Relating to the Patient

- Are you able to verify the true name and identity of the patient?
- Does the patient live within or outside the normal trading areas of the pharmacy? Is the distance so great that it is unlikely the patient would travel so far to fill a legitimate prescription?
- How far is the patient's residence from the prescriber's office?

- What do you know about the drug history of the patient?
- What is the patient's physical appearance and demeanor in relation to the drug being prescribed?
- When a third party picks up the prescription, what is his or her relationship to the patient? What is his or her physical appearance and demeanor?

## Questions Relating to the Prescribing Physician

- Is information present in the pharmacy regarding the prescribing patterns of the physician, including the type of drugs, their frequency and volume? If not, is that information readily available to you?
- Of the physician's total prescriptions filled at your pharmacy, does there appear to be an excessive percentage of prescription written for controlled substances and other potentially abusable drugs? Is that information readily available to you?
- What is the nature of the physician's practice, including any recognized area of specialty? Are the drugs prescribed appropriate for that practice or specialty?
- Are you aware of any prior criminal or disciplinary action taken against the prescriber?

## Questions Relating to the Therapeutic Appropriateness of the Prescription

- What are the abuse history and current patterns of abuse of the prescribed drug?

- If the patient's diagnosis is known, is the prescribed drug therapeutically appropriate?
- Is the frequency of refills or new prescriptions for the same drug the same as in the directions for use given by the physician?
- How do the length and quantity of the prescribed drug therapy compare to recognized and accepted prescribing practices?
- Is the physician prescribing unusual combinations of drugs or antagonistic or contraindicated drugs?

## Regulatory References

Under federal law and regulations (21 United States Code section 841, taken together with 21 Code of Federal Regulations section 1306.04[a]), a pharmacist is criminally liable for knowingly filling prescriptions for controlled substances for other than a legitimate medical purpose. State law, Health & Safety Code section 11153(b) is similar.

For disciplinary liability, the standard is clearly excessive furnishing for other than a legitimate medical purpose (Business & Professions Code section 4301[e], taken together with H&SC section 11153[a]) or dispensing a controlled substance prescription when the pharmacist knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose (Title 16 of the California Code of Regulations section 1761[b]).

# Attachment 6

*Minutes of the  
Enforcement Committee  
Meeting of December 8,  
2009*



**California State Board of Pharmacy**

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

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

**DATE:** December 8, 2009

**LOCATION:** Department of Consumer Affairs  
First Floor Hearing Room  
1625 N. Market Boulevard  
Sacramento, CA 95834

**COMMITTEE MEMBERS**

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

**COMMITTEE MEMBERS**

**NOT PRESENT:** Robert Swart, PharmD, Chair

**STAFF**

**PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Robert Ratcliff, Supervising Inspector  
Joshua Room, Deputy Attorney General  
Kristy Schieldge, DCA Staff Counsel  
Tessa Fraga, Staff Analyst

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**Call to Order**

Acting Chair Dr. Randy Kajioka called the meeting to order at 9:39 a.m.

**1. Presentation by GreenRx on Drug Management Programs to Use Drugs Before They Become Outdated**

**Presentation – Anand Shukla, GreenRx**

Dr. John Cronin provided background on the development of GreenRx.

Anand Shukla, representing GreenRx, provided an overview of the GreenRx system and presented a proposal he believes will reduce the amount of outdated prescription drugs that occur annually in pharmacies by monitoring non-moving, slow moving, overstocked and unwanted drugs within the inventories of participating pharmacies. His proposal is to better manage by a central coordinating firm so that these drugs do not become waste due to distribution problems among pharmacies.

Mr. Shukla provided comments on pharmaceutical waste and the cost of prescription drugs. He stated that GreenRx tracks and identifies specific drugs within the inventories of participating pharmacies to be resold and redistributed amongst GreenRx network pharmacies. Mr. Shukla explained that GreenRx provides information but does not take the possession of the drug.

Dr. Cronin provided comment regarding the legality of the GreenRx system. He reviewed Business and Professions Code section 4126.5 (a)(5) and its application to this proposal.

### **Committee Discussion**

The committee discussed the GreenRx process and its application to pharmacy law. Discussion focused on a protocol to ensure that the GreenRx system adheres to and promotes consumer protection. Advantages for allowing the redistribution of drugs between pharmacies were evaluated. Concern was expressed that the system may promote hoarding and price gouging in the event of a drug shortage.

### **Public Comment**

Greg Shapansky expressed concern regarding the transfer of drugs between pharmacies.

Mr. Shukla provided that the GreenRx business model represents a great opportunity for the state of California to set an example for other states.

There was no additional committee discussion or public comment.

## **2. Discussion of the Actions of the Department of Consumer Affairs Health Care Boards to Develop Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery/Monitoring Programs**

Dr. Kajioka provided that 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.

Dr. Kajioka provided that to facilitate implementation of these standards, the Department of Consumer Affairs (DCA) created a workgroup consisting of staff from each of the healing arts boards to draft recommended standards for the SACC consideration during public meetings. He stated that the recommended standards were vetted during public meetings akin to an informational hearing. Dr. Kajioka added that the draft standards were then presented during a public meeting to the SACC for consideration and action.

Ms. Herold provided that the board has been directed by the director of DCA to implement the recommended standards and to initiate any necessary statutory changes. She discussed the impact the new standards will have on the board's Pharmacists Recovery Program (PRP). Ms. Herold explained that the PRP is currently available to pharmacists and pharmacist interns. She stated that under the guidelines it will also be made available to pharmacy technicians and designated representatives with the implementation of the standards.

### **Presentation – Assistant Executive Officer Anne Sodergren**

Assistant Executive Officer Anne Sodergren provided an overview on SB 1441 and reviewed the following 16 standards:

1. Clinical diagnostic evaluation
  - Specifies that a licensee in a diversion program or on probation will be required to undergo a clinical evaluation at the licensee's expense.
  - Sets forth the qualifications for the licensed practitioner performing the evaluation as well as the required elements of the evaluation.
  - Provides for the timeframes to complete the process and prohibits the evaluator from having a financial relation, etc. with the licensee.
2. Temporary removal of practice for clinical evaluation
  - Specifies that license will be placed on an inactive status 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
  - 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 104 random drug tests per year for the first year and a minimum of 50 random drug tests per year thereafter.
  - 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.
5. Group meeting attendance
  - Sets forth the evaluation criteria that must be considered when determining the frequency of group meetings.
  - Specifies the qualifications and reporting requirements for the meeting facilitator.
6. Type of treatment
  - Sets forth 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 place a licensee's license on an inactive status 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.

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 act 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: placing the license on an inactive status; 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 attendance; 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 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.

Ms. Sodergren reviewed statutory, regulatory, and contractual changes needed in order to implement the standards.

### **Committee Discussion**

Kim Kirchmeyer, Deputy Director for Board and Bureau Programs, encouraged the board to direct staff and council to identify all necessary steps in order to implement the standards. She requested the following of the board and staff: submit proposed language for any needed legislation to the Director's Office, present proposed language to the board for approval at the next board meeting, place an item on any subsequent board meeting agenda to review the progress of the implementation of the standards, and to authorize the executive officer to implement the standards that do not require a regulatory or statutory change.

Ms. Herold provided that the PRP is an important safety element for the board. She stated that although many of the standards are already elements of the PRP, many statutory changes are still needed.

Kristy Schieldge, Senior Staff Counsel, provided that SB 1441 directs all healing arts boards to fully implement the standards.

Ms. Herold discussed necessary statutory changes and possible implications for these changes.

The committee discussed several issues including the fiscal impact for subsidizing PRP participation fees for two new license categories and the inactivation of a license for program noncompliance. Discussion focused on the increasing costs for participation that may result in the possible decline in PRP participation as well as a decline in the number of licensees who are willing to stipulate to settlements that include the PRP within their terms.

Ms. Herold provided that board staff will continue to work with counsel to develop proposed language and to update the board's disciplinary guidelines. She stated that these changes will be addressed at the January 2010 Board Meeting.

Ms. Sodergren provided that the PRP is currently administered by a contracted vendor that adheres to a specified scope of work and contract for seven boards within the department. She stated that implementation of the standards would require a new scope of work.

Mr. Room provided that it may be necessary to renegotiate this contract.

Ms. Herold provided that the contractual changes will be negotiated by the department.

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

### **3. DEA Reclassifies Carisoprodol into Schedule IV**

Dr. Kajioka provided that the federal Drug Enforcement Administration released proposed rules to reclassify carisoprodol to federal Schedule IV. He stated that currently this drug is not scheduled either at the federal or state level.

Dr. Kajioka provided that written comments on this reclassification are due by December 17, 2009.

Dr. Kajioka provided that board supervising inspectors strongly support this reclassification. He stated that when investigating drug diversion and misuse of drugs, carisoprodol (or Soma) is a frequently misused and diverted drug. Dr. Kajioka explained that patients often purchase such drugs from Web sites without legitimate prescriptions. He indicated that a recent citation and fine issued to a California pharmacy that was dispensing drugs to California patients involved carisoprodol in 52 percent of the more than 3,000 prescriptions identified by the board sent to California purchasers.

Dr. Kajioka provided that staff recommends that the board submit comments to the DEA in support of reclassifying carisoprodol into federal Schedule IV.

### **Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, sought clarification regarding the application of the federal and state schedule classifications. He encouraged the board to discuss this issue with the Department of Justice (DOJ).

Mr. Room provided that a statutory amendment to California law is needed in order to reclassify a drug as a controlled substance. He indicated that scheduling issues are typically handled by DOJ.

There was no additional committee discussion or public comment.

**MOTION:** Direct board staff to submit comments to support the Drug Enforcement Agency's reclassification of carisoprodol to a federal Schedule IV.

M/S: Lippe/Castellblanch

Approve: 2      Oppose: 0      Abstain: 1

#### **4. Update on California Drug "Take Back" Programs from Patients**

Dr. Kajioka provided that the next issue of the *The Script* will promote the California Integrated Waste Management Board's (CIWMB) guidelines for model programs for the "take back" or return of unwanted prescription drugs from patients. He stated that the article will advise that the board expects pharmacies to use these guidelines if they participate in taking back drugs from patients. Dr. Kajioka indicated that the newsletter issue is undergoing legal review and will be released shortly.

Dr. Kajioka provided that the board is aware that a number of communities are establishing collection programs for unwanted prescription drugs, which under California law are considered hazardous household waste. He stated that unlike used motor oil or plastic shopping bags, aggregations of prescription drugs have value. Dr. Kajioka indicated that few of these programs comply with the CIWMB guidelines and many also violate the federal Drug Enforcement Administration's requirements for the appropriate take back of controlled substances.

Dr. Kajioka provided that President Ken Schell, Executive Officer Virginia Herold, and Supervising Inspector Judi Nurse recently attended a conference convened by the California Integrated Waste Management Board on various recycling and disposal issues surrounding California. He stated that representatives from

various waste collection, recycling and disposal programs from most California cities and counties attended. Dr. Kajioka indicated that the board's purpose in attending this conference was to emphasize support for the CIWMB's guidelines.

Dr. Kajioka provided that recently the board's executive officer met with staff from Sharps, Inc. He stated that this firm provided a presentation on mail back options at the July 2009 Board Meeting. Dr. Kajioka indicated that they left Executive Officer Herold with a modified mail-back collection box that incorporates many of the suggestions made during the July Board Meeting.

Dr. Kajioka provided the following statistics about the costs per pound of mail back:

In July 2009 from Maine:

Number of envelopes received at the incinerator (7/17/09)	3,374
Total weight (pounds)	1,560
Average weight per envelope (pounds)	0.4624
Cost (\$3.49/envelope)	\$11,775
Price/weight (pounds)	\$7.55

San Francisco recently provided the board's executive officer with data from a San Francisco mail-back program (through November 9, 2009).

Number of envelopes distributed (before 11/09)	1,443
Number of envelopes returned to incinerator (11/09)	558 (38.7%)
Total weight (pounds)	417.4
Average weight per envelope (pounds)	0.7480
Cost	\$1,947.42
Price/weight (pounds)	\$4.67

Dr. Kajioka provided that San Francisco Household Hazardous Waste Collection Facility's manager is unable to explain the relatively low rate of return. He stated that another factor perhaps influencing the low weight returned per envelope may be due to the instructions, which state that the original container be included in the envelope, which takes a lot of space.

### **Committee Discussion**

Ms. Herold presented the features of the modified mail-back box designed by Sharps, Inc. She indicated that this box does not comply with the CIWMB guidelines.

The committee discussed current situations involving improper collection of controlled substances. It was reiterated that licensees will be encouraged to adhere to the CIWMB guidelines.

## **Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, sought clarification regarding the board's opinion on the legality of take-back programs for non-controlled substances.

Ms. Sodergren provided that the board developed a policy statement that is released specific to the implementation of drug take-back programs.

Ms. Herold highlighted the board's policy statement including permissible guidelines.

There was no additional committee discussion or public comment.

## **5. Consideration of Best Practices on How to Use CURES Data as Part of Drug Utilization Review**

Dr. Kajioka provided that in August, the California Department of Justice (DOJ) unveiled a new program allowing Internet access to prescribers and pharmacies for data regarding patients who had been dispensed controlled substances in Schedules II-IV as recently as three weeks in the past.

Dr. Kajioka provided that in California all drugs dispensed to patients by pharmacies or prescribers must be reported electronically to the Controlled Substances Utilization and Review System (CURES) each week. He stated that this is the data that is now accessible to prescribers and pharmacies via the Internet. Dr. Kajioka explained that the implementation of this feature is a major step forward in assuring that patients who are doctor shoppers are not able to obtain drugs from pharmacies or prescribers by going to multiple prescribers and pharmacies.

Dr. Kajioka stated that at the January 2010 Board Meeting, DOJ will present a demonstration of the new system. He provided a description of an article concerning a possible need for pharmacies to check the prescription monitoring programs operating in their state (such as CURES) before dispensing controlled drugs.

Dr. Kajioka advised that currently the board requires pharmacists to use corresponding responsibility.

## **Committee Discussion**

Dr. Castellblanch asked whether California has any sanctions against excessive furnishing.

Ms. Schieldge provided that excessive furnishing sanctions are in place.

### **Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, provided comment on the CURES program and discussed issues involving duplicative names, aliases, and false information.

There was no additional committee discussion or public comment.

## **6. Pharmacies Dispensing Prescriptions for Internet Web Site Operators**

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

Dr. Kajioka provided that many times these prescriptions are not valid because an appropriate exam by a prescriber has not occurred. He stated that California law allows the board to issue citations at \$25,000 per invalid prescription. Dr. Kajioka indicated that over the last 12 months, the board has issued multiple million dollar fines to California pharmacies for filling such false prescriptions. He advised that the Drug Enforcement Administration is also involved in some of these Web site investigations and has fined California pharmacies for their participation.

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

Dr. Kajioka provided that the July 2008 version of *The Script* reminded pharmacies not to participate in such scams.

### **Committee Discussion**

Ms. Herold provided an overview on the fines issued in the last year to California pharmacies aiding Internet providers in distributing prescription drugs without a valid prescription.

## Public Comment

Dr. John Cronin provided comment regarding the patient perspective of this issue. He encouraged the board to address consumer concerns and refer consumers to specific and relevant information when they have questions.

Discussion continued regarding the board's role with regards to this issue. It was emphasized that professional judgment must be used when partaking in this practice.

Bob Ratcliff, Supervising Inspector, provided that he frequently refers consumer questions regarding internet prescription to Business and Professions Code section 4067 and to relevant articles that have been featured in *The Script*.

There was no additional committee discussion or public comment.

## **7. Ongoing Discussion on Prevention of Medication Errors**

Dr. Kajioka provided that at every meeting of the Enforcement Committee in the last 18 months, there has been a discussion of medication errors and how to prevent them.

Dr. Kajioka provided that since the beginning of 2009, the board has been interviewed for at least four major media segments that have focused on medication errors. He stated that the board's messages in these segments are that:

- (1) medication errors do occur, there are 350 million prescriptions filled each year in California,
- (2) the board has requirements for all pharmacies to operate vigorous quality assurance programs that the board forcefully enforces to ensure all errors are closely reviewed by the pharmacy, staff are educated and process changes are made to prevent a recurrence,
- (3) there is no acceptable number of medication errors a pharmacy or pharmacist can make,
- (4) no pharmacist wants to make an error, and most live in fear of making an inadvertent error,
- (5) a grossly negligent error will result in formal discipline, other errors reported to the board, if substantiated, will be cited and fined,
- (6) patients need to take some actions to prevent medication errors from reaching or occurring to them,
- (7) the board's Notice to Consumer posters are there at the critical point in the pharmacy to aid patients in getting the right medicine,
- (8) the board is working to redesign labels to improve them for patients so they better understand how to take their medication,
- (9) patient consultation will prevent errors and patients, and

- (10) patients need to speak with a pharmacist when they come into a pharmacy and not be in a rush to leave before doing so – such a discussion can save their lives.

Dr. Kajioka provided that the board recently partnered with the Department of Consumer Affairs and a private firm to produce a three-minute video for consumers on how patients can prevent receiving a medication error. He stated that this video will be added to the board's Web site.

The committee viewed the video.

### **Committee Discussion**

Dr. Castellblanch sought clarification regarding current requirements for pharmacists to provide a consultation.

Dr. Kajioka provided that pharmacists are required to provide a consultation for any new prescription, for a prescription where there is a change of strength or direction, or when requested by the patient.

### **Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, provided comment on the consultation process outlined in the video.

Ms. Herold provided that the process was provided by the Pharmacy Foundation of California, and thanked them for their assistance.

Dr. Castellblanch asked whether workload standards have been established for pharmacists.

Ms. Herold provided that standards in this area have not been established.

Mr. Room reviewed current staffing ratio limitations.

Dr. Gray provided comment regarding fatigue among healthcare professionals.

There was no additional committee discussion or public comment.

**8. Reporting of Settlements to the Board as Required by California Business and Professions Sections 800-802**

Dr. Kajioka provided that the board's staff recently learned that some insurance companies and some licensees may not be aware of their responsibilities to report settlements to the board for errors and omissions pursuant to requirements in California Business and Professions Code sections 800, 801, and 802. He stated that as a result, these reports are not being submitted to the board.

**Committee Discussion**

Mr. Room provided that failure to report can result in action by the board and is considered a public offense.

Ms. Herold provided that licensees will be reminded of this obligation in the next issue of *The Script*. She stated that in 2008-09, the board received four reports under sections 800-802.

Ms. Schieldge provided that section 804 includes a procedure for healing arts boards to promulgate either regulations or due forms to assist in facilitating the collection of this information. She also stated that board staff is required to acknowledge receipt of all reports.

**Public Comment**

Dr. Steve Gray provided that this issue may cause confusion for licensees as it relates to the board's quality assurance program. He stated that the information provided may be misconstrued.

There was no additional committee discussion or public comment.

**9. Public Comment for Items Not on the Agenda**

No public comment was provided.

The meeting was adjourned at 1:13 p.m.

# Attachment 7

*Enforcement Statistics*  
*2009-10*

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2009/2010

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

**Complaints/Investigations**

Initiated	520	539			539
Closed	1087	1241			2328
Pending (at the end of quarter)	2346	2204			2204

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

Compliance Team	85	149			149
Drug Diversion/Fraud	60	80			80
Probation/PRP	25	30			30
Mediation/Enforcement	5	38			38
Criminal Conviction	1277	987			987

**Application Investigations**

Initiated	167	111			278
Closed					
Approved	39	58			99
Denied	33	7			40
Total*	90	82			173
Pending (at the end of quarter)	420	451			451

**Citation & Fine**

Issued	495	396			891
Citations Closed	210	214			424
Total Fines Collected	\$298,575.00	\$229,215.00			\$527,790.00

\* This figure includes withdrawn applications.

\*\* Fines collected and reports in previous fiscal year.

# Board of Pharmacy Enforcement Statistics Fiscal Year 2009/2010

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

**Administrative Cases** (by effective date of decision)

Referred to AG's Office*	78	91			169
Pleadings Filed	49	65			114
<b>Pending</b>					
Pre-accusation	160	180			180
Post Accusation	138	178			178
<b>Total</b>	<b>205</b>	<b>458</b>			<b>458</b>
<b>Closed**</b>					
<b>Revocation</b>					
Pharmacist	3	3			6
Pharmacy	0	1			1
Other	3	10			13
<b>Revocation, stayed; suspension/probation</b>					
Pharmacist	2	4			6
Pharmacy	2	1			3
Other	0	2			2
<b>Revocation, stayed; probation</b>					
Pharmacist	1	0			1
Pharmacy	0	0			0
Other	1	0			1
<b>Suspension, stayed; probation</b>					
Pharmacist	0	0			0
Pharmacy	0	0			0
Other	0	0			0
<b>Surrender/Voluntary Surrender</b>					
Pharmacist	0	2			2
Pharmacy	0	1			1
Other	1	0			1
<b>Public Reprival/Reprimand</b>					
Pharmacist	0	1			1
Pharmacy	0	0			0
Other	0	0			0
Cost Recovery Requested	\$43,046.75	\$84,477.00			\$127,523.75
Cost Recovery Collected	\$38,423.20	\$68,175.75			\$106,598.95

\* This figure includes Citation Appeals

\*\* This figure includes cases withdrawn

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2009/2010

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

### Probation Statistics

Licenses on Probation

Pharmacist	106	103			103
Pharmacy	6	6			6
Other	14	20			20
Probation Office Conferences	22	25			47
Probation Site Inspections	36	23			59
Probationers Referred to AG for non-compliance	2	2			4

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 12/31/09)

Program Statistics

In lieu of discipline	0	0			0
In addition to probation	1	3			4
Closed, successful	5	0			5
Closed, non-compliant	0	4			4
Closed, other	3	5			8
Total Board mandated Participants	50	46			46
Total Self-Referred Participants*	27	27			27
Treatment Contracts Reviewed	48	46			94

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 December 31, 2009

**California State Board of Pharmacy  
Citation and Fine Statistics  
July 1, 2009 - January 1, 2010**

**968 Citations were issued this fiscal year**

**Total dollar amount of fines issued this fiscal year  
\$218,695,875.00**

**Total dollar amount of fines collected  
\$527,790.00**

\*This amount also reflects payment of citations issued prior to July 1, 2009.

The average number of days from date case is opened until a citation is issued is 340.13

Average number of days from date case is routed to Citation Unit to date citation is issued 53.23

400 citations are closed. The average number of days from date citation is issued to date citation is closed is 124.82

**Citation Breakdown by license type**

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine**	PIC no fine**	TCH with fine	TCH no fine
968	260	49	400	93	154	27	32	34

**Citation Breakdown by Miscellaneous license type**

Wholesalers	Exemptee's	Clinics	Drug Room	Exempt Hosp.	Hosp. Pharmacy	Misc.*	Unlicensed Premises	Unlicensed person
7	10	1	1	2	7	27	36	9

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

\*\*These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

## Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	42%	4110(a)/4201(f) - No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board.../Pharmacy license shall authorize the holder to conduct a pharmac	58%	1716 - Variation from prescription	23%
1714(d) - Operational Standards and security; Pharmacist responsible for pharmacy security	14%	1716 - Variation from prescription	17%	1714(d) - Operational Standards and security; Pharmacist responsible for pharmacy security	20%
1716/1761(a) - Variation from prescription/Erroneous or uncertain prescription; no pharmacist shall compound or dispense any prescription which contains any significant error or omission...	8%	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	8%	4342 - Actions by board to prevent sale of preparations or drugs lacking quality or strength; penalties for knowing or willful violation of regulations governing those sales	10%
1761(a)/1716 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission.../Variation from prescription	7%	1761(a)/1716 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission.../Variation from prescription	3%	1716/1761(a) - Variation from prescription/Erroneous or uncertain prescription; no pharmacist shall compound or dispense any prescription which contains any significant error or omission...	8%
4342 - Actions by board to prevent sale of preparations or drugs lacking quality or strength; penalties for knowing or willful violation of regulations governing those sales	6%	1716/1761(a) - Variation from prescription/Erroneous or uncertain prescription; no pharmacist shall compound or dispense any prescription which contains any significant error or omission...	3%	4076(a)&(11)(A) - Prescription container requirements for labeling - physical description of dispensed medication	7%
1707.2(b)(1)(a) - In addition to the obligation to consult...a pharmacist shall provide oral consultation to his or her patients...whenever the prescription drug has not previously been dispensed to a pat	6%	4342 - Actions by board to prevent sale of preparations or drugs lacking quality or strength; penalties for knowing or willful violation of regulations governing those sales	3%	4104(b) - Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft diversion, or self-use of dangerous drugs, among licensed	7%
4076(a)&(11)(A) - Prescription container requirements for labeling - physical description of dispensed medication	5%	4076(a)&(11)(A) - Prescription container requirements for labeling - physical description of dispensed medication	2%	4169(a)(1) - Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity...	6%
4104(b) - Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft diversion, or self-use of dangerous drugs, among licensed	4%	4104(b) - Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft diversion, or self-use of dangerous drugs, among licensed	2%	1715(a) - Self-assessment form of a pharmacy by the pharmacist in charge; shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law	6%
4169(a)(1) - Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity...	4%	1707.2(b)(1)(a) - In addition to the obligation to consult...a pharmacist shall provide oral consultation to his or her patients...whenever the prescription drug has not previously been dispensed to a pat	2%	1761(a)/1716 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission.../Variation from prescription	6%
4115(e) - Pharmacy technician license required	4%	4115(e) - Pharmacy technician license required	2%	4115(e) - Pharmacy technician license required	6%

**Contested Citations Office Conference**  
 (These statistics also include contested Letters of Admonishment)

There were 6 office conferences held this fiscal year

<b>Number of Requests</b>	<b>138</b>
---------------------------	------------

<b>Number of Scheduled</b>	<b>138</b>
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<b>Number of Appeared</b>	<b>75</b>
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<b>Number of Postponed***</b>	<b>37</b>
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\*\*\*Please note these are added back into the number of requests and scheduled case totals above.

<b>Total number of requests withdrawn</b>	<b>13</b>
<b>Failed to appear</b>	<b>11</b>

<b>Total number of citations affirmed</b>	<b>29</b>
<b>Total number of citations waived</b>	<b>11</b>

<b>Decision</b>	<b>Total citations</b>	<b>Total dollar amount reduced</b>
<b>Modified</b>	<b>20</b>	<b>\$27,900.00</b>
<b>Dismissed</b>	<b>19</b>	<b>\$10,500.00</b>
<b>Reduced to Letter of Admonishment</b>	<b>0</b>	<b>\$0.00</b>

# Attachment 8

## *Second Quarterly Update of the Enforcement Committee Goals*

# GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

## ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months.						
Measure:	Percentage of cases closed.						
Tasks:	1. Complete all desk investigations within 90 days (for cases closed during quarter).						
		<u>N</u>	< 90 days	< 120 days	< 180 days	Longer	<u>Average Days</u>
	Qtr 1	710	351	10	26	323	364
			50%	1%	4%	45%	
	Qtr 2	800	156	16	26	602	494
			19%	2%	3%	75%	
	Qtr 3						
	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	269	121	34	56	58	208
			45%	13%	21%	22%	
	Qtr 2	286	68	61	60	97	265
			24%	21%	21%	34%	
	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.

<b>Qtr 1</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action	357	172	67	36	82
Rap sheet/CCU - 4301 letters and license denials	168	10	4	9	145
Cite and/or fine letter of admonishment	358	249	18	17	74
Attorney General's Office	90	6	11	15	58
<b>Qtr 2</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action	623	231	56	69	267
Rap sheet/CCU - 4301 letters and license denials	145	7	7	19	112
Cite and/or fine letter of admonishment	232	70	45	16	101
Attorney General's Office	86	19	19	19	30
<b>Qtr 3</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action					
Rap sheet/CCU - 4301 letters and license denials					
Cite and/or fine letter of admonishment					
Attorney General's Office					
<b>Qtr 4</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action					
Rap sheet/CCU - 4301 letters and license denials					
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>1. Administer the Pharmacists Recovery Program.</p> <table border="1" data-bbox="365 241 1510 535"> <thead> <tr> <th></th> <th>Voluntary Participants</th> <th>Participants Mandated Into Program</th> <th>Noncompliant, Terminated From Program</th> <th>Successfully Completed Program</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>27</td> <td>50</td> <td>3</td> <td>5</td> </tr> <tr> <td>Qtr 2</td> <td>27</td> <td>46</td> <td>4</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>2. Administer the Probation Monitoring Program.</p> <table border="1" data-bbox="365 598 1242 913"> <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>119</td> <td>121</td> <td></td> <td></td> </tr> <tr> <td>Sites</td> <td>7</td> <td>8</td> <td></td> <td></td> </tr> <tr> <td>Tolled</td> <td>15</td> <td>26</td> <td></td> <td></td> </tr> <tr> <td>Inspections Conducted</td> <td>36</td> <td>23</td> <td></td> <td></td> </tr> <tr> <td>Successfully Completed</td> <td>5</td> <td>6</td> <td></td> <td></td> </tr> <tr> <td>Petitions to Revoke Filed</td> <td>2</td> <td>2</td> <td></td> <td></td> </tr> </tbody> </table> <p>3. Issue all citations and fines within 30 days.</p> <table border="1" data-bbox="365 976 1421 1375"> <thead> <tr> <th></th> <th>N</th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th>Average Days</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>493</td> <td>62</td> <td>371</td> <td>56</td> <td>5</td> <td>44</td> </tr> <tr> <td></td> <td></td> <td>13%</td> <td>75%</td> <td>11%</td> <td>1%</td> <td></td> </tr> <tr> <td>Qtr 2</td> <td>405</td> <td>25</td> <td>152</td> <td>151</td> <td>77</td> <td>66</td> </tr> <tr> <td></td> <td></td> <td>6%</td> <td>38%</td> <td>37%</td> <td>19%</td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>4. Issue letters of admonishment within 30 days.</p> <table border="1" data-bbox="365 1459 1421 1858"> <thead> <tr> <th></th> <th>N</th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th>Average Days</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>17</td> <td>1</td> <td>11</td> <td>3</td> <td>2</td> <td>57</td> </tr> <tr> <td></td> <td></td> <td>5%</td> <td>65%</td> <td>18%</td> <td>12%</td> <td></td> </tr> <tr> <td>Qtr 2</td> <td>44</td> <td>5</td> <td>23</td> <td>16</td> <td>0</td> <td>51</td> </tr> <tr> <td></td> <td></td> <td>11%</td> <td>52%</td> <td>36%</td> <td>0%</td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>These data are actual number of citations and letters of admonishment (LOA) issued. One investigation may have multiple licensees that are issued a citation or LOA (split cases).</p>		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program	Qtr 1	27	50	3	5	Qtr 2	27	46	4	0	Qtr 3					Qtr 4						Qtr 1	Qtr 2	Qtr 3	Qtr 4	Individuals	119	121			Sites	7	8			Tolled	15	26			Inspections Conducted	36	23			Successfully Completed	5	6			Petitions to Revoke Filed	2	2				N	30 days	60 days	90 days	> 90 days	Average Days	Qtr 1	493	62	371	56	5	44			13%	75%	11%	1%		Qtr 2	405	25	152	151	77	66			6%	38%	37%	19%		Qtr 3							Qtr 4								N	30 days	60 days	90 days	> 90 days	Average Days	Qtr 1	17	1	11	3	2	57			5%	65%	18%	12%		Qtr 2	44	5	23	16	0	51			11%	52%	36%	0%		Qtr 3							Qtr 4						
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5. Obtain immediate public protection sanctions for egregious violations.

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

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

	30 days	60 days	> 60 days	N
Qtr 1	0	0	0	0
Qtr 2	1	0	0	1
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.

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	15	4 27%	7 47%	0 0%	3 20%	1 7%	537
Qtr 2	41	22 54%	12 29%	4 10%	0 0%	2 5%	379
Qtr 3							
Qtr 4							

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.																				
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																				
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.																				
	<table border="1"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Aggregate Inspections This Cycle</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>351</td> <td>4,273</td> <td>62%</td> </tr> <tr> <td>Qtr 2</td> <td>349</td> <td>4,350</td> <td>63%</td> </tr> <tr> <td>Qtr 3</td> <td></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	351	4,273	62%	Qtr 2	349	4,350	63%	Qtr 3				Qtr 4			
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	Qtr 1	351	4,273	62%																	
	Qtr 2	349	4,350	63%																	
	Qtr 3																				
	Qtr 4																				
* Decrease due to new licenses issued for CVS/Long's buyout.																					
2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.																					
<table border="1"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>76</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>112</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> </tr> </tbody> </table>		Number of Inspections	Number Inspected Late	Qtr 1	76	0	Qtr 2	112	0	Qtr 3			Qtr 4								
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3. Initiate investigations based upon violations discovered during routine inspections.																					
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Qtr 1	351	0	0																		
Qtr 2	349	5	1%																		
Qtr 3																					
Qtr 4																					

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="370 222 1490 556"> <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> </li> <li data-bbox="370 604 1490 821"> <p>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.</p> <p><i>Sept. 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="370 827 1490 1192"> <p>3. Monitoring the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.</p> <p><i>Nov 2006: Board submits letter supporting change in Drug Enforcement Administration policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.</i></p> <p><i>Sep 2008: Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.</i></p> <p><i>Dec 2009: Executive Officer meets with DEA officials in Washington D.C. to discuss interest in e-prescribing of controlled drugs.</i></p> </li> </ol>

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|  | <p>4. Evaluate establishment of an ethics course as an enforcement option.<br/> <i>Oct. 2008: Board holds regulation hearing on proposed requirements for the ethics class.</i><br/> <i>Jan. 2009: Board adopts regulation.</i><br/> <i>Sept. 2009: Regulation takes effect.</i></p> <p>5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.<br/> <i>Dec 2009: Executive Officer provides presentation on California's e-pedigree requirements to three national association meetings.</i></p> <p>6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.<br/> <i>Sept. 2007: Provided comments on proposed statutory requirements.</i><br/> <i>Dec. 2007: Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.</i><br/> <i>Provided comments on proposed e-prescribing initiatives.</i><br/> <i>Oct. 2008: Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.</i><br/> <i>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.</i><br/> <i>Jan. 2009: Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.</i><br/> <i>March 2009: Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.</i></p> <p>7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.<br/> <i>Oct. 2008: Requirements for security forms in place..</i><br/> <i>2nd Qtr. 09-10: Board executive staff and several board members attend California Healthcare Foundation's annual summit to implement e-prescribing.</i></p> |
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8. Liaison with other state and federal agencies to achieve consumer protection.
- 1st Qtr 07/08: Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.*
- 2nd Qtr 07/08: Bimonthly meeting with the Department of Health Care Services continue.  
Board inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services.  
Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.*
- 3rd Qtr 07/08: Bimonthly meetings with the Department of Health Care Services continue.  
Board works with the Drug Enforcement Administration on joint investigations and receives specialized training.*
- 4th Qtr 07/08: Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.*
- 3rd Qtr 08/09: Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.*
- 4th Qtr 08/09: Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.  
Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.  
The federal Drug Enforcement Administration provides training to board staff on new requirements for online pharmacies selling controlled substances.*
- 2nd Qtr. 09/10: Executive staff meet with Department of Health Care Services staff on mutual investigations; DEA staff in Washington D.C. on enforcement issues involving controlled drugs; the U.S. Attorney General's office in Sacramento on two major enforcement matters; and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

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 publishes guidelines in 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.*

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.*
- Sept. 2009: Stakeholder meeting convened.  
Recall guidelines evaluated and additional comments solicited.*
- Jan 2010: Board reviews final version of recommended steps.*
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.*
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.*