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ENFORCEMENT COMMITTEE MEETING

September 29, 2004
9:30 a.m. – 12:30 p.m.

Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019
(818) 843-6000

Revised Agenda (9/16/04)

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Members of the board who are not on the committee may attend and comment during the meeting.

AGENDA

CALL TO ORDER **9:30 a.m.**

A. Discussion Regarding the Reimportation of Prescription Drugs from Canada

B. Proposed Legislative Change to Update the Law Regarding the Pharmacist Recovery Program (Bus. & Prof. Code Sec. 4360– 4373)

C. Proposed Legislative Change to Update the Law Regarding the Pharmacy Technician Program (Bus. & Prof. Code Sec. 4115 and 4115.5)

D. Proposed Omnibus Legislative Change Related to Letter of Admonishment (Bus. & Prof. Code sec. 4315)

E. Proposed Regulation Change to Implement SB 1913 Related to the Use of Biometric Identification to Document Pharmacist Verification in lieu of the Pharmacist's Initials (CCR, title 16, sec. 1717)

F. Request by Longs Drug Stores for Waiver of CCR, title 16, sec. 1717(e) to Install 24-Hour Prescription Drop Kiosks Not on the Licensed Pharmacy Premise and to Use a Device to Dispense Prescription Medications When the Pharmacy is Not Open

G. Proposed Regulation Change to CCR, title 16, sec. 1717(e) to Authorize a Pharmacy to Use an Automated Dispensing Device and/or Other Secured Means to Depot Prescription Medications and Prescriptions

H. Discussion Regarding the Implementation of SB 151 (Chapter 406, Statutes of 2003) – New Requirements for Controlled Substance Prescriptions and the Elimination of the Triplicate Questions and Answers

I. Status Report on Legislation Relating to Wholesalers – AB 2682 (Negrete-McCleod) and SB 1307 (Senator Figueroa)

J. Discussion on How the Board of Pharmacy Can Improve and Facilitate Communications with the Public and Licensees

K. Review of Draft Self-Assessment Forms for Pharmacy

L. Discussion Regarding Enforcement Operations – Routine Compliance Inspections and Citation and Fine Program

M. New DEA Controlled Substance Registration Certificates

N. Adjournment **12:30 p.m.**

Committee materials will be available on the board's website by September 22, 2004

AGENDA ITEM A

Schwarzenegger Addresses Reimportation Legislation in Radio Interview

September 20, 2004

Gov. Arnold Schwarzenegger (R) on Friday in an interview with a Sacramento radio station "singled out" legislation that would direct the state to consider reimporting lower-cost, U.S. made prescription drugs from Canada, the Contra Costa Times reports. Schwarzenegger last month "strongly signaled" that he would veto the bills and offered lawmakers "an 11th hour compromise," according to the Times.

"I'm trying to do good things for the people, but [legislators] try to jam me so they can go back and say to their district: 'Look what this Republican governor did' so they can go and get their votes in November," Schwarzenegger said.

Sen. Deborah Ortiz (D-Sacramento), who sponsored one of the reimportation bills (SB 1149), said the measures will force Schwarzenegger to choose between drug companies and state residents seeking lower-cost medications, the Times reports. "Our job is not to cozy up to pharmaceutical companies but to help Californians," Ortiz said.

Dan Reeves -- chief of staff to Assembly Majority Leader Dario Frommer (D-Glendale), who sponsored another of the reimportation bills (AB 1957) -- said, "Don't say we're being unfair and mean to [Schwarzenegger] when we're standing up for what we believe in." Reeves added, "If he wants to be the people's governor he should just sign them" (Nissenbaum, Contra Costa Times, 9/18).

Please click here to return to the previous page.

Press Release

OFFICE OF THE GOVERNOR

GAAS:357:04
FOR IMMEDIATE RELEASE
08/20/2004

Text of Letter from Governor Schwarzenegger to Secretary Tommy Thompson

The following letter was sent by Governor Schwarzenegger to the Secretary of the U.S. Department of Health and Human Services today. A PDF version of the letter is attached.

August 20, 2004

The Honorable Tommy G. Thompson
Secretary
United States Department of
Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson,

I am writing in regard to my concern about the growing cost of prescription drugs and my strong desire in identifying approaches that can make medicine more affordable for California's most at-risk consumers.

As we are all acutely aware, domestic prescription drug spending is growing at a rate that outpaces all other categories of health care expenditures. This escalation in cost is disturbing on a number of levels. In particular, I am concerned that rising drug prices push medicines beyond the reach of hard working low-income residents who lack health insurance and do not qualify for public programs.

Considerable attention in California and elsewhere has focused on efforts to allow states to import drugs from Canada in order to combat rising domestic prices. Support for such efforts reflect the depth and scope of public frustration with prescription drug costs and the belief that drug importation will yield reduced prices for consumers. While I share those frustrations, I am concerned that quick legislative fixes at the state level would be contrary to federal law and over-simplify the complex safety, trade, supply and pricing issues involved. Approaches that depend on uncertain future changes in federal law and policy will not bring much needed price reductions to consumers in the near term.

I want to help low-income uninsured Californians in the near term. We have been exploring approaches that offer not just the promise but the reality of meaningful discounts for prescription drugs. One approach is to establish a drug discount program for low-income uninsured residents through a state contract with a Pharmacy Benefit Manager (PBM). Under this approach, hard working Californians who lack insurance would simply be able to present a discount card at their local pharmacy to receive a discount on their prescription drugs. The PBM would negotiate discounted prices with drug manufacturers for program participants. The discount program would also incorporate the existing drug discount and free drug programs that the drug companies have not sufficiently publicized or made user-friendly for the population they are designed to serve.

Another approach we are exploring is to offer Medi-Cal (California's Medicaid program) prices to low-income uninsured residents. Using the state's purchasing power on behalf of California's Medi-Cal population, our program has successfully negotiated deep discounts from drug manufacturers. By extending Medi-Cal prices to targeted low-income uninsured residents, this approach would build upon our state's existing system of negotiated drug discounts, thus making relatively quick implementation possible. We recognize that this approach requires federal approval, so I have asked my Administration's Secretary for the Health and Human Services Agency, Kim Belshe to follow-up shortly with your office to arrange a meeting with your appropriate staff to discuss in greater detail this approach and how California can best move forward.

While the effort to secure meaningful prescription drug discounts for low-income residents is a necessary near term action, it is insufficient. Rather, it is time for the broader issues associated with the global marketplace to be considered and addressed. In that regard, I believe it is unfair and inappropriate that American consumers bear a disproportionate share of the expense of developing new pharmaceutical products that benefit the international community. I encourage the Bush Administration to aggressively pursue its discussions with our trading partners to achieve fairer pricing of pharmaceuticals in the international marketplace and an equitable distribution of the costs of drug research and development.

I look forward to working with you in this important effort.

Sincerely,

Arnold Schwarzenegger

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THE STATE
Lawmakers Vote to Allow Drug Purchases From Canada
By Robert Salladay
Times Staff Writer

August 28, 2004

SACRAMENTO — Despite a large-scale lobbying effort by pharmaceutical companies and opposition from the Schwarzenegger administration, the Legislature on Friday gave final approval to a package of bills allowing cheaper drug imports from Canada.

The legislation puts California at the center of a national debate over the high cost of prescription drugs and could force Gov. Arnold Schwarzenegger to make a series of high-profile vetoes among the hundreds of bills sent to him before the end of the 2004 session.

"It's a far-reaching package to try to give some relief to seniors and the uninsured facing exorbitant prescription drug costs," said Anthony Wright, executive director of Health Access, a nonprofit advocacy group. "It would provide consumers with better information, more choices and, hopefully, cheaper drugs."

Although their actions are illegal, an estimated 1 million Americans already buy their drugs from Canadian pharmacies — costing U.S. pharmaceutical companies about $1 billion a year in lost revenue. Prices in Canada are as much as 40% cheaper, mostly because the government there caps prices.

Aides to the Republican governor already have dubbed some of the drug-importation legislation a "political ploy" and against the law because the federal government restricts drug imports from other countries. Schwarzenegger's health and welfare secretary said the bills would be "symbolic."

When Margita Thompson, a spokeswoman for the governor, was asked if Schwarzenegger would veto the importation bills, she said: "If legislation reaches his desk that would break the law, yes. Because right now, what we need to do is focus on what's right for the people and not breaking the law."

Among the bills sent to Schwarzenegger this week, two would set up a government-run Internet site that would compare prices between Canada and the United States, link consumers to Canadian

pharmacies and target shady and dangerous drug-selling websites.

Another bill would allow California pharmacies to sign contracts with Canadian pharmacies to purchase drugs for Medi-Cal and the AIDS drug-assistance program — saving $9 million a year in drug costs, advocates contend. The state would split the savings with the pharmacies.

Yet another measure would allow the state government to buy Canadian drugs in bulk for the prison, mental health and youth authority systems. That legislation could be more palatable to Schwarzenegger because it requires a federal waiver for approval.

Lawmakers also passed a measure that would allow state agencies to pool their purchasing power and negotiate for lower prescription drug prices.

"I think they hold extraordinary promise for bringing drug prices down," said Assemblyman Dario Frommer (D-Los Angeles). "The bulk-purchasing bills, for taxpayers, could be extremely meaningful. They could help us bring down drug prices. The website bills could provide immediate relief for consumers looking for answers."

According to Frommer's office, the state Medi-Cal program expects to have spent about $3.8 billion on prescription drugs for the 2003-04 fiscal year. The prison system pays about $125 million a year for drugs given to inmates, and the Public Employees' Retirement System spends $700 million every year, his office said.

Drug companies have said that consumers cannot trust the safety of drugs that flow through Canada and that comparing prices is misleading because of Canada's nationalized health system. They warn that siphoning money from the U.S. market would jeopardize the country's status as the world's leader in drug research and development.

And Republicans who argued against the bills said the U.S. Food and Drug Administration is the best agency to determine which drugs are safe.

"Ignoring the rule of law and encouraging illegal importation of drugs from Canada is the wrong way," said Assemblyman George Plescia (R-San Diego). "There is a reason that the federal government has a ban on drug importation. Drugs from foreign countries have not been proven safe."

Schwarzenegger last week proposed his own drug-pricing plan — allowing for seniors and others to pool their resources and buy at lower prices in bulk. The idea was summarily rejected by the Legislature. Lawmakers said it came too late in the session for in-depth consideration. They plan to take up his ideas next year, they said.

Consumer advocates have said Canadian imports are the best stopgap measure to allow senior citizens to get cheaper drugs right away. The FDA, they said, has looked the other way at five other states with Internet sites linking consumers to cheaper Canadian drugs, and some U.S. lawmakers have signaled a willingness to open the door to importation.

Biomedical research companies and national pharmaceutical manufacturers hired an army of lobbyists to defeat nearly a dozen bills before the Legislature this year. But their efforts now are turning to Schwarzenegger.

Drug makers, including biotech firms such as South San Francisco-based Genentech, have donated $186,000 to the governor since his election. That sum includes $100,000 from Pfizer Inc. in February to Schwarzenegger's California Recovery Team campaign committee. Pharmaceutical companies donated $103,000 to him during last year's recall campaign.

Thompson said Schwarzenegger makes his decisions based on the merits of legislation and nothing else. But Frommer and other lawmakers said the governor's contributions from drug companies will force him to make a critical decision as he considers the legislation.

"Californians are about to learn whether the governor is serious about standing up to special interests," Frommer said, "or is just

cc:
Subject: Rx Depot Drops Drug Importation Battle

FYI

Rx Depot Drops Drug Importation Battle

WASHINGTON - Rx Depot, a company that helped customers buy cheaper prescription drugs in Canada, gave up its legal battle Friday to reopen its storefronts that were ordered closed last year by a federal judge.

The Tulsa, Okla.-based company violated a law that allows only manufacturers to bring their drugs into the United States, U.S. District Judge Claire Eagan ruled. The judge acted at the request of the Food and Drug Administration (news - web sites).

The company, which operated in 25 states, faxed prescriptions and patients' medical histories to pharmacies in Canada, which then sent the drugs directly to patients.

Rx Depot had been appealing Eagan's order. It was unclear why the company dropped the appeal and agreed to a consent decree that makes the judge's order permanent.

Lawyers for the company did not immediately respond to requests for comment.

Dated: August 23, 2004

THE WALL STREET JOURNAL. ONLINE

FORMAT FOR PRINTING sponsored by PitneyBowes Engineering the flow of communication

August 18, 2004

WSJ ONLINE/HARRIS INTERACTIVE HEALTH-CARE POLL

Drug Costs for Patients Seen as Greater Burden In U.S. Than in Canada

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A WALL STREET JOURNAL ONLINE NEWS ROUNDUP
August 18, 2004

Almost all Americans believe the financial burden of drug costs for chronically ill patients is greater in the U.S. than in Canada, according to a recent Wall Street Journal Online/Harris Interactive Health-Care Poll.

The poll found, not-surprisingly, that generic drugs are seen by more Americans as having a very good or fairly good value (at 86%), compared with 26% who feel brand-name drugs represent a good value.

But while most Americans (73%) believe generic drugs are more expensive in the U.S. than in Canada, in many cases[1] the opposite is true, according to a recent Wall Street Journal article.

This misconception would help explain why 81% of those polled say chronically ill U.S. patients bear a greater financial burden because of the high costs of prescription drugs than patients in Canada.

"American angst about high drug prices in the U.S. is so strong that most people assume -- wrongly, in many cases -- that generic drugs cost more here than in Canada," says Humphrey Taylor, chairman of the Harris Poll at Harris Interactive.

"How would you rate each of the following in terms of the value for money they provide?"

Base: All Adults

Here are the results of the latest poll:

	Very Good Value	Fairly Good Value	Average Value	Somewhat Poor Value	Very Poor Value	Not Sure
Brand name prescription drugs	8%	18%	29%	19%	23%	3%
Over-the-counter						

(non-prescription) drugs	9	29	44	12	4	3
Vitamins and mineral supplements	8	25	41	13	5	6
Generic prescription drugs	25	36	25	7	2	2

Note: Numbers may not add up to 100% due to rounding.

* * *

"Please think about the last time you chose a generic drug over a brand name prescription drug. What was the main reason that you made that choice?

Base: All Adults

	Total
It was less expensive	40%
My doctor said it was just as good as a brand name alternative	14
My doctor prescribed it	13
The pharmacist said it was just as good as a brand name alternative	10
The pharmacist recommended it	4
I had taken this drug before	4
Some other reason	7
I have never chosen a generic drug over a brand name prescription drug	8

* * *

"Based on what you know or have heard, compared to Canada do you think the out-of-pocket costs for generic drugs in the US are . . .?"

Base: All Adults

	Total
Much/somewhat higher (NET)	73%
Much higher	44
Somewhat higher	28
About the same	9
Much/somewhat lower (NET)	6
Somewhat lower	4
Much lower	3

Not sure	12

Note: Numbers may not add up to 100% due to rounding.

* * *

"Overall, do you think that the amount of money chronically ill patients have to pay for their prescription drugs, including generics and brand name drugs, is a greater financial burden for patients in the U.S. or Canada?"

Base: All Adults

	Total
Greater financial burden to U.S. patients	81%
Greater financial burden to Canadian patients	3
About the same in both countries	4
Not sure	12

Methodology: This poll was conducted online in the U.S. between Aug. 6 and 10, 2004 among a nationwide cross section of 2,343 adults. Figures for age, sex, race/ethnicity, education, income and region were weighted where necessary to align with population proportions. Propensity score weighting was also used to adjust for respondents' propensity to be online. In theory, with probability samples of this size, one could say with 95% certainty that the results have a sampling error of ±3 percentage points of what they would be if the entire U.S. adult population had been polled with complete accuracy. This online sample was not a probability sample.

About Harris Interactive

Harris Interactive is a world-wide market research and consulting firm, best known for The Harris Poll and its use of the Internet to conduct scientifically accurate market research. For more information, see www.harrisinteractive.com[2]. To become a participant in The Harris Poll Online and join future online surveys, see www.harrispollonline.com[3].

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5. Enforcing Ban on Prescription Drug Reimportation 'Unsustainable,' But Practice Unlikely To Reduce Costs Substantially, Cato Institute Report Says

Access this story and related links online: http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=25112

A Cato Institute report released Wednesday states that legalizing the reimportation of drugs from other nations would "let the global marketplace sort out imbalances" in drug costs and force other countries to share the burden of funding new medical research, the Washington Post reports. The Cato report -- which represents a "direct conflict with [Cato's] allies in the Bush administration" -- notes that it is politically and economically "unsustainable" for federal regulators to control reimportation, according to the Post. In the report, Roger Pilon, Cato's vice president for legal affairs, states that drug makers need to earn large profits to guarantee investments in new treatments. However, Pilon adds that the drug industry should stop relying on the reimportation ban for profits and start negotiating higher prices with foreign customers. In the 20-page report, Pilon writes, "Removing the reimportation ban should not be seen ... as tantamount to reimporting foreign price controls." According to the report, legal reimportation would require companies to "shift some of the true costs of modern medicines" to what Pilon calls "free-rider" countries that pay low costs for drugs without having to invest in new research. The report noted that, with two million U.S. residents importing drugs illegally and a "diverse array" of lawmakers who support of lifting the reimportation ban, the current restrictions could present a political challenge to President Bush, the Post reports. "Senior citizens are a big voting bloc and a growing voting bloc," Pilon wrote, adding, "This is an issue of great concern to them." Russell Roberts, an economist at George Mason University, said that Pilon's plan would give U.S. residents "a better deal" but added that "it won't be so much in lower prices. It allows Americans to share the burden of future drug discoveries with a wider pool of payers" (Connolly, Washington Post, 8/4). The report is available online. Note: You must have Adobe Acrobat Reader to view this document.

The state pharmacy board says the proposal to list Canadian sources for medicines would violate federal law.
By Gabrielle Banks
Times Staff Writer

August 4, 2004

SACRAMENTO — State regulators are opposing one of the central ideas of Democratic legislators this year: to lower drug costs by identifying Canadian pharmacies where consumers can order them.

A Senate bill up for an Assembly committee vote today would require the state Board of Pharmacy to post names and Internet links to Canadian pharmacies on its website, as four other states do.

Days before the vote, the pharmacy board said the legislation would force it to endorse action that violates federal law against drug importation.

"We want patients to have access to safe medication," said Patricia Harris, the board's executive officer. But she said the board was uncertain about embracing something not approved by the U.S. Food and Drug Administration.

She said the board did not want to oppose the bill, "but this is not sanctioned by the FDA."

Although the pharmacy board does not report directly to Gov. Arnold Schwarzenegger, its position echoes some of the safety concerns expressed by the governor and the pharmaceutical industry.

The governor has said he wants to find ways to lower drug prices but is wary about Californians importing drugs from abroad if they would be violating federal laws. He has not taken a position on the pending legislation.

Pharmaceutical and biotech companies say they could lose profits that would otherwise go into research on new drugs if Californians buy pharmaceuticals from countries where they cost less.

The industries have spent more than $1 million lobbying against more than a dozen bills in the Legislature that would affect the way Californians get their prescriptions filled.

The industry's trade group, the Pharmaceutical Research and Manufacturers of America, has said that posting information about Canadian pharmacies on a state website would be illegal because the FDA does not permit bulk drug importation. The drug industry insists its prime concern is patient safety.

Peter Kellison, a lobbyist for the California Pharmacists Assn., said the group was opposed to the bill because there are not assurances that imported products "meet the same standards of safety and efficacy as those approved by the FDA."

The sponsors of SB 1149 hope an informational website would help Californians find places to purchase drugs more cheaply online.

The bill's author, Sen. Deborah Ortiz (D-Sacramento), said it included more safeguards than required by other states with similar websites. Under the bill, only pharmacies licensed by their Canadian province could be listed on California's website, and consumers would be required to have a prescription from a doctor licensed to practice in the United States.

Many Californians are already purchasing drugs from abroad, Ortiz said, adding, "Clearly, the pharmaceutical industry stands to lose outrageous and unfair profits in California."

The Legislature's lawyers examined the bill last month and concluded it would "not violate the importation or other provisions" of federal laws as long as the state only provided the names and contact information of Canadian pharmacies.

Democratic lawmakers have made the topic one of their top priorities for August, the last month of this year's session. Legislators are also considering a measure that would authorize the state to buy Canadian drugs in bulk for its healthcare programs for the poor.

Senate Democrats last week sent a fact-finding delegation of aides, activists for the elderly and others to Winnipeg and Vancouver to assess the quality of services at several mail-order pharmacies.

Narinder Singh, who directs 14 pharmacies for healthcare centers and prisons in Santa Clara County, said the pharmacies "we saw met or exceeded the standards for a mail-order pharmacy."

Mark Beach, a spokesman for AARP in California who also went on the trip, said, "Most Americans probably believe the Canadians have high standards. The pharmaceuticals industry is making a strong effort to cast aspersions on the safety of drugs from Canada."

Wisconsin, Minnesota, North Dakota and New Hampshire provide links to Canadian pharmacies on their state websites.

Although the FDA prohibits importation of medication from other countries, an estimated 1 million Americans do so anyway, according to Ortiz's office.
http://www.latimes.com/news/local/la-me-pharmacies4aug04,1,306200,print.story?coll=la-headlines-california

Pamela Mares, Information Officer
California Department of Consumer Affairs
Communications & Education Division
(916) 327-4529
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FDA fears drugs a terror target

Acting commissioner says imported drugs biggest concern

WASHINGTON (AP) -- "Cues from chatter" gathered around the world are raising concerns that terrorists might try to attack the domestic food and drug supply, particularly illegally imported prescription drugs, acting Food and Drug Administration Commissioner Lester M. Crawford says.

In an interview with The Associated Press, Crawford said Wednesday that he had been briefed about al-Qaeda plans uncovered during recent arrests and raids, but declined further comment about any possible threats.

"While we must assume that such a threat exists generally, we have no specific information now about any al-Qaeda threats to our food or drug supply," said Brian Roehrkasse, spokesman for the Homeland Security Department.

Crawford said the possibility of such an attack was the most serious of his concerns about the increase in states and municipalities trying to import drugs from Canada to save money.

"We get our cues from chatter that occurs around the world, which is related to us by the intelligence community, and also from past incidents and things that happened domestically," he said.

Crawford noted the 1982 Tylenol case, in which packages of the extra-strength variety of the leading painkiller were removed from store shelves on Chicago's west side, filled with cyanide and returned to stores for purchase. Seven unsuspecting consumers were killed, and the incident prompted widespread adoption of tamperproof packaging.

"I would think that's something they would be looking at," Crawford said of terrorists. "Nothing like that has happened," he added. "But it is a source of continuing concern."

FDA is under mounting pressure -- and faces a lawsuit filed by the state of Vermont -- to soften its opposition to importing drugs from Canada, which is seen by many consumers and state and local government officials as a way to shave thousands to millions of dollars from drug bills.

The FDA has held fast, saying it is concerned about the safety and effectiveness of the illegally imported drugs. So far, however, the agency has done little more than issue warning letters. And Crawford said the agency has not decided whether to

vigorously defend itself against the Vermont lawsuit.

The agency's jitters about Canadian prescription imports are many. According to Crawford, some drugs are shipped without proper refrigeration, some have the wrong potency and some are counterfeit, lacking active ingredients.

Crawford's top concern is that terrorists could strike at drugs.

Commissioner briefed on terror threats

He said he was briefed about the al-Qaeda threats uncovered by recent arrests and raids. Asked whether the briefing covered potential terror strikes against products the agency regulates -- including food and drugs -- Crawford declined further comment.

Two recent product tampering episodes the agency faced this summer ended without injury or death.

Baby food, which Crawford said was probably singled out for its "shock" effect, was laced with ground castor beans in Irvine, California. The contamination source is unclear; no arrest has been made. Ricin, a deadly toxin, is made from castor beans.

And a shipment of lemons from Argentina allegedly impregnated with an unidentified "harmful biological substance" was barred from entry at the Port of Newark, New Jersey, on Aug. 6. The U.S. Coast Guard, Homeland Security Department and the FDA worked on the investigation, freezing the lemons to preserve the contaminant.

"There was nothing we could find in there," Crawford said.

On other issues, Crawford said:

- A second review links antidepressants with higher suicide rates among children. While outside observers who have read both reports say they contain enough detail for the FDA to recommend Prozac as the first drug of choice for depressed youths, Crawford said the agency will wait until its advisory committee meets in mid-September to give the FDA an expert basis for action.
- The agency approved two new injectable drugs, pentetate calcium trisodium and pentetate zinc trisodium, that speed the body's ability to rid itself of radioactive contamination. The drugs are the first products approved to treat contamination with plutonium, americium or curium, which could be released by a "dirty" bomb.
- Before year's end, the agency will provide regulations that define low-, reduced- or carbohydrate-free items. The FDA is leaning toward educating

the public by highlighting healthier foods with a "starburst" tag or color-coded label.

AGENDA ITEM B

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: September 15, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Pharmacists Recovery Program

Attached is a draft proposal for updating statutory provisions related to the Pharmacists Recovery Program (program). Most of the proposed changes are minor, technical revisions to more closely conform the statute to the current operation of the program. However, some of the changes offer substantive changes to the existing program. The following summarizes the changes offered in each section.

Section 4360 – The changes add a directive to operate the program and clarifies that the board may allow intern pharmacists to participate in the program.

Section 4361 – The changes eliminate unnecessary definitions.

Section 4362 – Recasts the provisions specifying who is eligible to enter the program and the terms of entry into the program. First, a licensee can be referred to the program instead of or in addition to disciplinary action. Second, a licensee can enter the program voluntarily. This largely reflects current operation of the program.

The substantial change made is that licensees that enter the program voluntarily will not have their identities withheld from the board. Current law indicates that such "self-referrals" are confidential and the board is generally not informed of their identities. This "confidentiality" can be voided if the program administrator believes the licensee may present a threat to the public. However, participants sign disclosure agreement upon entering the program that permits the program to release their identity to the board. This statutory change would conform to existing practice by the program.

The draft proposes a instead to prohibit the board from taking enforcement action against the self referred licensee based on their entry into the program or any information obtained from the licensee while participating in the program. This change more closely mirrors the diversion programs operated by other boards in the department. The proposal does allow the board to take an enforcement action against a licensee in the program if the board independently obtains information supporting such an action.

Section 4363 – This section is repealed to conform with the treatment of self referred participants discussed above.

Section 4364 – The changes in this section are largely technical and allow the board to adopt criteria for participation outside of the rulemaking process.

Section 4365 – The changes are technical in nature.

Section 4366 – The changes are largely technical and several provisions are relocated to this section.

Section 4367 – This section is repealed. Specifying a staff position in statute is unnecessary. The board may do this through its internal personnel process.

Section 4368 – This section is repealed. The board has not entered into such a contract with a professional association for over five years and the provision is unnecessary as the board may enter into a contract without this specific statute.

Section 4369 – This section recasts existing provisions related to terminating a participant from the program.

Section 4370 – This section is repealed. This section specified procedures for self referred licensees. However, it is unnecessary based on the changes proposed in Section 4362 which treat participants similarly regardless of their method of entering the program.

Section 4371 – The changes to this section are largely technical and conform the section to the change in handling of self referred participant information proposed in Section 4362.

Section 4372 – The changes are largely technical and clarifying in nature.

Section 4373 – The changes are technical and conform to the elimination of "volunteer intervenor" and "contracting professional association" in other sections.

Board of Pharmacy
Draft Changes for the Pharmacists Recovery Program

Section 4360 of the Business and Professions Code is amended to read:

4360. ~~It is the intent of the Legislature that the~~ The board ~~seek ways and means to~~ shall operate a pharmacists recovery program to ~~identify and~~ rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, ~~and other drugs~~ drug use, or ~~due to~~ mental illness. The intent of the pharmacists recovery program is to return ~~, so that~~ these pharmacists and pharmacist interns ~~may be treated and returned~~ to the practice of pharmacy in a manner that will not endanger the public health and safety. ~~It is also the intent of the Legislature that the board shall implement this legislation by establishing a diversion program as a voluntary alternative to traditional disciplinary actions.~~

Section 4361 of the Business and Professions Code is amended to read:

4361. As used in this article:

(a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.
(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacist.

~~(a) "Diversion program" means a rehabilitation program designed and administered by a contracting Employee Assistance Program, available to the board in conjunction with, or as an alternative to, other traditional sanctions that the board may impose upon pharmacists pursuant to disciplinary actions within its jurisdiction.~~
~~(b) "Employee assistance program" means an agency or organization that provides confidential assessments and referral services for persons experiencing problems related to alcohol, drug abuse, or mental illness.~~
~~(c) "Pharmacists recovery program" or "program" means the rehabilitation program created by this article for pharmacists whose competency may be threatened or diminished due to abuse of alcohol or other drugs.~~
~~(d) "Volunteer intervenor" means a pharmacist recruited through a pharmacists' professional association who is available and trained to assist pharmacists seeking the benefits of the pharmacist's recovery program.~~

Section 4362 of the Business and Professions Code is amended to read:

4362. (a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:
(1) The pharmacist or intern pharmacist is referred by the board instead of or in addition to other means of disciplinary action; or,
(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.
(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board based solely on the pharmacist's or intern pharmacist's entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or pharmacist intern would pose a threat to the health and safety of the public. However, if the board independently receives information

regarding the conduct of the pharmacist or intern pharmacist such information may serve as a basis for discipline or other enforcement action by the board.

~~The program shall fulfill two distinct functions. It shall serve as a diversion program to which the board may refer licentiates, where appropriate, instead of, or in addition to, other means of disciplinary action, and it shall be a confidential source of treatment for pharmacists who, on a strictly voluntary basis, and without the knowledge of the board, desire to avail themselves of its services.~~

Section 4363 of the Business and Professions Code is amended to read:

4363. ~~The board shall administer this article, provided that the names and all identifying information pertaining to those pharmacists who voluntarily seek the services of the program, apart from the institution of any disciplinary action of the board, shall not be disclosed to the board, except as provided in Sections 4370 and 4371.~~

Section 4364 of the Business and Professions Code is amended to read:

4364. (a) The board shall establish criteria for the participation of pharmacists and intern pharmacist in the pharmacist recovery program.
(b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.
(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Section 4365 of the Business and Professions Code is amended to read:

4365. The board shall contract with one or more ~~employee assistance programs~~ qualified contractors to administer the ~~pharmacists~~ pharmacists recovery program. ~~statewide. The contractor shall be selected through a competitive bid process, and the contract may be renewed annually.~~

Section 4366 of the Business and Professions Code is amended to read:

4366. The functions of the ~~employee assistance~~ contractor administering the pharmacists recovery program shall include, but are not limited to, the following:
(a) To evaluate those pharmacists and intern pharmacist who request participation in the program. ~~according to the guidelines prescribed by the board~~.
(b) To develop a treatment contract with each participant in the pharmacists recovery program. ~~To review and designate those treatment facilities and services to which pharmacists in the program may be referred.~~
(c) To monitor the compliance of each participant with their treatment contract.
~~To receive and review information concerning a pharmacist's~~ or pharmacist intern's ~~participation in the program.~~
(d) ~~To assist pharmacists' professional associations in publicizing the program.~~
~~(e)~~ To prepare reports ~~to be submitted to~~ as required by the board.
(e) To inform each participant of the procedures followed in the program.
(f) To inform each participant of their rights and responsibilities in the program.
(g) To inform each participant of the possible consequences of noncompliance with the program.

Section 4367 of the Business and Professions Code is repealed.

4367. ~~The board shall designate a program coordinator whose responsibilities shall include the following:~~
~~(a) To serve as liaison between the board and the employee assistance program.~~
~~(b) To monitor and evaluate the employee assistance program.~~
~~(c) To assist the board enforcement unit in tracking pharmacists referred to the program as part of, or alternative to, disciplinary proceedings.~~

Section 4368 of the Business and Professions Code is repealed.

4368. ~~The board shall contract with a pharmacists' professional association with statewide representation for the following purposes:~~
~~(a) To coordinate the voluntary participation in the program.~~
~~(b) To recruit volunteer intervenors and to train them.~~
~~(c) To promote the program within the profession and to the public.~~
~~(d) To establish and maintain a 24-hour statewide toll-free telephone "hotline" service.~~
~~(e) To report to the board on these functions.~~

Section 4369 of the Business and Professions Code is amended to read:

4369. (a) ~~The board shall inform, in writing, each pharmacist referred to the employees assistance program as part of a board action of the procedures followed in the program, of the rights and responsibilities of the pharmacist in the program, and of the possible consequences of noncompliance with the program.~~
~~(b)~~ Any failure to comply with the ~~provisions of the~~ treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the pharmacist's or intern pharmacist's participation in the ~~diversion~~ pharmacists recovery program. The name and license number of a pharmacist or intern pharmacist who is terminated ~~for failure to comply with the provisions of the treatment~~ from the pharmacists recovery program and the basis for the termination shall be reported to the board.
~~(c)~~ (b) Participation in ~~a~~ the pharmacists recovery program ~~under this article~~ shall not be a defense to any disciplinary action that may be taken by the board.
(c) ~~Further, no~~ No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program. ~~a program under this article.~~

Section 4370 of the Business and Professions Code is repealed.

4370. ~~(a) The employee assistance program shall inform, in writing, each pharmacist who voluntarily participates in the diversion program without referral by the board of the procedures followed in the program, the rights and responsibilities of the pharmacist in the program, the possible consequences of noncompliance with the program.~~
~~(b) The board shall be informed of the pharmacist's noncompliance with the treatment program if the employee assistance program determines that the pharmacist's resuming the practice of pharmacy would pose a threat to the health and safety of the public. The board shall be informed of the basis for the pharmacist's termination and of the determination that the pharmacist's resuming the practice of pharmacy would pose a threat to the health and safety of the public.~~
~~(c) Participation in a program under this article shall not be a defense to any disciplinary action that may be taken by the board. Further, no provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from a program under this article.~~

Section 4371 of the Business and Professions Code is amended to read:

4371. The board shall review the ~~activities of the employee assistance~~ pharmacists recovery program on a quarterly basis. As part of this evaluation, the board shall review files of all participants in the ~~diversion~~ pharmacists recovery program. ~~Names of those pharmacists who entered the program voluntarily without the knowledge of the board shall remain confidential from the board except when monitoring by the board reveals misdiagnosis, case mismanagement, or noncompliance by the participant.~~

Section 4372 of the Business and Professions Code is amended to read:

4372. All board records and records of the ~~employee assistance~~ pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery, ~~or~~ subpoena, or disclosure pursuant to Chapter 3.5 of Division 7 of the Government Code (commencing with Section 6250). However, board records and records of the ~~employee assistance~~ pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program ~~pursuant to Section 4369 or 4370~~, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

Section 4373 of the Business and Professions Code is amended to read:

4373. No member of the ~~board or the contracting professional association or any volunteer intervenor~~ shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: November 26, 2003**

From: **Anne Sodergren**
Board of Pharmacy

Subject: **Overview of the Pharmacists Recovery Program**

Background

In 1985, legislation became effective creating the Pharmacists Recovery Program (PRP). This legislation requires the board to seek way and means to identify and rehabilitate pharmacists whose competency may be impaired due to the abuse of alcohol or other drugs, or due to mental illness, so that pharmacists and interns so afflicted may be treated and returned to the practice of pharmacy in a manner which will not endanger the public health and safety. The law requires the board to contract with one or more employee assistance programs to administer the PRP and to contract with a pharmacist's professional association to perform outreach and promote voluntary access to the program.

As required by statute, the program fulfills two distinct functions. The PRP serves as a diversion program to which the board may refer licentiates, where appropriate, either in lieu of or in addition to disciplinary action. The PRP is also a confidential source of treatment for pharmacists who enter the program on a voluntary basis and without the knowledge of the board. Irrespective of the type of referral into the program, all participants are afforded the same treatment opportunities in the PRP.

Board policy is to expedite a pharmacist's the entry into the PRP rather than wait until the completion of an investigation. This is done by an inspector who will refer a pharmacist informally into the PRP. This early intervention assists the licensee in his or her recovery, but more importantly protects the public. Early intervention and referral results in the pharmacist or interns receiving treatment and being monitored while the case is being investigated.

When determining if a participant should be referred to the PRP in lieu of discipline the executive officer considers several factors including:

1. Danger to the public
   a. If drugs were diverted
   b. Quantity of drugs diverted
   c. Injury to consumer
2. Variety and severity of violations
3. Severity of addition or habituation
4. Types of drugs used
5. Frequency and use pattern
6. Prior entrance into the PRP and other mitigating circumstances.

Current Program Overview

For the first time since the PRP's inception, the contract was to a new vendor last July. Along with six other boards and bureaus under the Department of Consumer Affair's Umbrella, the board contracts with Maximus to oversee the Pharmacist Recovery Program. To ensure a seamless transition for the participants, board staff has been working diligently with the new contractor to ensure consistency of care for those in the program.

The general contract requirements for the diversion program are the same for each of the board's with special nuances specific to each board's program. This ensures that all participants in the diversion/recovery programs receive consistent treatment, e.g., inpatient and/or outpatient treatment, health support groups, attendance at AA/NA meetings etc. Several of the boards, utilize Diversion Evaluation Committees (DECs) to monitor participant treatment and compliance in the program as allowed by their specific legislative authority. These meetings can prove costly to the participants who are required to travel to the meetings and also relinquishes the confidentiality and anonymity treatment programs usually adhere to as the participant must appear before the DECs.

The Board of Pharmacy does not have the statutory authority to establish or use DECs. Rather, the board uses a Pharmacy Review Committee (PRC) to review and determine the proper treatment for all board-referred participants (those referred either in addition to or in lieu of formal discipline). The PRC is comprised of the assigned Clinical Case Manager from Maximus, a Supervising Inspector and a staff manager trained in drug recognition and the treatment of substance abuse.

The PRC meets monthly to discuss participants' treatment contracts, compliance and assessment notes as well as to review any participant requests. At minimum each participant's treatment contract and compliance is reviewed on a quarterly basis. However, a participant's treatment contracts may be reviewed more frequently at the participant's request of if the participant is non compliant. All self-referred participants (and board informal) are monitored solely by the Clinical Case Manager therefore ensuring the confidentiality of those participants as required by statute. In the event that a self referred or board informal participant is deemed to be a threat to themselves or to the public, Maximus is required by law to notify the board. This is to ensure that the board's public protection mandate is met.

Ultimately, the board is responsible for public protection first and foremost. While ensuring licensees afflicted with mental illness or chemical dependency are treated and rehabilitated so they can return to the practice of pharmacy safely, this cannot be done at the expense of the board's mandate to protect the public.

Treatment Contracts

All participants entering the PRP are evaluated by a licensed clinician. The initial evaluation identifies the nature and severity of the problem. Initial recommendations are made regarding the treatment and an initial treatment contract is established based on the recommendations.

Rehabilitation plans for a chemically dependent participant typically include total abstinence from alcohol or other mood altering chemicals, inpatient or outpatient treatment, documented attendance 3-5 self-help groups such as Alcoholics Anonymous (AA) and/or Narcotics Anonymous (NA) per week and at least 1-2 support groups. The support groups are conducted under the guidance of a licensed clinician and are comprised of health care professionals in recovery. These support groups serve as a forum for health care professional

to discuss their recovery and may be used to confront a participant who may be acting inappropriately or who is not embracing recovery. A random body fluid testing scheduled is established usually averaging between 24 – 36 urines screens a year (depending on the length of sobriety and severity of the addiction). Failure to maintain sobriety results in the immediate suspension from practice and usually requires at least a 30 - 90 day stay in residential treatment. Upon completion of this residential treatment, outpatient treatment is typically required in addition to support group attendance and attendance at AA and/or NA meetings.

The Pharmacy Review Committee (PRC) will evaluate all board mandated participants progress in the program and determine when it is appropriate for the participant to return to work. The contract will specify the type of pharmacy practice which is acceptable, and any restrictions placed on that participant's practice, e.g. the participant must work with another pharmacist at all times, cannot supervise intern, etc. Prior to returning to work the participant must designate a work site monitor - - typically a pharmacist, who is in a supervisory capacity or at least one management step above the participant. The work site monitor must be aware of the PRP contract and provide regular assessment of the participant's work performance to the PRC members. As a participant continues to gain strength in recovery, the PRC, with approval of the executive officer, will gradually remove the restrictions placed on the pharmacist's practice and reduce the treatment contract requirements by reviewing compliance with the treatment contract, relapse history, if any, and seeking input from the support group leader.

PRP participation is usually a three to five year commitment depending on the severity of the drug abuse or mental illness. The mandatory length of participation must be at minimum one year unless two separate assessments are completed, both of which must conclude that the licensee is not appropriate for diversion. A transition phase, which may begin after at least 24 consecutive months of recovery and a minimum of 24 negative random body fluid tests allows the participant the opportunity to be responsible for his or her own recovery while still in the PRP. A participant who meets all the criteria set by the PRC for completion and who has demonstrated that he or she is a rehabilitated will be successfully completed from the PRP after completing this transition phase and a negative hair test.

About the Participant Population

Since the program inception, 539 pharmacists and interns have received services from the program and 472 participants have been closed out of the program.[1] Approximately 50% of the licensees enrolled in the program are either self-referrals or board informal referrals. Of the participants closed from the program, 109 participants were closed out for either non-compliance or failure to derive benefit. In all circumstances where a participant has been mandated into the program and fails to successfully complete the program, the board will pursue additional disciplinary action. If a participant was a self-referral, the board will also complete an investigation and take appropriate action if the licensee was identified by the contractor as posing a threat to the health and safety of the public.

During the last fiscal year the average age of new participants was between 35 – 54 years old. Practice settings at the time of enrollment for these new participants included 42% in the retail pharmacy, 30% in the hospital pharmacy and the balance working in an assortment of other work settings. Alcohol was the highest reported drug used by these new participants in the previous 12 months prior to enrollment. The other most frequently reported drugs used included Tussionex® (or the generic equivalent), Soma®, Valium®, Heroine®, Hydrocodone, Hydromorphone, Morphine.

Program Statistics[2]

	00/01	01/02[3]	02/03
Enrolled in the Program			
Self	10	9	10
Board Informal	1	2	3
In Lieu Of Discipline	6	14	9
In addition to Discipline	3	0	4
Total Enrolled	20	25	26
Closures from the Program			
Successful Completion	9	10	9
Dismissed Failure to Derive Benefit	1	1	3
Dismissed Non-compliance	5	4	11
Other*	4	3	2
Total Closed	19	18	25
Number of Participants at the end of FY	56	63	63

* Other includes participant death, move to another state, or determined ineligible.

Statistics as reported by Maximus through August 31, 2003. Historical data was provided to Maximus by Managed Health Network, the previous contractor.

[1] Statistics as reported by Managed Health Network
[2] Statistics through May 2002.

AGENDA ITEM C

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee

Date: September 15, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Pharmacy Technician Clean-up

The attached draft of changes to statutes regarding pharmacy technicians and intern pharmacists. Most of the changes are technical and designed to make the statutes more clear. The most significant change is standardizing the terminology relating to the supervision of ancillary personnel. The different code sections used slight variations of language requiring the supervision of ancillary personnel. This draft adopts the most common verbiage of "direct supervision and control" of the pharmacist.

Section 4038 – This change moves the definition from Section 4115.5 to this section for definitions.

Section 4114 – This change applies the standard supervision verbiage to intern pharmacists.

Section 4115 – The changes in this section are mostly technical clean up to eliminate duplicative and unnecessary language. However, one substantive change is made to eliminate the exemption that permits unlicensed personnel to act as a pharmacy technician during their first year of employment at the Department of Corrections, California Youth Authority, Department of Mental Health, Department of Developmental Services or the Department of Veterans Affairs. This provision was added to allow personnel to work in those facilities until they could accumulate enough hours to qualify for licensure as a pharmacy technician. However, experience is no longer a means of qualifying for licensure as a pharmacy technician and this provision is no longer appropriate.

Section 4115.5 – The changes in this section are technical clean-up and conforming to the standard verbiage on supervision of ancillary personnel.

Section 4202 – The changes in this section are technical clean-up.

Board of Pharmacy
Technical Cleanup for Ancillary Personnel

Amend Section 4038 of the Business and Professions Code, to read:

4038. (a) "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115.
(b) A "pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education.

Amend Section 4114 of the Business and Professions Code, to read:

4114. An intern pharmacist may perform any activities pertaining to the practice of pharmacy as the board may determine by regulation. Whenever in this chapter the performance of an act is restricted to a pharmacist, the act may be performed by an intern pharmacist under the direct supervision and control of a pharmacist. The pharmacist shall not supervise more than two intern pharmacists at any one time.

Section 4115 of the Business and Professions Code is amended to read:

4115. (a) ~~Notwithstanding any other provision of law, a~~ A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of~~,~~ a pharmacist.
(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty. ~~, nor does this section authorize the use of a pharmacy technician to perform tasks specified in subdivision (a) except under the direct supervision and control of a pharmacist.~~
(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.
(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the ~~direct~~ supervision ~~and control~~ of a pharmacist. Any pharmacy that employs a pharmacy technician ~~to perform tasks specified in subdivision (a)~~ shall do so in conformity with the regulations adopted by the board ~~pursuant to this subdivision~~.
(e) ~~(1)~~ No person shall act as a pharmacy technician without first being ~~registered with~~ licensed by the board as a pharmacy technician ~~as set forth in Section 4202~~.
~~(2) The registration requirements in paragraph (1) and Section 4202 shall not apply during the first year of employment for a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.~~
(f) ~~(1) The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy technician may perform the duties, as specified in subdivision (a), only under the immediate, personal supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view. A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient, or by engaging in other verification procedures that are specifically approved by board regulations.~~

~~(2) This subdivision shall not apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility. Notwithstanding the exemption in this subdivision, the requirements of subdivisions (a) and (b) shall apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility.~~

For the purposes of this chapter "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist involved in the preparation and dispensing of medications.

(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist' s responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (a) and (b) ~~and (f)~~, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(k) A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient, or by engaging in other verification procedures that are specifically approved by board regulations.

Section 4115.5 of the Business and Professions Code is amended to read:

4115.5. (a) Notwithstanding any other provision of law, a pharmacy technician trainee ~~student~~ may be placed in a pharmacy ~~as a pharmacy technician trainee~~ to complete an externship for the purpose of obtaining practical training required to become ~~that is required by the board as a condition of becoming~~ ~~registered~~ licensed as a pharmacy technician. ~~A "pharmacy technician student" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education.~~

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the ~~immediate, personal~~ direct supervision and control of a pharmacist. ~~A pharmacist supervising a pharmacy technician trainee shall be on the premises and have the trainee within his or her view at any time the trainee performs the duties described in subdivision (a) of Section 4115.~~

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations..

(4) ~~No more than one pharmacy technician trainee per pharmacist may participate in an externship as described in subdivision (a) under the immediate, personal supervision and control of that pharmacist at any time the trainee is present in the pharmacy.~~
A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no more than 120 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her student status.

Section 4202 of the Business and Professions Code is amended to read:

4202. (a) ~~An applicant for a pharmacy technician license shall be issued a certificate of registration~~ The board may issue a pharmacy technician license to an individual if he or she is a

high school graduate or possesses a General Education Development ~~general education development~~ equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy ~~accredited by the American Council on Pharmaceutical Education or a school of pharmacy~~ recognized by the board. Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician certificate of registration must be returned to the board within 15 days.

(4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the licensure ~~registration~~ of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for ~~registration~~ licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure ~~registration~~, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a ~~registration~~ license issued pursuant to this section on any ground specified in Section 4301.

AGENDA ITEM D

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: September 16, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Letters of Admonishment

Below is a revision of Section 4315 which authorizes the executive officer of the board to issue a letter of admonishment for a violation of the Pharmacy Law. This section was added last year to provide the board with a broader range of enforcement options. One requirement in the new section is that the licensee receiving the Letter of Admonishment must keep a copy of that letter in the pharmacy for three years. This requirement is problematic for licensees that do not work regularly in the same pharmacy or do not work in a pharmacy at all (exemptee, wholesaler, etc.). Accordingly, staff is recommending the elimination of this requirement.

Section 4315 of the Business and Professions Code is amended to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with this chapter or regulations adopted pursuant to this chapter, directing the licensee to come into compliance.
(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.
(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.
(B) Prior to or at the office conference the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.
(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).
(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified

mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) ~~The licensee shall maintain and have readily available on the pharmacy premises a copy of the letter of admonishment and corrective action plan for at least three years from the date of issuance of the letter of admonishment.~~

~~(f)~~ Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

AGENDA ITEM E

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: September 16, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Pharmacist Identification

Senate Bill 1913 amends Section 4115 to permit the board to allow the use of electronic technologies to satisfy the requirement that a pharmacist sign off on prescriptions filled by pharmacy technicians. The regulation text below allows the use of electronic methods of identifying the reviewing pharmacist.

§1712. Use of Biometric Identifiers.

(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.[1]
(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) shall be immediately retrievable in the pharmacy.

Note:

Authority cited: Sections 4005, Business and Professions Code. Reference: Sections 4005 and 4115, Business and Professions Code.

[1] This provision was approved by the board at its July 2004 meeting. SB 1913 contains a statutory provision authorizing this regulation.

AGENDA ITEM F

Longs Drug Stores

General Offices: 141 North Civic Drive, P.O. Box 5222, Walnut Creek, California 94596, (925) 937-1170

RECEIVED BY CALIF. BOARD OF PHARMACY
2004 SEP -1 AM 9:46

August 27, 2004

Patricia Harris, Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

RE: REQUEST FOR WAIVER—CCR 1717(e)

Dear Ms. Harris:

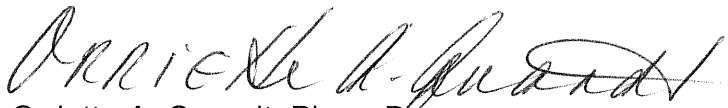
I want to thank you for speaking with Mr. Cantrell and I today regarding the July 19, 2004 letter that Chris Gong, on behalf of Longs Drug Stores, submitted to the Board. In that letter, Longs Drug Stores expressed interest in being able to install convenient, yet secure and private, 24-Hour Prescription Drop Kiosks. These kiosks would be installed adjacent to or in the parking lot at various Longs Drug Stores in California, for patients to use as an easy means to drop off those prescriptions they want the pharmacy to fill. Caution in reviewing all prescriptions placed in the kiosk, to determine the prescription's validity, authenticity, verify it has no uncertainties, etc. would be addressed in the same manner as prescriptions today, that are called, faxed, or brought directly into the pharmacy, are handled.

Since the California lifestyle is very diverse, yet also extremely time conscious, if a patient's access to a pharmacy service can be improved, that patient's drug therapy compliance level could also be expected to improve. Currently the California Code of Regulations, Section 1717(e) states in pertinent part that licensees may not participate in any arrangement that allows prescriptions to be accepted by or left at any place other than a licensed retail pharmacy. This same section though, also allows for the Board to waive this section for good cause.

As such, Longs Drug Stores is requesting a waiver for California Code of Regulations, Section 1717(e), so that it may install and utilize 24-Hour Prescription Drop Kiosks at many of its pharmacies throughout the state. In requesting this waiver, Longs asks that the matter be added to the agenda of the Board's next Enforcement meeting and also be placed on the full agenda for the Board's October Board meeting.

Should you have any questions, please do not hesitate to contact me.

Sincerely,



Orriette A. Quandt, PharmD
Corporate Pharmacy Compliance Manager,
Longs Drug Stores

Longs Drugs

General Offices: 141 North Civic Drive, P.O. Box 5222, Walnut Creek, California 94596, (925) 937-1170

SENT VIA E-MAIL AND U. S. MAIL

September 20, 2004

Patricia Harris, Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Re: REQUEST FOR WAIVER—CCR 1717(e)

Dear Ms. Harris:

Pursuant to our previous letters and recent communication, Longs Drug Stores would like to request a waiver to install and utilize self service dispensing units, such as the Asteres ScriptCenter, at various Longs Drug Stores in California.

The Asteres ScriptCenter Unit is an automated, self-contained instrument that allows patients to access their filled prescriptions. These units would be installed in close proximity to the pharmacy area. To improve patient convenience and therapeutic compliance, these units may be accessed by a patient during pharmacy hours or during those times when the main store is open, but the pharmacy is closed.

At the request of a patient and through the use of a secure method designed to guard against inappropriate access, a patient may retrieve his/her filled prescription from the unit at their convenience. New prescriptions, or those prescriptions requiring consultation, will not be available through these units.

Prescriptions would be filled by a pharmacist, using the same safeguards that are currently in place. These filled prescriptions would then be input into these units either by a pharmacist or a pharmacy staff member, under the supervision of a pharmacist. As medications are input into the units, security measures are used to ensure accurate dispensing.

Longs has also requested that the manufacturer of the Asteres Dispensing Unit provide the Board with additional information, specifically illustrating the unit's numerous privacy and security features.

Since the California lifestyle is very diverse, Longs Drug Stores is seeking ways to improve a patient's access to pharmacy services, in hopes of improving the patient's compliance with their prescribed drug regimen. Currently the California Code of Regulations, Section 1717(e) places limitations as to how a patient may receive his/her prescription, but also allows the Board to waive this section for good cause.

As such, Longs Drug Stores is requesting a waiver for California Code of Regulations, Section 1717(e), so that it may install and utilize self service dispensing units at its pharmacies throughout the state. In requesting this waiver, Longs asks that the matter be added to the agenda of the Board's next Enforcement meeting and also be placed on the full agenda for the Board's October Board meeting.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

LONGS DRUG STORES CALIFORNIA, INC.

Michael Cantrell, RPh, Esq.
Vice President Professional Services

MLC/me

cc: Cooky Quandt, R.Ph.

AGENDA ITEM G

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: September 16, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Receipt and Delivery of Prescriptions

Requests have been made by Longs Drugs, Inc. to permit the use of secure drop boxes for receiving prescription orders from patients and to permit the use of secure devices for dispensing filled prescriptions after hours. Those requests are attached for your reference. Below is proposed regulation language to permit both these activities. The prescription drop boxes will allow patients to drop off prescriptions while the pharmacy is closed. The secure devices for dispensing prescriptions after hours is restricted to refill prescriptions that are not subject to the consultation requirement. The proposed draft relocates existing provisions in Section 1717(e) into a new section and provides the authorization for both the drop boxes and dispensing devices.

Add Section 1713

§1713 Receipt and Delivery of Prescriptions

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.[1]
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services.[2]
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address or adjoining the licensed premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use a device to dispense refilled prescriptions when the pharmacy is not open provided:

(1) The device is located at the same address or adjoining the licensed premises.
(2) The device has a means to identify the patient and only release that patient's prescriptions.
(3) The device is secure from access by unauthorized individuals.
(4) The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
(5) The pharmacy is responsible for the prescriptions stored in the device.

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[1] Moved from 1717 (e).
[2] Moved from 1717 (e).

§1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~
~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716.
Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

AGENDA ITEM H

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, California 95814
Phone (916) 445-5014 Fax (916) 327-6308
www.pharmacy.ca.gov

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

MORE SB 151 QUESTIONS AND ANSWERS

Q Can a California pharmacy fill a controlled substance prescription from an out of state prescriber for a patient in California?

A California Code of Regulations section 1717(d), in accordance with Business and Professions Code section 4005(b), allows written and oral prescriptions from out-of-state prescribers. Pharmacies must verify the prescription. The pharmacist should use his or her best professional judgment when filling out-of-state prescriptions. Nothing in the law prohibits out-of-state prescribers from ordering their own tamper-resistant security prescription forms from approved security printers for prescribing controlled substance prescriptions to their California patients.

Q Can the new tamper-resistant security prescription form be preprinted with more than one prescriber; for example, a group practice setting?

A Yes. The forms should include check boxes or some other means to identify the specific prescriber's name, category of licensure, state license number, and DEA number who has written the prescription.

Q What should a prescriber do if he or she is out of the triplicate prescription forms and/or has not yet received his or her new tamper-resistant security prescription forms but needs to write a controlled substance prescription?

A The Board of Pharmacy is most concerned that the healthcare needs of legitimate patients be met during the transition to the new tamper-resistant prescription form and has issued a memo dated August 11, 2004, that allows prescribers to temporarily use the exception to the special form requirement in Health and Safety Code section 11167. Prescribers must make good faith efforts to obtain the new prescription forms in compliance with the law.

Prescribers must write "11167 exemption" on the prescription and pharmacists' should exercise their professional judgment when filling these prescriptions with the highest priority given to evaluating whether a prescription is authentic and issued for a legitimate medical purpose.

Health and Safety Code section 11167 allows, in an emergency, where failure to issue the prescription could result in loss of life or intense suffering, an order for a controlled substance to be dispensed on an oral, faxed or plain paper prescription as long as the order contains all of the required information. Written orders must be signed and dated by the prescriber. The pharmacist must reduce oral or faxed prescription orders to hard copy form. The prescriber is required to provide a written prescription on the appropriate prescription form by the 7th day following the order. The pharmacist must notify the Bureau of Narcotic Enforcement within 144 hours of the prescriber's failure to do so, including the date and method of notification.

Q What are the quantity check-off boxes on the new tamper-resistant prescription forms?

A The quantity check-off boxes are a security feature that ensures the quantity the prescription is written for is not tampered with in any way. The prescriber writes the prescription as usual, including the quantity, in the body of the prescription. In addition, the prescriber checks the box next to the applicable quantity range confirming the quantity for each prescription written. If the prescription is for anything other than tablets or capsules, the prescriber must also designate the units referenced in the quantity range.

Q How does a prescriber mark the quantity check-off boxes on the new tamper-resistant security prescription form when writing a prescription for multiple drugs on one prescription form?

A Some of the new tamper resistant prescription forms provide separate sections for writing multiple drug prescriptions, which include separate quantity check-off boxes for each. However, some form designs include only one set of quantity check-off boxes. Prescribers' check the appropriate quantity range confirming the quantity for each prescription written. For example, if a prescriber writes one prescription for 100 tablets and, on the same form, writes another prescription for 25 tablets, the prescriber would check the quantity ranges 75 to 100 and 25 to 49. If the quantity of more than one prescription falls within the same range, simply check the quantity range once. For example, if the prescriber writes three prescriptions and two are for 100 tablets each and one is for 300 tablets, the prescriber would check the quantity ranges 75–100 and 151 and over.

Q Does my facility qualify as a "licensed health care facility" so that we can order "institution" style tamper-resistant prescription forms?

A *"Licensed health care facility"* means a facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code, such as, a general 24-hour acute care hospital, acute psychiatric hospital, skilled nursing facility, or intermediate care facility.

Q Where can I find a list of all controlled substances including the drug schedule?

A Please reference the following California Health and Safety Code sections:

Schedule II	section 11055
Schedule III	section 11056
Schedule IV	section 11057
Schedule V	section 11058

For a Federal list of controlled substances including the drug schedule please visit the Drug Enforcement Administration's website at http://www.deadiversion.usdoj.gov/schedules. California law is more stringent than Federal law; therefore, drugs listed in the Federal schedules may have been upgraded in Schedule through California regulations found in the above mentioned Health and Safety Code sections.

Q Can a Schedule II controlled substance prescription be refilled?

A No. Prescribers should mark zero (0) or no refills (NR). The new tamper-resistant forms include an area for refills because the form can be used for any controlled or non-controlled substance prescription.

Q Can more than one Schedule II medication be written on the same form?

A Yes. As long as the new prescription form has the statement at the bottom that reads, "Void if the number of drugs is not noted" and a line provided for the physician to write in the number of drugs prescribed.

Q Can a pharmacist fill a prescription for a controlled substance if an error is found on the prescription?

A The prescriber's signature and the date written are required to be written by the prescriber. Everything else can be written by the prescriber or his or her agent. Therefore, the pharmacist can make changes to any other information on the prescription as long as the pharmacist verifies the change with the prescriber first.

Q Is the pharmacy still required to keep a separate record for Schedule II prescriptions filled? If so, what if there is more than one prescription on the form?

A Pharmacies are required to keep a separate record in the pharmacy of Schedule II prescriptions filled regardless of whether or not the prescription includes other non-Schedule II medications. Additionally, the pharmacy is required to submit the Schedule II prescription information to CURES electronically or on disk, and effective January 1, 2005, must submit both Schedule II and III prescription information to CURES.

Q Can a prescriber electronically transmit a Schedule III through V controlled substance prescription from a computer or personal digital assistant (PDA) to a pharmacy's computer or fax machine?

A Yes. Advice from the Drug Enforcement Administration in a letter from Patricia M. Good, Chief of the Liaison and Policy Section, Office of Diversion Control for the U.S. Department of Justice dated September 28, 2001, states that current DEA regulations allow for Schedule III, IV, or V controlled substances that are electronically created or transmitted, which includes PDA's, either directly to a computer or via facsimile machine, be treated as an oral prescription. This means the prescription must be reduced to hard copy form by the pharmacist and retained for at least three years. Additionally, a pharmacist that receives an electronically transmitted prescription via facsimile, or other methods, must ensure the validity of the prescription prior to dispensing the controlled substance (Title 21, Code of Federal Regulations section 1306.21).

Electronically transmitted prescriptions, including those sent via PDA, must contain an electronic signature of the prescriber. Pharmacies must ensure the authenticity, integrity, non-repudiation, and confidentiality of the document. Authentication means ensuring that the prescriber is the person he or she purports to be. Integrity means ensuring that both the document and the signature have not been altered in the course of transmission. Non-repudiation means ensuring that a party to the transaction cannot later disclaim it. Moreover, a pharmacist has an affirmative obligation to verify a prescription when appropriate to do so.

The pharmacy must also ensure that a prescription has been electronically transmitted to the pharmacy of the patient's choice. This may be done a number of ways, including, but not limited to, an affirmative statement on the prescription that the prescriber advised the patient of this right.

AGENDA ITEM I

A report on the status of AB 2682 (Negrete McLeod) and SB 1307 (Figueroa) will be given at the Enforcement Committee meeting. Governor Schwarzenegger has until September 30, 2004, to act on all pending legislation.

BILL NUMBER: AB 2682 ENROLLED
BILL TEXT

PASSED THE SENATE AUGUST 27, 2004
PASSED THE ASSEMBLY AUGUST 27, 2004
AMENDED IN SENATE JULY 6, 2004
AMENDED IN SENATE JUNE 17, 2004

INTRODUCED BY Assembly Member Negrete McLeod

FEBRUARY 20, 2004

An act to amend, repeal, and add Section 4043 of, to add and repeal Section 4162.5 of, and to repeal and add Section 4161 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2682, Negrete McLeod. Pharmacy: out-of-state wholesalers.

The Pharmacy Act provides for licensing and regulation of manufacturers and wholesalers of prescription drugs and devices by the California State Board of Pharmacy and makes a violation of its provisions a crime. Existing law requires out-of-state manufacturers and wholesalers of prescription drugs and devices selling or distributing those drugs and devices in this state to obtain an out-of-state dangerous drugs and devices distributor's license from the board, unless they sell or distribute only through a licensed wholesaler.

This bill would delete these requirements applicable to out-of-state manufacturers and wholesalers of prescription drugs and devices on January 1, 2006. The bill would instead, on and after January 1, 2006, require a nonresident wholesaler, as defined, that ships, mails, or delivers dangerous drugs or dangerous devices in this state to obtain a nonresident wholesaler's license from the board. The bill would, on and after January 1, 2006, require, until January 1, 2011, a nonresident wholesaler to submit a surety bond of $100,000, or an equivalent means of security for each place of business owned or operated by the nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in California. Because this bill would require additional persons to pay fees to the board to obtain a license, it would result in the deposit of additional revenue in the Pharmacy Board Contingent Fund, a continuously appropriated fund, and would thereby make an appropriation.

Because a violation of the Pharmacy Act is a crime, the bill would impose a state-mandated local program by revising the definition of a crime.

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

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

This bill would become operative only if SB 1307 is also enacted and becomes effective on or before January 1, 2005.

Appropriation: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4043 of the Business and Professions Code is amended to read:

4043. (a) "Wholesaler" means and includes every person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or out-of-state distributor, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

(b) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 2. Section 4043 is added to the Business and Professions Code, to read:

4043. (a) "Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

(b) This section shall become operative January 1, 2006.

SEC. 3. Section 4161 of the Business and Professions Code is repealed.

SEC. 4. Section 4161 is added to the Business and Professions Code, to read:

4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale shall be considered an out-of-state distributor.

(b) An out-of-state distributor shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by an out-of-state distributor from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of an out-of-state distributor license, or within 30 days of a change in the following information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners, if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) An out-of-state distributor shall comply with all directions

and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) An out-of-state distributor wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

(h) An out-of-state distributor shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for an out-of-state distributor license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew an out-of-state distributor license until the out-of-state distributor identifies an exemptee-in-charge and notifies the board in writing of the identity and license number of the exemptee-in-charge.

(j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as an out-of-state distributor.

(l) The license fee shall be the fee specified in subdivision (f) of Section 4400.

(m) A pharmacy that meets the requirements of Section 4001.2, as added by Senate Bill 1149 of the 2003-04 Regular Session, including any subsequent amendment thereto, shall not be considered an out-of-state distributor for purposes of this section.

(n) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 4.5. Section 4161 is added to the Business and Professions Code, to read:

4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) A pharmacy that meets the requirements of Section 4001.2, as added by Senate Bill 1149 of the 2003-04 Regular Session, including any subsequent amendment thereto, shall not be considered a nonresident wholesaler for purposes of this section.

(n) This section shall become operative January 1, 2006.

SEC. 5. Section 4162.5 is added to the Business and Professions Code, to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) for each site to be licensed, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may

require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SEC. 6. This act shall become operative only if Senate Bill 1307 is also enacted and becomes effective on or before January 1, 2005.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

BILL NUMBER: SB 1307 ENROLLED
BILL TEXT

PASSED THE SENATE AUGUST 26, 2004
PASSED THE ASSEMBLY AUGUST 23, 2004
AMENDED IN ASSEMBLY AUGUST 5, 2004
AMENDED IN ASSEMBLY JULY 8, 2004
AMENDED IN ASSEMBLY JUNE 14, 2004
AMENDED IN ASSEMBLY MAY 28, 2004
AMENDED IN SENATE APRIL 14, 2004
AMENDED IN SENATE APRIL 1, 2004

INTRODUCED BY Senator Figueroa

FEBRUARY 17, 2004

An act to amend Sections 4054, 4165, and 4166 of, to amend, repeal, and add Sections 4053, 4059.5, 4081, 4100, 4105, 4160, 4163, 4163.6, 4164, 4196, 4301, 4305.5, 4331, and 4400 of, to add Sections 4022.5, 4034, 4084, 4085, 4086, 4126.5, 4163.5, and 4168 to, to add and repeal Sections 4053.1 and 4169 of, and to repeal and add Section 4162 of, the Business and Professions Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, Figueroa. Wholesalers and manufacturers of dangerous drugs and devices.

(1) Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and wholesalers of dangerous drugs or dangerous devices by the Pharmacy Board. Existing law requires that dangerous drugs or dangerous devices be dispensed only by licensed pharmacists and only to certain persons or entities. Existing law provides certain exemptions from this requirement for manufacturers, veterinary food-animal drug retailers, and wholesalers, including those that employ sufficient qualified supervision by a person who possesses a certificate of exemption. Existing law also requires the board to take action against a licensee who is guilty of unprofessional conduct, as defined. Existing law makes a violation of the Pharmacy Law a crime.

This bill would revise the list of persons to whom a pharmacy may furnish dangerous drugs. The bill would also revise the exemption provisions related to manufacturers, veterinary food-animal drug retailers, and wholesalers, and would change the certificate of exemption requirement to a requirement of licensure as a designated representative, as defined. The bill would require a wholesaler to keep track of excessive purchases of dangerous drugs by a pharmacy that primarily or solely dispenses those drugs to patients of long-term care facilities, and would make the clearly excessive furnishing of dangerous drugs to that pharmacy by a wholesaler unprofessional conduct. The bill would make other related changes.

This bill would, on and after January 1, 2007, require a pedigree, as defined, to accompany each distribution of a dangerous drug, except if the compliance date is extended. It would, on and after that date, prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without a pedigree, and would prohibit a wholesaler or pharmacy from acquiring a dangerous drug without receiving a pedigree.

(2) Existing law prohibits a person from acting as a wholesaler of dangerous drugs or devices without a license.

This bill would require dangerous drugs or dangerous devices to be acquired from a person authorized by law to possess or furnish them.

The bill would exempt a licensed drug manufacturer that only ships drugs of its own manufacture from the provisions governing wholesalers, except for the prohibition against furnishing dangerous drugs or devices to an unauthorized person.

(3) Existing law imposes certain licensing and registration requirements on out-of-state manufacturers and wholesalers doing business in this state, and on their principals and agents.

This bill would delete these requirements.

(4) Existing law requires any manufacturer who sells or transfers a dangerous drug or dangerous device into this state or who receives a dangerous drug or dangerous device from a person in this state to, upon request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer. Existing law makes a manufacturer who fails or refuses to comply with that request subject to a citation and a fine, an order of abatement, or both.

This bill instead would apply these provisions to a wholesaler licensed by the board. The bill would delete the provision that makes the failure or refusal to comply with a request subject to a citation and a fine, an order of abatement, or both. The bill would require a wholesaler to submit a surety bond of $100,000, or an equivalent means of security, for all sites to be licensed.

(5) The bill would prohibit a county or municipality from issuing a business license for an establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board.

The bill would prohibit a person or entity from purchasing, trading, selling, or transferring a dangerous drug or device under specified circumstances, including if he or she knew, or reasonably should have known, the drug or device was adulterated or misbranded. The bill would make a violation of those provisions subject to a specified fine.

The bill would specify to whom a pharmacist may furnish dangerous drugs.

(6) The bill would make its provisions operative on January 1, 2006, except as specified.

(7) Because a violation of the requirements and prohibitions created by this bill would be a crime, the bill would impose a state-mandated local program.

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

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

(9) This bill would become operative only if AB 2682 is also enacted and becomes effective on or before January 1, 2005.

(10) This bill would incorporate additional changes in Sections 4059.5 and 4081 of the Business and Professions Code proposed by SB 1913, to be operative only if SB 1913 and this bill are both enacted and take effect, and this bill is enacted last.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4022.5 is added to the Business and Professions Code, to read:

4022.5. (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053.

(b) "Designated representative-in-charge" means a designated representative or a pharmacist who is the supervisor or manager of a wholesaler or veterinary food-animal drug retailer.

(c) This section shall become operative on January 1, 2006.

SEC. 3. Section 4034 is added to the Business and Professions Code, to read:

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source.

(2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(d) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(e) This section shall become operative on January 1, 2007.

SEC. 6. Section 4053 of the Business and Professions Code is amended to read:

4053. (a) Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler if the board shall find that sufficient, qualified supervision is employed by the veterinary food-animal drug retailer or wholesaler to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) An individual employed by a veterinary food-animal drug retailer or wholesaler may apply for an exemption from Section 4051. In order to obtain and maintain that exemption, the individual shall meet the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(A) Knowledge and understanding of state and federal law relating to the distribution of dangerous drugs and dangerous devices.
(B) Knowledge and understanding of state and federal law relating to the distribution of controlled substances.
(C) Knowledge and understanding of quality control systems.
(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.
(4) The board may, by regulation, require training programs to include additional material.
(5) The board may, by regulation, require training programs to include additional material.
(6) The board shall not issue a certificate of exemption until the applicant provides proof of completion of the required training to the board.
(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or an individual in possession of a certificate of exemption on its premises.
(d) Only a pharmacist or an individual in possession of a certificate of exemption shall prepare and affix the label to veterinary food-animal drugs.
(e) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative before January 1, 2006, amends or repeals that date.
SEC. 7. Section 4053 is added to the Business and Professions Code, to read:
4053. (a) Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler that employs a designated representative to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).
(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate or possess a general education development equivalent.
(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(C) Knowledge and understanding of quality control systems.
(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.
(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) This section shall become operative on January 1, 2006.

SEC. 8. Section 4053.1 is added to the Business and Professions Code, to read:

4053.1. (a) Certificates of exemption issued or renewed pursuant to Section 4053 prior to January 1, 2005, shall remain valid until their expiration date or until January 1, 2007, whichever date is earlier.

(b) Individuals in possession of a current and valid certificate of exemption shall be issued a license as a designated representative if the individual satisfies the requirements of Section 4053 and pays the fee required by subdivision (i) of Section 4400.

(c) This section shall become inoperative and be repealed on January 1, 2007, unless a later enacted statute, that becomes operative on or before December 31, 2006, amends or repeals that date.

SEC. 9. Section 4054 of the Business and Professions Code is amended to read:

4054. Section 4051 shall not apply to a manufacturer or wholesaler that provides dialysis drugs and devices directly to patients.

SEC. 10. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge. Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to any person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drug or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. Any person or entity receiving delivery of any dangerous drugs or dangerous devices, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drugs or dangerous devices.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to any person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in

compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 10.5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether

it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 11. Section 4059.5 is added to the Business and Professions Code, to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge. Where a licensee is permitted to operate through a designated representative, the designated representative may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to any person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or physical therapist acting within the scope of his or her license. A person or entity receiving delivery of any dangerous drugs or dangerous devices, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drugs or dangerous devices.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to any person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) This section shall become operative on January 1, 2006.

SEC. 11.5. Section 4059.5 is added to the Business and Professions

Code, to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining

records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall become operative on January 1, 2006.

SEC. 12. Section 4081 of the Business and Professions Code is amended to read:

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

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or exemptee shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or exemptee had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 12.5. Section 4081 of the Business and Professions Code is amended to read:

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

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or exemptee-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or exemptee-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

SEC. 13. Section 4081 is added to the Business and Professions

Code, to read:

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

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on January 1, 2006.

SEC. 13.5. Section 4081 is added to the Business and Professions Code, to read:

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

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on January 1, 2006.

SEC. 14. Section 4084 is added to the Business and Professions Code, to read:

4084. (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.

(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated or counterfeit, a board inspector shall remove the tag or other marking.

(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.

(d) For the purposes of this article "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.

(e) For the purposes of this article "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

SEC. 15. Section 4085 is added to the Business and Professions Code, to read:

4085. (a) It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or dangerous device without permission of the board.

(b) When a board inspector has reasonable cause to believe, that the embargo will be violated, a board inspector may remove the embargoed dangerous drug or dangerous device from the premises.

SEC. 16. Section 4086 is added to the Business and Professions Code, to read:

4086. (a) If a dangerous drug or dangerous device is alleged to be adulterated or counterfeit, the board shall commence proceedings in the superior court in whose jurisdiction the dangerous drug or dangerous device is located, for condemnation of the dangerous drug or dangerous device.

(b) If the court finds that an embargoed dangerous drug or dangerous device is adulterated or counterfeit, the dangerous drug or dangerous device shall, after entry of the judgment, be destroyed at the expense of the claimant or owner, under the supervision of the board. All court costs and fees and all reasonable costs incurred by the board in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing, shall be paid by the claimant or owner of the dangerous drug or dangerous device.

(c) A superior court of this state may condemn any dangerous drug or dangerous device pursuant to this article. In the absence of an order, the dangerous drug or dangerous device may be destroyed under the supervision of the board who has the written consent of the owner, his or her attorney, or authorized representative. If the board cannot ascertain ownership of the dangerous drug or dangerous device within 30 days of establishing an embargo, the board may destroy the dangerous drug or dangerous device.

SEC. 17. Section 4100 of the Business and Professions Code is amended to read:

4100. (a) Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, every pharmacist, intern pharmacist, technician, or exemptee shall notify the executive officer of the board of the change of address or change of name.

(b) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 18. Section 4100 is added to the Business and Professions Code, to read:

4100. (a) Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, a pharmacist, intern pharmacist, technician, or designated representative shall notify the executive officer of the board of the

change of address or change of name.

(b) This section shall become operative on January 1, 2006.

SEC. 19. Section 4105 of the Business and Professions Code is amended to read:

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the exemptee, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 20. Section 4105 is added to the Business and Professions Code, to read:

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect

the board's authority under this section or any other provision of this chapter.

(f) This section shall become operative on January 1, 2006.

SEC. 23. Section 4126.5 is added to the Business and Professions Code, to read:

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

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

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

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

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

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

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

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities may subject the persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

SEC. 24. Section 4160 of the Business and Professions Code is amended to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee-in-charge. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior

exemptee-in-charge ceases to be the exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) A drug manufacturer licensed by the Food and Drug Administration or pursuant to Section 111615 of the Health and Safety Code that only ships dangerous drugs or dangerous devices of its own manufacture is exempt from this section.

(g) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 25. Section 4160 is added to the Business and Professions Code, to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) A drug manufacturer licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler.

(g) This section shall become operative on January 1, 2006.

SEC. 29. Section 4162 of the Business and Professions Code is repealed.

SEC. 30. Section 4162 is added to the Business and Professions Code, to read:

4162. (a) (1) An applicant for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten

million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SEC. 31. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.

(b) No person shall acquire dangerous drugs or dangerous devices from a person not authorized by law to possess or furnish those dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

SEC. 32. Section 4163 is added to the Business and Professions Code, to read:

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) A wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.

(e) This section shall become operative on January 1, 2007.

SEC. 33. Section 4163.5 is added to the Business and Professions Code, to read:

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Section 4163 until January 1, 2008, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the

distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 33.1. Section 4163.6 is added to the Business and Professions Code, to read:

4163.6. If the Legislature determines that it is not yet economically and technically feasible for pharmacies to implement electronic technologies to track the distribution of dangerous drugs within the state, the Legislature may extend the date for compliance with the requirement for a pedigree for pharmacies set forth in Section 4163 until January 1, 2009.

SEC. 34. Section 4164 of the Business and Professions Code is amended to read:

4164. (a) All wholesalers licensed by the board and all manufacturers who distribute controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 35. Section 4164 is added to the Business and Professions Code, to read:

4164. (a) A wholesaler licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) Each wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. The system shall be capable of identifying purchases of any dangerous drug at preferential or contract prices by customers that vary significantly from prior ordering patterns for the same customer, including by identifying purchases in the preceding 12 calendar months by that customer or similar customers and identifying current purchases that exceed prior purchases by either that customer or similar customers by a factor of 20 percent. Each wholesaler shall have the tracking system required by this subdivision in place no later than January 1, 2006.

(c) Upon written, oral, or electronic request by the board, a wholesaler shall furnish data tracked pursuant to subdivision (b) to the board in written, hardcopy, or electronic form. The board shall specify the dangerous drugs, the customers, or both the dangerous drugs and customers for which data are to be furnished, and the wholesaler shall have 30 calendar days to comply with the request.

(d) As used in this section, "preferential or contract prices" means and refers to purchases by contract of dangerous drugs at prices below the market wholesale price for those drugs.

(e) This section shall become operative on January 1, 2006.

SEC. 36. Section 4165 of the Business and Professions Code is amended to read:

4165. A wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an

authorized officer of the law with all records or other documentation of that sale or transfer.

SEC. 37. Section 4166 of the Business and Professions Code is amended to read:

4166. (a) Any wholesaler that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.

(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

SEC. 38. Section 4168 is added to the Business and Professions Code, to read:

4168. A county or municipality may not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California.

SEC. 39. Section 4169 is added to the Business and Professions Code, to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy, in violation of Section 4163.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

SEC. 40. Section 4169 is added to the Business and Professions Code, to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall become operative on January 1, 2007.

SEC. 41. Section 4196 of the Business and Professions Code is amended to read:

4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, an exempt person, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or exemptee shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. Each veterinary food-animal drug retailer shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge. A pharmacist

may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 42. Section 4196 is added to the Business and Professions Code, to read:

4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. Each veterinary food-animal drug retailer shall identify, and notify the board of, a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) This section shall become operative on January 1, 2006.

SEC. 43. Section 4301 of the Business and Professions Code is amended to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.
(b) Incompetence.
(c) Gross negligence.
(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.
(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.
(j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.
(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.
(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty,

or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 44. Section 4301 is added to the Business and Professions Code, to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent

or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.

(j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known,

not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code.

(t) This section shall become operative on January 1, 2006.

SEC. 45. Section 4305.5 of the Business and Professions Code is amended to read:

4305.5. (a) Any person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) Any person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee, and who continues to operate the licensee in the absence of a pharmacist or an exemptee approved for that location, shall be subject to summary suspension or revocation of his or her license to conduct a wholesaler or veterinary food-animal drug retailer.

(c) Any pharmacist or exemptee who takes charge of, or acts as manager of a wholesaler or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(d) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 46. Section 4305.5 is added to the Business and Professions Code, to read:

4305.5. (a) A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated representative-in-charge. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of the designated representative-in-charge, and who continues to operate the licensee in the absence of the designated representative-in-charge for that

location, shall be subject to summary suspension or revocation of his or her license to conduct a wholesaler or veterinary food-animal drug retailer.

(c) A designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(d) This section shall become operative on January 1, 2006.

SEC. 47. Section 4331 of the Business and Professions Code is amended to read:

4331. (a) Any person who is neither a pharmacist nor an exemptee and who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) Any person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) Any person who has obtained a license to conduct a wholesaler and who fails to place in charge of that wholesaler a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 48. Section 4331 is added to the Business and Professions Code, to read:

4331. (a) A person who is neither a pharmacist nor a designated representative and who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) A person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) A person who has obtained a license to conduct a wholesaler and who fails to place in charge of that wholesaler a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) This section shall become operative on January 1, 2006.

SEC. 49. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy or medical device retailer annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars ($100).

(i) The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(j) The fee for an out-of-state drug distributor's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(l) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(n) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

(w) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

SEC. 50. Section 4400 is added to the Business and Professions Code, to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) The fee for application and investigation for a designated

representative license issued pursuant to Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer designated representative, for whom the fee shall be one hundred dollars ($100).

(i) The fee for a designated representative license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer designated representative license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(j) The fee for a nonresident wholesaler's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(l) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(n) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a

veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

(w) This section shall become operative on January 1, 2006.

SEC. 51. This act shall become operative only if Assembly Bill 2682 is also enacted and becomes effective on or before January 1, 2005.

SEC. 52. Sections 10.5 and 11.5 of this bill incorporate amendments to Section 4059.5 of the Business and Professions Code proposed by both this bill and SB 1913. Sections 10.5 and 11.5 shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2005, (2) each bill amends Section 4059.5 of the Business and Professions Code, and (3) this bill is enacted after SB 1913, in which case Sections 10 and 11 of this bill shall not become operative.

SEC. 53. Sections 12.5 and 13.5 of this bill incorporate amendments to Section 4081 of the Business and Professions Code proposed by both this bill and SB 1913. Sections 12.5 and 13.5 shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2005, (2) each bill amends Section 4081 of the Business and Professions Code, and (3) this bill is enacted after SB 1913, in which case Sections 12 and 13 of this bill shall not become operative.

SEC. 54. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

AGENDA ITEM J

Board President Stan Goldenberg requested each committee discuss how the Board of Pharmacy can better improve and facilitate communications with the public and licensees.

Enforcement Committee Meeting
Agenda Item I

State of California

Department of Consumer Affairs

Memorandum

To: Communication and Public Education Committee

Date: September 10, 2004

From: Virginia Herold

Subject: How Can the Board of Pharmacy Improve Communication with the Public and Licensees

At the board's July Meeting, President Goldenberg stated that one of the priorities for his term is to improve the communication of the board with its licensees and with the public.

To this end, each of the board's committees will hold a public meeting before the October board meeting with this topic listed as a discussion item. The goal is to establish a dialogue with our stakeholders on improving communication, and to bring these to the next board meeting.

The board has several broad-based means of communication with the public and with licensees:

- Quarterly board meetings, where public input for each agenda area has public input scheduled as a component.
- Web site information
- Consumer education materials
- Co-sponsorship of public education events (e.g., 2003's Hot Topic Seminars with the UCSF School of Pharmacy)
- Attendance at continuing education fairs
- Attendance/staffing at public education fairs and events
- A subscriber e-mail notification system about major new information added to the board's site (about to be implemented)

The board has at least 19 public meetings annually, where an agenda is mailed and posted on our Web site 10 days before a meeting. There are four board meetings, and at least 15 additional public meetings of board committees (all meetings of Public Education, Enforcement and Licensing are public, at least two Legislation and Regulation Committee meetings are public each year, as is at least one Organizational Development Committee meeting).

In addition, the board currently uses various means of communication with licensees:

- *The Script* newsletter

- Presentations by board members and supervising inspectors of the board's CE outreach programs to groups of pharmacists, typically at professional meetings (at least 34 presentations were provided during 2003/04)
- Attendance and staffing of information booths at major educational fairs hosted by the major pharmacist associations
- In rare cases, letters are mailed directly to licensees advising them about major changes in programs (for example, changes in wholesaler requirements or foreign graduation evaluations)
- *Health Notes,* a health monograph developed by the board in a particular area that contains current drug treatment modalities, and which provides continuing education for pharmacists in subjects of importance to the board.

Perhaps less broad-based, but certainly important means of communicating with the public or licensees include:

- Inspections (2,582 inspections were conducted during 2003/04)
- Written, faxed and telephone inquiries directly to the board.
- Surveys of all complainants following closure of their complaints
- Coming is a "Web site User Survey" (currently the board's Web site is being redesigned. One new component will be a "Web site user survey" to seek feedback on the Web site. This information will be used to enhance our Web site)

The board periodically attempts new means of providing information to licensees and other interested parties. As an example, since April, board staff have provided at least three teleconferenced continuing education sessions dealing with the implementation of SB 151 regarding new requirements for the prescribing and dispensing of controlled substances. We also have produced our first audio tape of one of these teleconferences which is now available on our Web site, so individuals can obtain the information whenever convenient for them.

A board member and staff also attended each of the four California schools of pharmacy this spring to advise graduating students about the new licensure examinations and processes.

AGENDA ITEM K

This agenda item has been deferred to the December Enforcement Committee meeting.

AGENDA ITEM L

5 Office conferences were held this quarter

Citation and Fine Statistics for July 1, 2004 – September 21, 2004

Contested Citations Office Conference

Requested	Scheduled	Appeared	Affirmed	Modified	Dismissed	Reduced to letter of admonishment	Withdrawn
192	184	148	26	34	50	4	3

Amount of fines issued this quarter $108,200.00

Amount of fine collected this quarter $12,225.00

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
188	29	2	50	34	34	15	6	1

Miscellaneous Citation Breakdown by license type

Wholesalers	Exemptee's in charge	Clinics	Hypo permits	Hospital pharmacy	Unlicensed Premises	Unlicensed person
2	2	3	1	2	6	1

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	70%	1716 - Variation from prescription	37%	1716 - Variation from prescription	17%
1715.5 - Implementation of electronic monitoring of schedule II prescriptions	6%	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	12%	4125/1711 - Quality assurance program	15%
17612(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	6%	4125/1711 - Quality assurance program	11%	4342/USP 25th edition page 10 - Actions by board to prevent sales of preparations or drugs lacking quality or strength	12%
1715 - Self-assessment of a pharmacy by PIC	3%	4342/USP 25th edition page 10 - Actions by board to prevent sales of preparations or drugs lacking quality or strength	8%	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	10%
1716/1761 - Variation from Rx / Erroneous Rx	3%	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	7%	1304.04(f) - Each registrant shall maintain inventories and records of controlled substances	8%
1714(d) - Operational standards and security; pharmacy responsible for pharmacy security	3%	4113(a)/1709.1 – Pharmacist in charge, notification to the board, Responsibilities /Designation of a pharmacist in charge	7%	1714(c) - Operational standards and security; the pharmacy must be maintained in a sanitary condition	8%
4063 - Refill of prescription for dangerous drug or device; prescriber authorization	3%	1716/1761 - Variation from Rx / Erroneous Rx	6%	1714(d) - Operational standards and security; pharmacy responsible for pharmacy security	8%
1707.1 - Duty to maintain medication profiles	3%	1707.1 - Duty to maintain medication profiles	5%	1707.1 - Duty to maintain medication profiles	6%
1707.3 - Preprinted, multiple checkoff prescription blanks	3%	1304.04(f) - Each registrant shall maintain inventories and records of controlled substances		1715.5(a)(b) - Self-assessment by the pharmacist in charge; / within 30 days ...	6%
4125/1711 - Quality assurance program	3%	1715.6 - Reporting drug loss	4%	1716/1761 – Variation from prescription/Erroneous or uncertain prescriptions	6%

Citation Statistics from May 15, 2001 – September 21, 2004

1843 citations have been issued with fines totaling $1,560,054.00.

135* of these citations totaling **$310,950.00**, in fines, have not been collected.

Of the **135: (see all bolded totals)**

19 citations totaling **$125,500.00**, have been closed as uncollectible.

12 fines totaling **$9,250.00**, have been added to license renewal fees and the licenses have been placed on hold.

25 citations totaling approximately **$44,230.00**, are currently under review for possible renewal hold.

27 citations totaling $30,750.00 fines have been issued to canceled/unlicensed technicians.

12 of these citations totaling $3,875.00 have been collected.

15 citations issued to canceled/unlicensed technicians totaling **$26,875.00**, remain uncollected.

29 citations totaling $41,620.00 have been issued to unlicensed premises.

12 of these citations totaling $6,275.00 of these fines have been collected.

17 citations issued to unlicensed premises totaling **$35,345.00**, remain uncollected.

92 citations have been issued with a fine to canceled premise licenses totaling $116,400.00.

45 of these fines totaling $46,650.00 have been collected.

47 citations issued to canceled premise licenses totaling **$69,750.00**, remain uncollected

* This number represents less than 7.5% of the citations issued.

ENFORCEMENT COMMITTEE - TEAM REPORT
ENFORCEMENT ADMINISTRATIVE TEAM

WORKLOAD STATISTICS	July-Sept	Oct-Dec	Jan-Mar	Apr-Jun	FY 04/05
Complaints (as of 09/17/04)					
Total pending	661				661
Total received	297				297
Total closed	453				453
Inspections (Transmitted as of 9/21/04)					
Routine	493				493
Probation	11				11
Total Overall	633				633
Application Investigations (as of 09/17/04)					
Initiated	40				40
Total closed*	13				13
Approved	10				10
Denied	2				2
Pending	63				63
*This figure includes application investigations withdrawn					
Administrative Cases (as of 09/17/04)					
Cases referred to AG's Office*	28				28
Pleadings filed	22				22
Cases closed	14				14
Pending at the AG's Office					
Pre-accusation	59				59
Post accusation	84				84
Total*	149				149
Cost recovery collected	$29,641.89				$29,641.89
*This figure includes citations.					
PC 23's Granted	2				2
ISO's Issued	2				2
Citations (as of 09/17/04)					
Issued	186				186
Abated	303				303
Fines collected	$62,501.00				$62,501.00

AGENDA ITEM M

U. S. Department of Justice
Drug Enforcement Administration

RECEIVED BY CALIF.
BOARD OF PHARMACY

2004 SEP 13 PM 12: 58

www.dea.gov

Washington, D.C. 20537

AUG 27 2004

Ms. Patricia Harris
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814

Dear Ms. Harris:

The Drug Enforcement Administration's (DEA), Office of Diversion Control, is in the process of changing the style and appearance of the DEA Controlled Substance Registration Certificate. As of October 1, 2004, the revised Certificate of Registration will consist of two parts: one that can be displayed on the wall and a smaller wallet size version (see enclosure). The certificate will have an imbedded watermark logo, which will provide authentication of the certificate and also deter counterfeiting.

Registrants that are currently allowed to renew their DEA registration via the Diversion Control Program's website (i.e., Retail Pharmacies, Hospitals, Practitioners, Mid-level Practitioners and Teaching Institutions) may print their Certificate of Registration upon completion of the registration renewal process as long as no changes have been made to their registration since their last renewal. The Diversion Control Program's website may be accessed at www.DEAdiversion.usdoj.gov. The DEA will continue to send Certificates of Registration via the United States Postal Service to all new registrants and all other DEA registrants renewing their DEA registration.

At this time we are seeking your organization's assistance with informing your members of the new revised DEA certificate. Should you have any questions, please feel free to contact Lynn Bossert, Program Analyst, Liaison and Policy Section, at (202) 307-7297.

Sincerely,

Patricia M. Good

Patricia M. Good, Chief
Liaison and Policy Section
Office of Diversion Control

Enclosure

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BR0123456	12-31-2007	PAID

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N 3,3N,4,5	PRACTITIONER	11-23-2004

JANE D REGISTRANT
1234 MAIN AVE
PO BOX 1234

ANYCITY US 12345-0123

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C, 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacturer, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (11/03)

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C, 20537

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