California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Enforcement Committee

Robert Swart, PharmD, Chair and Board Member
Jim Burgard, Board Member
D. Timothy Dazé, Esq. Board Member
Stan Weisser, RPh, Board Member

The Enforcement Committee and the Workgroup on E-Pedigree met on October 6, 2008 in Sacramento. Minutes of this meeting are provided in **Attachment A** at the back of this tab section.

1. For Information: Work Group on E-Pedigree Report

The Legislative Session ended September 30, which is date when the Governor signed SB 1307 (Ridley-Thomas). A copy of this bill is provided as **Attachment 1.**

This law now staggers implementation of e-pedigree requirements away from 2011 to:

- 50 percent of a manufacturer's products by 2015
- the remaining 50 percent of the manufacturer's products by 2016
- Wholesalers and repackagers must accept and pass e-pedigrees by July 1, 2016, and
- Pharmacies and pharmacy distribution centers must accept e-pedigrees by July 1, 2017

There is preemption language that would repeal California's provisions if federal law regarding e-pedigrees is enacted, or if federal standards are enacted, they would take effect in CA.

There are provisions that define drop shipments, third party logistics firms, repackagers and manufacturers. Grandfathering provisions for drugs already in the supply chain are included. The board will ultimately have to develop regulations for various components, including inference.

Senator Ridley-Thomas added a letter to the Senate Journal, reflecting the agreement of those who worked on amendments to California's e-pedigree law and that this would be the last extension. A copy of this letter is also included **Attachment 1**.

During this board meeting, Executive Officer Herold will provide a PowerPoint presentation of the major provisions enacted to California law by SB 1307.

Bob Celeste of GS1 will update the committee of the work of this standards setting organization.

Also during this Board Meeting, those in attendance will be offered an opportunity to comment on the e-pedigree requirements. PhRMA has provided the board with a copy their cost-benefit analysis to manufacturers of serialization, working with both 2-D bar codes and RFID. This report is in **Attachment 2**.

Executive Officer Herold and Mr. Celeste provided presentations during the Workgroup on E-Pedigree Meeting. There was also a presentation by Proctor and Gamble Pharmaceuticals on the readiness of their company to implement e-pedigree requirements. This company has three lines, and spoke about the readiness of several other pharmaceutical companies.

During the Workgroup on E-Pedigree Meeting, comments were made by various organizations, including McKesson and PhRMA on the need for the provisions in SB 1307, and the work of all parties to reach a compromise on the amendments to California's law. The supply chain is moving forward with serialization and compliance with California's law, although many companies indicate they are taking a breath and a more thoroughly planned approach (less rushed) to the requirements. The current economic conditions and push-back in implementation dates have also led some companies to reduce the funding going into serialization since implementation will not be 2011.

In **Attachment 3** is a recent survey by *Pharmaceutical Commerce* magazine regarding the supply chain's readiness for serialization and e-pedigree.

2. Enforcement Committee Report

a. FOR DISCUSSION: E-Prescribing Forum Set for November 20, 2008

On November 20, 2008, the Board of Pharmacy will host an e-prescribing forum in conjunction with the Department of Consumer Affairs' Professionals Achieving Consumer Trust summit. Other healing arts boards whose licensees prescribe drugs have been invited, as have public interest groups. The Dental Board and Medical Board have joined us as partners.

A number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing for all medicine. A principal reason is that statistics indicate that medication errors cost the health care system $77 billion and cause 7,000 deaths annually. A number of these errors could be prevented by full implementation of e-prescribing.

By the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. Since then, various provisions have been added or amended to keep law supportive of allowing electronic prescriptions.

For the November 20 forum, the agenda contains a review of California's laws authorizing e-prescribing. There will be presentations by a software company that provides the software to perform e-prescribing. There will also be presentations by several large entities that are currently using e-prescribing to describe their experiences – what works and lessons learned.

Meanwhile, the California HealthCare Foundation is also sponsoring a forum on e-prescribing on November 20 in San Francisco. Executive Officer Herold is a member of the group formed by the California HealthCare Foundation to work towards achieving e-prescribing, although she will miss this forum to attend the summit of the board.

These two forums will provide opportunities for strong policy initiatives to move forward encouraging e-prescribing in California. Legislation may be one outcome of these efforts.

b. FOR DISCUSSION AND POSSIBLE ACTION: Presentation on the Controlled Substance Utilization Review and Evaluation System (CURES) Moving to Provide Online, Near Real Time Reports to Practitioners in the Future

For a number of years, the board has fully supported the Controlled Substance Utilization Review and Evaluation System (CURES) to electronically track all Schedule II-IV medicine dispensed to patients. This data is submitted each week to the California Department of Justice by pharmacies and prescribers who dispense controlled substances, and contains information about the specific drug, strength and quantity dispensed by a pharmacy or practitioner, as well as the prescriber, the dispenser and the patient.

Underway for several years is a process whereby prescribers and dispensers can obtain from the Department of Justice copies of the dispensed drugs of a particular patient reported to CURES. This allows these practitioners to determine whether a patient is a "doctor shopper" for controlled drugs, and thereby prevent the prescribing and dispending of controlled drugs to such patients. A copy of the required form, a "Patient Activity Report" (PAR, included in this tab section), can be downloaded from the board's Web site (under "publications," and "applications and forms"), and mailed or faxed to the Department of Justice.

Data is reported weekly by practitioners into the system, but by the time processing occurs and a PAR report is obtained, it can be weeks – usually not in time to prevent the prescribing or dispensing of controlled drugs, unless a patient returns to the practitioner or pharmacy for future controlled drugs.

Underway for several years is an effort spearheaded by public citizen Bob Pack working with several state agencies (including this board) to secure online, near real time reports for practitioners via a secured Internet system operated by the Department of Justice. Such a system would allow significantly faster access to CURES data. Mr. Pack was a founder of Netzero, so he has the technology background and contacts to help drive this initiative. A feasibility study report was developed for the Department of Justice for this system.

Mr. Pack will attend this Board Meeting to describe how he is seeking private donations to pay for this system, which is necessary given the state's current fiscal condition. A copy of background material for this project is provided in **Attachment 4**. Kaiser Permanente has committed to donate money to this cause, but additional funding is still needed. Mr. Pack states that, "Although we are seeking $1.5M ... I am looking for ways to cut the costs, and can probably get it down to $1M."

c. **FOR ACTION: <u>The Federal Drug Enforcement Administration's Proposed Rule to Allow E-Prescribing of Controlled Substances</u>**

In late June 2008, the DEA announced proposed regulations to allow the e-prescribing of prescriptions for controlled substances. The proposed rule would allow pharmacies to receive and dispense controlled drugs pursuant to electronically transmitted prescriptions. Comments were solicited by the DEA, and due September 25, 2008.

An important piece needed to permit full scale adoption of e-prescribing is the ability to prescribe controlled substances via this manner. Federal requirements prohibit the use of e-prescribing; however, with the DEA reconsidering its position on e-prescribing of controlled substances (see topic (a) above) wider adoption and use of e-prescribing can be expected.

Whereas controlled substances account for 10-15 percent of prescription drugs dispensed, the inability for these drugs to be e-prescribed has been considered a deterrent to wide adoption of e-prescribing.

During the July 2008 Board Meeting, the board discussed the DEA proposed regulations that would allow e-prescribing of prescriptions for controlled substances. At the conclusion of the board's discussion in July, the board voted to prepare comments to the DEA in support of the proposed rule to allow e-prescribing of controlled substances.

In September, a letter was sent on behalf of the board that confirmed that the board is encouraged that the DEA is moving forward to permit e-prescribing of controlled substances. The letter also detailed board concerns over some of the onerous requirements contained within the proposed regulations. Specifically the board's letter identifies possible obstacles to implementation that make far more stringent demands upon e-prescriptions than paper prescriptions, including e-record retention of five years and verifying the DEA permit of the practitioner every time before filling a controlled substances e-prescription. The letter encouraged the DEA to reconsider the necessity of some of the requirements.

A copy of the letter is provided in **Attachment 5.**

d. FOR ACTION: Implementation of Drug Take Back Programs from Patients by California Pharmacies

Recommendation: Submit comments of model drug take-back programs to the California Integrated Waste Management Board

Last year, SB 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated Waste Management Board to develop the parameters for "model" drug take-back programs in pharmacies (a copy of this law is provided in **Attachment 6**). These model programs are intended to provide consumers with the ability to dispose of unwanted prescription and OTC drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage. Under SB 966, these model programs must be in place by December 2008.

State and federal law regulates prescription medicine until it is dispensed to patients. It is not regulated again unless it is collected at consolidated points, at which point it becomes medical waste, and must be handled and destroyed in specific, mandated ways.

Patients are often confounded about what to do with unwanted medicine. Californians are increasingly wanting "green" options for disposing of unwanted medicine, which current law does not allow. There is no viable process, other than to make the discarded drug products unpalatable (mixing with kitty litter or other substance, wrapping in duct tape, etc.) and then placing them in the trash. Some drugs may be flushed down the toilet, and are specifically labeled by the manufacturer to be disposed of in this manner.

Pharmacies have in some cases agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not authorized in law.

Some communities periodically offer community take-back events, or special days at landfills where the public can take back drugs.

Some drug manufacturers (and the state of Maine, where there is a pilot program underway) provide mailers that patients can use to send unwanted medicine to a predetermined location for destruction. This is the process preferred by the DEA for patients to dispose of controlled drugs.

Currently, the Integrated Waste Management Board has compiled parameters of model programs, and plans on presenting this information to its board in November. A draft copy, that the Integrated Waste Management Board clearly emphasizes is a draft, is attached as **Attachment 6**.

Drug diversion of prescription medicine is a serious issue in this country. Unwanted prescription medicine is highly valuable to some individuals, and certainly has street value. There are those who purchase over the Internet without prescriptions, steal from pharmacies, buy drugs on the street or otherwise seek to obtain these drugs from a number of criminal sources. Here are some stats (LA Times, September 2008):

- 1 in 20 Americans aged 50-59 told researchers they had used illicit drugs in the last month.
- Among 12-25 year olds, one third who used illicit drugs had abused prescription drugs, including painkillers, tranquilizers and stimulants
- Among 12-17 year olds, 3.3 percent had abused prescription drugs in the last month.
- Among 17-25 year olds, 6 percent had abused drugs in the last month

Also:

- Among 45-54 year olds, overdose deaths by prescription drugs surpass is the number 1 cause of accidental death, surpassing death by motor vehicles
- Nearly 7 million Americans abuse prescription drugs – up from 3.8 million in 2000.

Since late winter, some board staff have been attending meetings with a group of individuals from the California Integrated Waste Management Board, Toxics Program and Medical Waste Program, all divisions within various state agencies. Additionally Executive Officer Herold has made three presentations on California pharmacy law and pharmacy drug take back programs in recent months to those who deal with water quality and waste management throughout California.

The greatest problem for the board with drug take-back programs is the potential for these drugs to be diverted to the streets. As discussed above, there is a serious prescription drug abuse problem in the US, and the uncontrolled aggregation of prescription medicine is an attractive enticement. In some cases, drugs collected in collection bins could re-enter the prescription

drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain.

Moreover, pharmacies are areas where health care is provided – it is difficult for this purpose to be combined with a recycling center, which is not necessarily an area of high sanitation.

While some pharmacies support such programs, other pharmacies have expressed concern that they may be required to absorb the costs of paying for disposal of these drugs, for sorting out controlled drugs (which potentially would require a pharmacist's time) and for assuring the safety and periodic emptying of collection bins.

Appropriate destruction of unwanted prescription medicine is a national issue, and the National Association of Boards of Pharmacy has a task force formed to develop policy for the NABP for discussion at its annual meeting in May. Ken Schell is on this task force.

During the Enforcement Committee Meeting of October 6, it was clear that some pharmacies are concerned with having to take back drugs from patients. Additionally, board staff have concerns with the openness of the model programs, that would greatly expand collection sites for prescription drugs without adequate controls.

Action:

The board may wish to provide comments on these proposed model programs. During this part of the board meeting, Executive Officer Herold will provide the board with the staff's recommendations to these model programs. These comments will be generated in a meeting scheduled for Friday, October 24. Should the board wish to provide comments on the model programs, the California Integrated Waste Management's Board Meeting is November 18.

There will be staff from the Integrated Waste Management Board available to answer questions.

In January, staff will have recommendations for additional statutory modifications to ensure protection of the public.

e. FOR DISCUSSION: Role of Reverse Distributors in Picking Up Medical Waste and Returned Drugs

During the October Enforcement Committee, the committee heard a presentation about how the disposal of drugs from pharmacies and hospitals occurs. Sometimes unwanted drugs are returned to manufacturers,

sometimes they are disposed by medical waste haulers. There are specially licensed firms who are authorized to perform these services.

The board regulates reverse distributors, who are licensed as wholesalers. The board does not license medical waste haulers, who must be licensed by another state agency.

At the October Board Meeting, the Medical Waste Management Program of the Department of Public Health will provide a brief presentation on how they regulate medical waste haulers.

f. FOR ACTION: Discussion of Sharps Take Back by Pharmacies

Recommendation: Pursue statutory amendment and develop interim policy for pharmacy take-back of sharps

A related, but separate issue to the problem of how society will dispose of unwanted drug products is the issue of disposal of used sharps.

According to estimates by the California Integrated Waste Management Board, California patients use 1 billion needles and syringes each year. This does not include lancets.

Since September 1, 2008, California law has prohibited the disposal of sharps in trash or recycling containers. I am attaching information from the Integrated Waste Management Board's Web site (**Attachment 7**). Pharmacies are listed as one of the disposal locations. However, pharmacy law does not authorize pharmacies to take back sharps, unless there is a county-adopted needle exchange program in place.

Regarding appropriate destruction, the Department of Public Health states that:

> California Health and Safety Code, Section 118286 (b)
>
> On or after September 1, 2008, home-generated sharps waste shall be transported only in a sharps container, or other containers approved by the enforcement agency, and shall only be managed at any of the following:
> (1) A household hazardous waste facility pursuant to Section 25218.13.
> (2) A "home-generated sharps consolidation point" as defined in subdivision (b) of Section 117904.
> (3) A medical waste generator's facility pursuant to Section 118147.
> (4) A facility through the use of a medical waste mail-back container approved by the department pursuant to subdivision (b) of Section 118245.
>
> The CDPH Medical Waste Management Program is recommending the use of sharps containers approved by the U.S. Food and Drug Administration (FDA).

In July, recognizing that there was a potential problem for consumers since pharmacy law does not authorize pharmacies to take back sharps, and yet on September 1, the law would limit how patients could simply dispose of these items, board staff proposed an amendment to California Pharmacy Law to allow such a practice. However, the bill to authorize this was dropped at the end of August by Senator Simitian for other reasons. The amendment was simple, and would add:

> A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container as defined by Health and Safety Code section 117750.

Staff will bring this as a proposal for approval of the board to the October Legislation and Regulation Committee and Board Meeting.

In the interim, since California pharmacy law does not allow pharmacies to take back sharps containers, and beginning September 1, patients cannot dispose of sharps by tossing them into the trash, this does create problems for patients.

The executive officer and President Schell recommend that in the interim, the board adopt as policy that:

> California law does not authorize pharmacies to accept the return of sharps when appropriately contained in an approved sharps container. Nevertheless, the board believes that it is in the public interest that willing pharmacies do take back such items. The board reserves its enforcement discretion about whether to intervene with any pharmacy that takes back sharps containers inappropriately. However, until this matter is fully resolved, the board does not anticipate intervening in such practices. Nevertheless, this policy may change as a result of a complaint or public safety issue.

Additionally, the issue of how and where patients return sharps and who will pay for the expense of these returns continues. At the end of September, AB 501 was vetoed by the Governor. This bill, which the board supported, would have required manufacturers of prefilled injection devices (e.g., epipens) to provide information to patients about how to dispose of the items. A copy of the bill and the Governor's veto message are provided in **Attachment 7**.

g. FOR DISCUSSION: Summary of Medication Errors Made by California Pharmacies: 2007-08

At the July 2008 Board Meeting, the board held a forum on medication errors. Michael Cohen of the Institute for Safe Medication Practices, John Keats of California Patient Safety Action Coalition (CAPSAC), and Bob LeWinter of the California Department of Public Health provided presentations on activities

underway to prevent pharmacies from making or repeating medication errors. A discussion also involved another discussion of the findings of the 2006 SCR 49 Medication Errors Task Force report.

Also at the July Board Meeting, Executive Officer Herold provided a presentation of the medication errors cited and fined by the Board of Pharmacy during 2007-08. There were 402 medication errors reported to the board during this period, and 600 medication error cases closed during the period. Of these cases 94 percent were substantiated as errors.

During the discussion during the board meeting and then later during the Communication and Public Education Committee Meeting (held in conjunction with the board meeting), Executive Officer Herold suggested including information in the board's Newsletter or in a separate issue on some of the medication errors investigated by the board.

Attachment 8 contains a list of drugs involved in the medication errors reported to the board. This list will be published in the next *The Script.* In the Communication and Public Education Report for the meeting is a more lengthy discussion of what will be published in the newsletter on medication errors.

h. FOR ACTION: Hospital Pharmacies' Control of Drugs within a Hospital

Recommendation: Form a Task Force of Two Board Members and Work With Other Interested Parties to Improve Drug Distribution in Hospitals

As the board was advised at the June and July 2008 Board Meetings, by early June, the board had completed its inspections of 533 hospital pharmacies in California and identified 94 hospitals where recalled drugs were still in patient care areas. The board has cited and fined the hospitals and pharmacists-in-charge and consultant pharmacists in those hospitals for failure to secure the hospitals' drug supplies by allowing recalled drugs to remain in the pharmacies, dispensing machines and in patient care areas. Several wholesalers and their designated representatives who shipped recalled drugs have received citations and fines as well.

Currently, the board's senior staff is holding office conferences with those who are contesting the fines. There may be administrative hearings for the next level of appeal. As such, the board cannot discuss the specifics of the heparin recall with the board members at this time.

At the October Committee Meeting, the committee floated the idea of forming a task form with hospital pharmacies and pharmacists, the hospital association and others to discuss how pharmacies, and the pharmacists-in-charge can better maintain control of drugs within a facility. The committee heard from UCLA on how it handles drug distribution within its multiple pharmacies, and also from Woodland Hospital on how it supplies drugs through the hospital from its one pharmacy.

It may also be time to look to revising California Pharmacy Law with respect to hospitals, which are very different than what they were when the laws were created. There has been no substantial review in the last 20 years, if not longer.

i. **FOR INFORMATION: Minutes of the Meeting of October 6**

Minutes of the Enforcement Committee and Workgroup on E-Pedigree Meeting of October 6 are provided in **Attachment A**.

B. FOR INFORMATION: 4TH Quarterly Report on Enforcement Committee Goals for 2007/08

Attachment 9 contains the strategic plan update for the Enforcement Committee for the 1st quarter of 2008-09.

C. For Information: Enforcement Statistics, 2008-09

Attachment 10 contains enforcement statistics from the first quarter of 2008-09.

Attachment 1

Senate Bill SB 1307
And Senator Ridley-Thomas'
Letter to the Senate Journal

MEMBERS
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California Legislature

Senate Committee on Business, Professions & Economic Development

MARK RIDLEY-THOMAS
CHAIR

August 25, 2008

Mr. Gregory Schmidt
Secretary of the Senate
State Capitol, Room 400
Sacramento, CA 95814

Dear Mr. Schmidt:

I submit this letter to the Senate Journal to clarify legislative intent for Senate Bill 1307, regarding California's electronic pedigree (ePedigree) requirement for prescription drugs. The provisions of this bill reflect an agreement between myself, the California Board of Pharmacy (Sponsor) and members of the pharmaceutical distribution chain regarding California's efforts to protect consumers from counterfeit, diverted or misbranded drugs.

In response to threats to the prescription drug supply chain, California adopted an ePedigree requirement that was scheduled to go into effect January 1, 2007, to provide a system of tracking prescription drugs from the point of manufacture until they reach a pharmacy or hospital. However, the compliance date was delayed twice to 2009 and 2011 because of a number of technological and production line complexities. Many drug supply chain participants have expressed great concern in their ability to be ePedigree compliant by January 1, 2011. To give the pharmaceutical industry the necessary time, flexibility and guidance to comply with California law, I introduced SB 1307 to address a number of ePedigree implementation issues that were not addressed in the original legislation, including provisions that delay, for the final time based on this agreement, the effective date of the electronic pedigree requirement.

Over the course of the last 18 months, my staff attended and convened a number of stakeholder meetings to identify and develop statutory solutions to a number of unresolved ePedigree issues. Much of SB 1307 addresses implementation issues. At the request of the State and Consumer Services Agency, representatives of the pharmaceutical industry convened their own meetings for the purpose of attaining industry-wide consensus on the safest and most cost efficient way to protect California's drug supply. Representatives from drug manufacturers (brand and generic), wholesalers, retailers, independent pharmacies, clinics, hospitals, California counties and their respective trade organizations participated in those meetings and unanimously agreed to support SB 1307 if it was amended to (1) include specific language on preemption by subsequently enacted federal pedigree laws or regulations and (2) create

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a graduated implementation schedule for compliance with the ePedigree law beginning on January 1, 2015, and ending on July 1, 2017.

In consultation with the Board of Pharmacy, I agreed to accept the amendments with the pharmaceutical industry's assurances that all involved parties will operate in good faith and in a diligent manner to implement the requirements as soon as possible and be fully compliant with the requirement by the dates contained in the bill. Those amendments were incorporated into SB 1307 on August 14th and the following organizations have now written in support of this measure:

California Board of Pharmacy (Sponsor)
Abbott Laboratories
Amgen
Arena Pharmaceucticals
Barr Pharmaceuticals
Baxter Healthcare
Bayer Healthcare
Biocom
California Healthcare Institute
California Pharmacists Association
California Retailers Association
California Society of Health-System Pharmacists
California State Association of Counties
Cardinal Health
Compressed Gas Association
Council on Radionuclides and Radiopharmaceuticals
Daiichi-Sankyo
Genentech
Generic Pharmaceutical Assn
Gray Panthers
Healthcare Distribution Management Assn
Hospira
Johnson and Johnson
McKesson Corporation
Merck, Inc.
Mylan, Inc.
National Association of Chain Drug Stores
National Coalition of Pharmaceutical Distributors
Novartis Pharmaceuticals
Pfizer
Pharmaceutical Research and Manufacturers of America (PhRMA)
Rite Aid
Sandoz, Inc.
Teva Pharmaceuticals, USA
Walgreens
Wyeth

After many months of negotiation and compromise, and with agreement on the part of all of the aforementioned organizations, SB 1307 now has the support and commitment of the entire pharmaceutical drug manufacturing and distribution chain to begin compliance with the ePedigree law beginning on January 1, 2015, and to be fully compliant by July 1, 2017. The delayed implementation dates in the August 14, 2008 amendments give the industry ample time to meet the state's electronic pedigree requirement. Therefore, SB 1307 represents the last time legislation will be needed to give the pharmaceutical industry time to comply with the state's electronic pedigree law and to ensure Californians have access to safe, lifesaving medication.

Sincerely,

MARK RIDLEY-THOMAS
Senator, 26th District

Senate Bill No. 1307

CHAPTER 713

An act to amend Sections 4033, 4034, 4162, 4162.5, and 4163 of, to add Sections 4034.1, 4044, 4045, 4163.1, 4163.2, 4163.3, and 4163.4 to, and to repeal and add Section 4163.5 of, the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 30, 2008. Filed with Secretary of State September 30, 2008.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, Ridley-Thomas. Pharmacy: pedigree.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy, in the Department of Consumer Affairs. Under existing law, on and after January 1, 2009, pedigree means an electronic record 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 one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. On and after January 1, 2009, existing law prohibits a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree. Existing law, on and after January 1, 2009, requires that a pedigree include certain information, including, but not limited to, the source of the dangerous drug and the trade or generic name of the drug. Existing law exempts specified transactions from the pedigree requirement, and authorizes the board to extend the January 1, 2009, compliance date to January 1, 2011, in specified circumstances. Existing law makes it a crime to knowingly violate the Pharmacy Law.

This bill would instead, on and after January 1, 2015, define a pedigree, as specified, and would revise the information required to be contained in a pedigree to, among other things, include a specified unique identification number.

The bill would prohibit a wholesaler or repackager, as defined, on and after July 1, 2016, or a pharmacy, on and after July 1, 2017, from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree, except as specified. The bill would prohibit a pharmacy warehouse, as defined, on and after July 1, 2017, from acquiring a dangerous drug without receiving a pedigree. The bill would delete the board's authority to extend these compliance dates. The bill would also prohibit a repackager or pharmacy from furnishing a

dangerous drug or dangerous device to an unauthorized person. The bill would require a manufacturer of a dangerous drug distributed in California to designate certain percentages of the drugs that it manufactures to comply with the pedigree requirement by specified dates, and to notify the board of the drugs so designated and of the technology to be used to meet that requirement. The bill would also revise certain exemptions from the pedigree requirement and would exempt specified additional transactions from the pedigree requirement.

The bill would authorize a manufacturer, wholesaler, or pharmacy in possession of dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements to designate those drugs as not subject to the requirements by preparing a specified written declaration under penalty of perjury, which would be considered trade secrets and kept confidential by the board. The bill would authorize dangerous drugs designated on such a declaration to be purchased, sold, acquired, returned, or otherwise transferred, without meeting the pedigree requirements if the transfer complies with specified requirements. Because a knowing violation of the bill's provisions would be a crime under the Pharmacy Law and because the bill would expand the crime of perjury, the bill would impose a state-mandated local program.

The bill would require the board to promulgate regulations defining the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, if certain standard operating procedures are complied with and made available for the board to review. The bill would require board regulations to specify liability associated with accuracy of product information and pedigree using inference. The bill would declare the intent of the Legislature in this regard.

The bill would make the pedigree requirements inoperative upon the effective date of federal law addressing pedigree or serialization measures for dangerous drugs, or as otherwise specified in the event of a conflict with federal law.

Existing law requires an applicant for issuance or renewal of a wholesaler or nonresident wholesaler license to submit a surety bond of $100,000 or an equivalent means of security to secure payment of any administrative fines and costs imposed by the board. Existing law makes this requirement inoperative and repeals it on January 1, 2015.

This bill would delete the date upon which these provisions become inoperative and are repealed.

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.

The people of the State of California do enact as follows:

SECTION 1. Section 4033 of the Business and Professions Code is amended to read:

4033. (a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer" means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's third party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

SEC. 2. Section 4034 of the Business and Professions Code is amended 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 one or more wholesalers, manufacturers, repackagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

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

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, 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.

(5) The unique identification number described in subdivision (i).

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number. Dangerous drugs that are repackaged shall be serialized by the repackager and a pedigree shall be provided that references the pedigree of the original package or packages provided by the manufacturer.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler or repackager, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the "smallest package or immediate container" of a dangerous drug shall include any dangerous drug package or container made available to a repackager, wholesaler, pharmacy, or other entity for repackaging or redistribution, as well as the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) 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.

(g) The following transactions are exempt from the pedigree requirement created by this section:

(1) An intracompany sale or transfer of a dangerous drug. For purposes of this section, "intracompany sale or transfer" means any transaction for any valid business purpose between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of the same corporate or legal entity.

(2) Dangerous drugs received by the state or a local government entity from a department or agency of the federal government or an agent of the federal government specifically authorized to deliver dangerous drugs to the state or local government entity.

(3) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(4) (A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.

(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the compliance date for manufacturers set forth in subdivision (k) of Section 4034 or Section 4163.5, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a radioactive drug is sufficient to require a pedigree. Two years following the date of any such determination, this paragraph shall become inoperative.

(5) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as "for veterinary use only."

(6) The sale, trade, or transfer of compressed medical gas. For purposes of this section, "compressed medical gas" means any substance in its gaseous or cryogenic liquid form that meets medical purity standards and has application in a medical or homecare environment, including, but not limited to, oxygen and nitrous oxide.

(7) The sale, trade, or transfer of solutions. For purposes of this section, "solutions" means any of the following:

(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.

(8) Dangerous drugs that are placed in a sealed package with a medical device or medical supplies at the point of first shipment into commerce by the manufacturer and the package remains sealed until the drug and device are used, provided that the package is only used for surgical purposes.

(9) A product that meets either of the following criteria:

(A) A product comprised of two or more regulated components, such as a drug/device, biologic/device, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.

(B) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products or device and biological products.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture and supplemented by a linked unique identification number in the event that drug is repackaged, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, repackagers, and pharmacies for the pedigree of a dangerous drug. No particular data carrier or other technology is mandated to accomplish the attachment of the unique identification number described in this subdivision.

(j) The application of the pedigree requirement shall be subject to review during the board's evaluation pursuant to Section 473.4.

(k) This section shall become operative on January 1, 2015.

SEC. 3. Section 4034.1 is added to the Business and Professions Code, to read:

4034.1. (a) (1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.

(2) Within 90 days of the enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs, the board shall publish a notice that Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are inoperative.

(3) Within 90 days of the enactment of federal legislation or adoption of a regulation that is inconsistent with any provision of California law governing the application of any pedigree or serialization requirement or standard, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(b) (1) If the Food and Drug Administration (FDA) enacts any rule, standard, or takes any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, that provision of California law shall be inoperative.

(2) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall publish a notice that the provision is inoperative.

(3) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(c) If the board fails to recognize the inoperation within 90 days pursuant to this section, nothing in this section shall preclude a party from filing an action in state or federal court for declaratory or injunctive relief as an alternative to filing a petition with the board.

SEC. 4. Section 4044 is added to the Business and Professions Code, to read:

4044. "Repackager" means a person or entity that is registered with the federal Food and Drug Administration as a repackager and operates an establishment that packages finished drugs from bulk or that repackages dangerous drugs into different containers, excluding shipping containers.

SEC. 5. Section 4045 is added to the Business and Professions Code, to read:

4045. "Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

SEC. 6. Section 4162 of the Business and Professions Code is amended to read:

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, 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.

SEC. 7. Section 4162.5 of the Business and Professions Code is amended 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), 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 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 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.

(4) A person to whom an approved new drug application or a biologics license 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 or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(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.

SEC. 8. Section 4163 of the Business and Professions Code is amended to read:

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

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. 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) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not acquire a dangerous drug without receiving a pedigree.

(e) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(f) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not acquire a dangerous drug without receiving a pedigree.

(g) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy warehouse may not acquire a dangerous drug without receiving a pedigree. For purposes of this section and Section 4034, a "pharmacy warehouse" means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.

SEC. 9. Section 4163.1 is added to the Business and Professions Code, to read:

4163.1. (a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:

(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

SEC. 10. Section 4163.2 is added to the Business and Professions Code, to read:

4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written

declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.

(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

SEC. 11. Section 4163.3 is added to the Business and Professions Code, to read:

4163.3. (a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.

(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

SEC. 12. Section 4163.4 is added to the Business and Professions Code, to read:

4163.4. (a) All units of dangerous drug in the possession of a wholesaler or pharmacy, for which the manufacturer does not hold legal title on the effective date of the pedigree requirement set forth in Section 4163.5, shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163. However, if any units of those drugs are subsequently returned to the manufacturer, they shall be subject to the pedigree requirements if the manufacturer distributes those units in California.

(b) All units of dangerous drug manufactured in California but distributed outside the state for dispensing outside the state shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163 at either the time of initial distribution or in the event that any of those units are subsequently returned to the manufacturer.

SEC. 13. Section 4163.5 of the Business and Professions Code is repealed.

SEC. 14. Section 4163.5 is added to the Business and Professions Code, to read:

4163.5. (a) The Legislature hereby finds and declares that:

(1) The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

(2) At the same time, it is recognized that the process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.

(b) Before January 1, 2015, each manufacturer of a dangerous drug distributed in California shall designate those dangerous drugs representing a minimum of 50 percent of its drugs, generic or single source, distributed in California, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with the January 1, 2015, deadline of the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(c) Before January 1, 2016, each manufacturer of a dangerous drug distributed in California shall designate the final 50 percent of its drugs, generic or single source, distributed in California for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, 2016. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized

electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(d) For purposes of designating drugs to be serialized as required by subdivisions (b) and (c), manufacturers shall select from any of the following measures:

(1) Unit volume.

(2) Product package (SKU) type.

(3) Drug product family.

(e) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.

SEC. 15. 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.

O

Attachment 2

PhRMA-Commissioned Cost-Benefit Report Involving Serialization & E-Pedigree Requirements

Forrester Consulting

MAKING LEADERS SUCCESSFUL EVERY DAY

Prepared For the Pharmaceutical Research and Manufacturers of America (PhRMA)

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Evaluating The Economic Impact Of Item Serialization: Concepts to Inform Advocacy

Prepared by:

Patrick Connaughton

Robert Cormier

Sharyn Leaver

Roy Wildeman

Esther Yuen

FORRESTER

FORRESTER

Headquarters

Forrester Research, Inc., 400 Technology Square, Cambridge, MA 02139 USA

Tel: +1 617.613.6000 • Fax: +1 617.613.5000 • www.forrester.com

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Executive Summary

To help enhance the security of the pharmaceutical supply chain, both state and federal lawmakers are directing manufacturers to serialize packaged items of prescription drugs through legislation. In order to respond to these activities, a complete understanding of the economic impacts of implementing serialization technologies is essential to PhRMA's advocacy efforts at the federal level and useful in exploring other approaches to supply chain security with the California Board of Pharmacy and other US states that may pursue serialization legislation.

In assessing various advocacy positions related to serialization, radio frequency identification (RFID) and two-dimensional (2-D) bar codes are the two technology categories that are the most widely available and valid alternatives to meeting these developing requirements. [1] This study made the assumption that supply chain partners (i.e., distributors and pharmacy retailers) will be capable of reading and authenticating serialized products in order to realize a complete chain of custody at the product's item level but that the analysis would assess and quantify business value for US manufacturers from serialization only for these two technologies.

To better understand the costs and benefits and how they apply to different manufacturing firms, the team synthesized findings from confidential interviews and surveys and scaled the business impacts to one packaging line of a hypothetical pharmaceutical manufacturer (e.g., "hypothetical XYZ Pharmaceutical Corporation") with typical operations. Although there are some minor differences, the total estimated capital costs of $1.3 million per packaging line are largely equivalent across technology choices, while recurring expenses can vary from $130,000 to $1.5 million, depending on the different costs of 2-D labels, ultra-high frequency (UHF) RFID, or high-frequency (HF) RFID tags. In terms of benefits from serialization, surveyed manufacturers expect to see some *qualitative* benefits in improving patient safety through reducing counterfeits, tighter control of diversion, and faster product recalls, but they only expect nominal *quantifiable* benefits across a series of opportunity areas for both 2-D bar codes and RFID tags.

In addition to these direct benefits, serialization could enable manufacturing companies to pursue and realize additional value through end-to-end supply chain opportunities. These "flexibility options" depend on complementary investments by wholesalers and retailers, but ultimately would result in processes becoming *cheaper, better, or faster* through extended leverage of a manufacturer's current investments in serialization. For example, establishing item-level supply chain events today affords manufacturers the future opportunity to correlate basic event data with the business data found in related supply chain applications and in turn drive better supply decisions. Given the strong dependence on wholesalers to capture and share high volumes of item-level transactions and their apparent preference to avoid line-of-sight technologies, RFID technology may offer greater options for improved supply chain efficiency and further improvements in financial integrity across trading partners.

In conclusion, an overview of the estimated costs, benefits, flexibility options, and risks of implementing 2-D bar codes and RFID for a typical packaging line is presented. This economic view will vary tremendously by individual operation, and we stress that assessing the impacts on any given manufacturer would require tailoring this general framework more specifically to each manufacturer's unique operational characteristics.

Background

Why Pharmaceutical Manufacturers Care About Serialization

The US Legislative And Regulatory Environment Triggers Firms To Evaluate Serialization Investments

To help enhance the security of the supply chain for prescription drugs, California has enacted legislation that requires manufacturers to serialize all packaged items of prescription drugs sold within the state by January 1, 2009. Furthermore, Congress has provided direction to the Food and Drug Administration (FDA) to "develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain" through "a standardized numerical identifier . . . to be applied to a prescription drug at the point of manufacturing and repackaging . . . at the package or pallet level."[2]

To develop policy responses to these legislative actions, manufacturers must consider the business impacts of the statutes. At the federal level, these costs and benefits are formally reviewed by the Office of Management and Budget (OMB), and any implementing regulation whose industry-wide costs exceed $100 million requires a more formal economic impact assessment. At the state level, California has the discretion to delay implementation of its pedigree and serialization requirements if the pharmaceutical supply chain requires additional time to implement electronic technologies, and patient safety would be better served by a delay. Thus, a complete understanding of the costs and benefits for implementing serialization technologies will be essential to PhRMA's advocacy efforts at the federal level and useful in exploring other approaches to supply chain security with the California Board of Pharmacy and other US states that may be considering legislative or regulatory action regarding serialization.

Overview Of Serialization Technology

In the context of this regulatory environment, serialization refers to the requirement for each packaged unit of prescription drugs to have a unique identification number established at the point of manufacture. Importantly, the packaging hierarchy — which items were packed in each case — and master data context (i.e., batch, lot, expiration, and NDC data) must also be established to satisfy pedigree requirements. As packaged items are distributed throughout the pharmaceutical supply chain, information on each item's transaction resulting in a change of drug ownership — shipping, receiving, and repackaging — is captured electronically through an interoperable, standards-based system by downstream trading partners.[3] In assessing the business costs and benefits of implementing serialization, the two technology categories that are the most widely available and valid alternatives to meeting these requirements must be compared: RFID and 2-D bar codes.[4]

RFID

RFID is a data collection technology that uses electronic tags to store identification data and a wireless transmitter or reader to capture it. Radio frequency technology is not new; it has been a viable track-and-trace technology in industries such as aerospace and defense for many years. Recent advances in hardware, software, and data standards — like the electronic product code (EPC) standard that helps to track and trace product items as they pass between partners in the supply chain — have raised RFID's potential as a viable track-and-trace technology for pharmaceutical firms. HF and UHF technologies are both viewed as viable options for RFID serialization but vary in cost, performance, and data storage size (see Table 1).

2-D Bar Codes

2-D bar codes contain more information than conventional one-dimensional bar codes and would support unique identification of saleable items across the US volume of prescription drug sales. Conventional one-dimensional bar codes found on consumer goods and shipping labels get wider as more data is encoded, whereas 2-D bar codes resemble a small checkerboard and make use of the vertical dimension to compress more data into a smaller space. 2-D bar codes are possible as charge-couple device (CCD) scanners and imaging scanners have replaced the original pen or wand of scanner.

Table 1: Cost And Performance Differences Between RFID Technologies

	UHF	HF
Ideal read ranges	10-15 feet	Three feet or less
Performance on liquids	Low read rates (traditional tags)	Little effect
Typical memory storage	96 bits	256 bits to 8 kilobytes
Practical read rates	~400 tags per second	~30 tags per second
Estimated tag costs (for the first million tags)	$0.19 per tag	$0.37 per tag

Source: Matt Ream, Zebra Technologies, "UHF or HF RFID?," RFID World 2007 speech, March 27, 2007

Methodology

Analysis Scope And Assumptions

The scope of this analysis was to assess both serialization alternatives (i.e., RFID and 2-D bar codes) as they relate to domestic pharmaceutical manufacturing operations over a period of five years. Given the current focus of both federal and state lawmakers, the analysis focused solely on prescription medicines manufactured by US companies. The study was based on the assumption that supply chain partners (i.e., distributors and pharmacy retailers) will be capable of reading and authenticating serialized products in order to realize a complete chain of custody at the product's item level, but that the analysis would only assess and quantify business value from serialization for US manufacturers. Other assumptions in place during the team's evaluation of serialization costs and benefits include:

- Tagging/labeling is performed at the unit-of-sale level (in addition to pallet and case).
- Tags/labels are applied at the point of manufacturer packaging.
- Wholesalers will make basic receipt and shipment information available to manufacturers through the use of standard services.
- Planning and implementing serialization technology takes place within one year, and benefits are realized starting in Year 2.[5]
- Manufacturers will implement the necessary process redundancy to ensure that read accuracy for RFID and 2-D bar codes both approach 100%.

- Drug stability and effectiveness are assumed to be unaffected by either RFID or 2-D bar codes, and the FDA allows the use of RFID tags for all Rx products.[6]

- The reading of RFID tags was assumed to be compatible with permeable containers (e.g., liquids or sensitive products in plastic bottles), have no negative effects on cold chain products through additional handling, and have no effect on sensitive line equipment such as checkweighers.

Sources Of Data

PhRMA Member Interviews

In order to collect in-depth information about current operations, anticipated costs, and perceived benefits from serialization, the Forrester team conducted separate interviews with 10 PhRMA members who have significant US manufacturing operations. Some of these stakeholders offered additional detailed cost information based on their initial pilots and experience with serialization technology.

Direct information from these interviews and the survey described below is confidential and has not been shared with PhRMA or member companies. Only aggregated information from multiple companies has been included in this report.

Vendor And System Integrator Interviews

To complement the stakeholder interviews and validate detailed cost information, the team also conducted interviews with four providers of serialization technology, as well as three systems integrators offering serialization implementation and tax consultation services.

Survey Data

To further assess prevailing perceptions of the business benefits of serialization, a written survey was issued to 10 key contacts at PhRMA member companies. The team received nine responses, and one company declined to respond.

Scaling The Impacts

Characteristics Of The Hypothetical XYZ Pharmaceutical Corporation

To better understand the costs and benefits and how they apply to different manufacturing firms, the team synthesized findings from all interviews and surveys and scaled the business impacts to a hypothetical pharmaceutical manufacturer (e.g., "the hypothetical XYZ Pharmaceutical Corporation") with the following assumed characteristics:

- Annual sales of $10 billion, of which $8.5 billion is due to US prescription drug sales.[7]

- Annual production volume of 200 million packages across 50 packaging lines (e.g., average capacity per line is 4 million packages per year, or around 10,000 packages per minute) that support 80% of US demand for prescription drugs.[8]

- Prescription finished goods inventory levels of $620 million (at the manufacturer only).[9]

- Product recalls that occur an average of 2.5 times per year with an average cost of $2.8 million per recall.[10]
- Product returns make up 1.3% of prescription drug sales.[11]

Cost Analysis

Capital Costs Are $1.3 Million Per Packaging Line, Regardless Of Technology

The Forrester team aggregated the cost estimates derived from its interviews of manufacturers, vendors and system integrators and surveys of manufacturers to generate average estimated costs to the hypothetical XYZ Pharmaceutical Corporation. In total, the average packaging line upgrade would require approximately $1.3 million in capital expenses. Although there are some minor capital differences between technology options (e.g., an additional "tunnel reader" is required for HF RFID, and a quality assurance reader may not be required for 2-D bar codes), the total capital costs are largely equivalent across technology choices, and the most significant capital costs are implementation labor, software licenses, and equipment modification. Notably, lost revenue from line installation and testing time were assumed to be zero since most pharmaceutical firms we spoke with indicated that line utilization across all packaging lines does not approach 100%. Costs by category, in order of significance are:

$1,080,000 For Implementation Labor

We've assessed implementation labor to be $1.08 million per packaging line, assuming 270 implementation days and including design, application development and hardware configuration, testing, validation, and deployment, with five FTEs being billed at $100 per hour, working 8 hour days. Importantly, this addresses only the basic systems integration necessary to extract required fields like the batch, dose, and NDC from the host systems (e.g., ERP, MES) that establish an item's master data context. *Our research also concludes that each systems implementation is likely to be completely different for each individual packaging line and that efficiencies from reusing design, configuration, and development code across packaging lines will be minimal.* In short, we've assumed the most basic level of application integration to tag items and send this information to trading partners.

$120,000 For Software Licensing And Hardware (For All Packaging Lines)

Software license costs are estimated to be $80,000. This includes the license cost of the network/device management software required to orchestrate data capture across devices and the EPCIS required to share item-level data with trading partners, but it does not include the license cost of any additional software required to satisfy ePedigree mandates. In most cases, an additional application server is also required to run the new software with an estimated cost to manufacturers of $40,000. We've assessed these license and server costs to be the total costs for all packaging lines, assuming that one central server processor is sufficient to handle the volumes of serialization data being generated across a manufacturer's packaging lines.

$62,000 For Equipment Modifications

Since most manufacturers can leverage existing labelers, $45,000 will be required to modify the line code on each existing labeling machine to accommodate either RFID or 2-D bar codes. The general infrastructure costs (i.e., running new power lines, network connections) were assessed to be $2,000, and an additional $15,000 was estimated for any conveyor extensions that are required.

$9,000 To $12,000 For Labelers And Readers

Manufacturers indicated that three fixed readers costing, on average, $3,000 apiece, are required per line to commission the item tags, validate the item tags, and commission the case or pack. In the case of RFID, a fourth handheld reader is often required to ensure 100% accuracy by serving the role of a dedicated QA station. Since most manufacturers we interviewed indicated that an existing labeler can be used, we estimated the costs to purchase new labelers to be zero.

$15,000 For Additional Tunnel Reader (HF Tags Only)

Due to the realities of implementing HF, an additional tunnel reader is often required. This results in an additional estimated $15,000 in capital expenses per packaging line.

Recurring Expenses Vary From $130,000 To $1.5 Million, Depending On Technology Choice

The average packaging line upgrade would also require between $130,000 and $1.5 million in annual expenses, depending on the choice of 2-D bar codes, UHF RFID tags, or HF RFID tags. Costs by category, in order of significance are:

$20,000 For Labels, $700,000 For UHF Tags, Or $1.3 Million For HF Tags

For purchasing volumes between 1 million and 500 million, HF tag costs were estimated to be $0.33 per tag, UHF tag costs at $0.17 per tag, and label costs at $0.005 per label. Our analysis also assumes 0.5%, 3%, and 1% defect rates for each of these technology options, respectively, which equates to $1.3 million (HF), $700,000 (UHF), and $20,000 (label) in total tag/label expenses, assuming an average packaging line throughput of 4 million items per year. Notably, economies of scale discounts would only apply after purchasing volumes of 500 million. Also, while HF tag costs are estimated to decrease by 5% year over year, UHF costs are projected to remain constant given our understanding of the level of current prices relative to tag manufacturers' cost structures.

$100,000 For Ongoing Labor

Additional ongoing labor to support the software system was assessed at $100,000 starting in the second year (i.e., immediately after the 12-month implementation).

$12,000 For Software Maintenance

A 15% maintenance fee is assumed year over year on the initial $80,000 licensing costs.

Costs May Be Higher For Specific Implementations

Naturally, individual manufacturing firms will have varying as-is conditions, timelines, and deployment hurdles that may increase the costs required to implement serialization. For example, implementation time and labor are likely to vary widely by a firm's current systems landscape and integration requirements. Furthermore, any packaging lines that require completely new high-speed labeling equipment (rather than modifying existing equipment) may almost double capital costs and require 12 months of lead time. Notably, accelerating implementation timelines can spell both premium labor billing rates as budgeted project hours expand into overtime hours and inventory write-offs from unplanned obsolescence of cartons, bottles, or labels. Sometimes getting to "go-live" is only half the battle. Early pilots of serializing items with RFID have encountered both reduced packaging line throughputs and slower distribution cycle times as a result of recurring system issues and line stoppages — impacts that could also constrict the supply of scarce medicine in the case of biologics and vaccines.

Benefits Analysis

Overview Of Potential Serialization Benefits

Like the costs, estimated benefits were derived by aggregating the results of the manufacturer, vendor, and system integrator interviews and manufacturer surveys to develop an average value for the hypothetical XYZ Pharmaceutical Corporation. At the highest level, the benefits of deploying serialization technology can be categorized in terms of improving the integrity of product across the supply chain, improving the integrity of financial transactions across the supply chain, and improving a company's internal operational efficiency. While many of these benefits may extend throughout the supply chain, only those benefits that align to the manufacturer have been assessed in keeping with the research scope of this study. Importantly, a majority of these benefits can be realized with either of the serialization technology options (see Table 2).

Table 2: Overview Of Serialization Benefits By Technology Option Per Packaging Line

Benefit category	Benefit area	Benefits with RFID		Benefits with 2-D bar codes	
		Qualitative	Quantitative	Qualitative	Quantitative
Improved product integrity	Increased ability to identify counterfeit product	Improved patient safety	-	Improved patient safety	-
	Increased ability to identify diverted product	Improved patient safety	$32K	Improved patient safety	$32K
	Faster and more accurate product recalls	Improved patient safety	$2K	Improved patient safety	$2K
Improved financial integrity	Gains from improved chargeback administration	-	$28K	-	$28K
	Improved visibility to invalid returns and corresponding payouts	-	$11K	-	$11K
	Automated identification of item-level shipped versus received discrepancies*	-	-	-	-
Improved operational efficiency	Automated process for handling returns (incl. expiry mgmt.)	-	$100K	-	$100K
	Research and development tax credits[12]	-	$77K	-	$77K
	Faster identification of inventory shrinkage problems	-	$5K	-	-
	Reduction in shipping and receiving cycle time*	-	-	-	-

Source: Forrester Research, Inc.

*These benefit areas were not studied in detail since preliminary findings indicated that item-level serialization would not significantly improve these processes for the typical manufacturer.

Manufacturers Recognize Significant Benefits In Improving Patient Safety

Increased Ability To Identify Counterfeit Products

The need to protect patients is the key driver for serialization within the supply chain. Manufacturers we spoke with strongly agreed that protecting consumer safety must be a top consideration when investing in serialization technology, and most manufacturers agreed that product serialization would be a part of a multifaceted solution to lower counterfeit drugs within legal distribution channels.[13] However, attempting to quantify the business benefits from reducing counterfeits has several important pitfalls, including:

1. Drawing direct causality from serialization to reducing counterfeits is very difficult, as serialization is really one component of a larger mix of measures that companies will adopt to tackle counterfeits. As an example, manufacturers recognize the reality that serialization only ensures that the package — and not the actual product within the package, which can be substituted — is tracked.

2. The amount of revenues that an individual company could reclaim as a result of reduced counterfeits is highly variable by manufacturer and region (with international counterfeits perceived as a larger problem relative to the US market). Furthermore, no reliable data exists to quantify the size of the global counterfeiting problem with a sound degree of accuracy.

3. In terms of a potential to reduce the costs of investigations into counterfeit drugs, manufacturers agreed that current company procedures and resources would not likely change as a result of serialization, and hence these costs would be constant.

Given these practical limitations in claiming quantifiable benefits from reducing counterfeits, we have chosen to list this as a purely qualitative benefit. And since RFID technology is harder to duplicate, more expensive to copy, and provides more data storage for authentication identifiers, we've rated this technology option as carrying somewhat more value in terms of reducing counterfeits and improving patient safety.

Increased Ability To Identify Diverted Product

When legitimate products are not purchased through legitimate channels, those drugs are classified as "diverted." Serialization would enable trading partners and investigators to better confirm, based on packaging, that a drug was indeed an original product but illegally sold.[14] Since the risk of the mishandling or unsafe storage of drugs increases with incidents of product diversion, this increased ability to identify diverted product would benefit patient safety by better ensuring correct storage and handling of the drug throughout the supply chain. Notably, there is a strong dependency on item-level and electronic pedigree transactions to be captured by trading partners. Wholesalers' distribution volumes and strong preference for reading items without a line-of-sight requirement this tends to favor RFID as a technology choice toward this benefit.

Faster And More Accurate Product Recalls

Though the occurrence and size of product recalls is highly variable by manufacturer, product, year and level of distribution beyond the production stage, in general the firms we spoke with agreed that serialization could allow faster and more accurate recalls by identifying where items from a specific manufacturing lot are in the supply chain — thereby improving patient safety. However, similar to the other product integrity areas, there is a strong dependency on trading partners to record and share item-level and electronic pedigree transactions such that manufacturers would be able to contact specific, individual distribution centers, pharmacies, and even doctors in the event of a recall. Given wholesaler's preference for non-line-of-sight reads, this also tends to favor RFID as a technology choice toward this benefit.

Manufacturers See Nominal Quantifiable Benefits

Forrester assessed the serialization benefits to pharmaceutical manufacturers based on a manufacturer's entire sales of prescription drugs and then scaled those benefits by an individual packaging line upgrade for the hypothetical XYZ Pharmaceutical Corporation. Nearly all benefits can be realized with both 2-D bar codes and RFID tags with the exception of reducing inventory shrinkage given the non-line-of-sight requirements. Total benefit assessments by category and in order of significance are:

$100,000 From Automated Process For Handling Returns And Expiry Management

Item-level serialization has the potential to enable automated processing and reconciliation of drug returns. Manufacturers responded that an average of $260,000 in labor savings could be realized through automation if all prescription drugs were serialized, and that 3.3% of current payouts could be reduced through identification and reconciliation of product expiry on current return levels of 1.3% of annual sales. Scaling these benefits for one packaging line equates to approximately $7,000 in labor savings and $93,000 in reduced payouts on expired or nearly-expired drug returns.

$77,000 From R&D Tax Credits[15]

US federal corporate tax law has allowed corporations to claim up to 6.5 cents of every dollar spent on activities that qualify as research and development activities under federal tax law as a credit against U.S. federal income taxes. Similarly, many also states have laws generally allowing between 1% and 7.5% of a manufacturer's R&D expenditures to be claimed as a tax credit.[16] So which serialization expenditures may qualify? One guiding principle is that companies should design, develop and/or utilize the technology in a fundamentally new way that involves an experimental process. So while buying a packaged application or hardware doesn't qualify, systems integration expenses may qualify — provided the developed software is innovative, not commercially available, and that the development effort involved a significant economic risk due to technical uncertainty.[17] Assuming a conservative state deduction rate of 1% and a corporate tax rate of 28%, manufacturers can expect to claim an estimated $77,000 in federal and state tax credits per packaging line.

$32,000 From Increased Ability To Identify Diverted Product

While most manufacturers we interviewed perceived that serialization would reduce the incidents of contract diversion (e.g., when product originally sold at contract prices to select organizations for their "own use" is ultimately sold to others at a higher rate), the first-year and ongoing reduction estimates were quantified as 0.0050% and 0.0150% of prescription drug sales, respectively. This equates to $11,000 and $32,000 in recaptured revenues in the first year and ongoing years for the hypothetical XYZ Pharmaceutical Corporation.

$28,000 From Improved Chargeback Administration

Most manufacturers also perceived that serialization would improve the accuracy and accountability of reverse chargebacks as wholesalers engage in ongoing sales and returns with contracted-price buyers. First-year and ongoing reduction estimates were quantified as 0.0088% and 0.013% of prescription drug sales, respectively, which equates to an estimated first-year savings of $18,000 and estimated ongoing savings of $28,000 per packaging line.

$11,000 From Improved Visibility To Invalid Returns And Corresponding Payouts

Manufacturers may also see benefits from identifying and reducing return payouts for counterfeit drugs being returned. Assuming as much as 0.5% of returns are counterfeit, and that 80% of incidents could be detected given the risks of repackaging, product replacement, and loss of secondary/original packaging, this represents an $11,000 opportunity on an average return rate of 1.3% per packaging line.[18]

$5,000 From Faster Identification Of Inventory Shrinkage Problems (RFID Only)

Manufacturers responded that 0.03% of current inventory levels could be reclaimed annually through item-level cycle counting and faster identification of inventory shrinkage. Given an average manufacturer's inventory level of $620 million, this equates to $5,000 per packaging line.

$2,000 From Faster And More Accurate Product Recalls

Our analysis of FDA enforcement reports from 2005, 2006, and 2007 shows the average amount of products recalled to be approximately $2,800,000, and the average manufacturer experienced 2.5 recalls per year. Manufacturers estimated that of these recall volumes, 1.25% could be reduced through product serialization.

Economic Impact Of Serialization

Future Flexibility Options With RFID

In assessing advocacy options, it will be important to recognize that in addition to these direct benefits, product serialization could enable manufacturing companies to pursue and realize additional value through end-to-end supply chain opportunities. These opportunities depend considerably on complementary investments by wholesalers and retailers but ultimately would be *cheaper, better, or faster* because of manufacturers' investments in serialization. For example, the establishment of item-level supply chain events (e.g., shipment and receipt transactions across trading partners) affords manufacturers the future opportunity to correlate basic event data with the business data found in related supply chain applications and, in turn, drive better supply decisions. These additional benefits only result from RFID technology, given the strong dependence on wholesalers to capture and share high volumes of item-level transactions and an assumption that inference would not be supported in the long-term by lawmakers — both of which preclude 2-D bar codes given the line-of-sight requirements.

Improved Supply Chain Efficiencies

End-to-end supply chain visibility of serialized inventory would enable manufacturers to better forecast and/or release appropriate inventory into the supply chain. While current stock-outs are relatively rare and therefore seen as a low-priority problem (i.e., bottle counts might not be exact but are "close enough" to satisfy orders) smoothing order demand and/or reducing over-ordering by wholesalers translates to manufacturing efficiencies and reduced product returns. To achieve this

capability, manufacturers would need to partner with wholesalers and pharmacies to engage in a mutual exchange of electronically-captured event data.

Further Improvements In Product And Financial Security

Lastly, the nominal benefits in both reduced product diversion and improved chargeback reconciliation are likely to be extended as more electronic sharing of transaction events and business context are shared across supply chain partners. Some manufacturers estimate that complete product and financial reconciliation could result in single-digit millions of reclaimed revenues. Similar to all the flexibility options, however, this opportunity requires significant partnership and collaboration across supply chain partners.

Assessment Of Risks

Additionally, the following risks of implementing serialization technology were identified:

Changes In Laws And Regulatory Requirements

The potential exists that Congress, the FDA, and other US states may continue to develop laws and/or regulations relating to pedigree and serialization issues, which could create uncertainty for manufacturers. For example, the current requirements for the state of California hold several unanswered questions for pharmaceutical manufacturers, including the degree to which inference will be allowed throughout the supply chain, as well as the priority and methods of enforcement — two critical considerations for manufacturers as they prioritize their serialization road maps.

Varying Trading Partner Technology Requirements

One leading healthcare distributor has formally and publicly stated a preference for manufacturers to apply RFID UHF Gen2 RFID tags with a 2-D bar code backup on all saleable items. Similarly, other major distributors have said publicly that they are considering their own formal guidance, and it is expected that retailers will start to announce their own guidelines starting in 2008. With the diversity of potentially different guidelines en route, manufacturers risk investing in a technology that is incongruent with the direction of some of their trading partners.

Changes In Pedigree Data Management Approach

Today, many healthcare firms are using a direct-connect, document-based model to comply with pedigree laws as quickly as possible. However, in the future, firms across the supply chain might look to extend to more on-demand, event-based data sharing with the ultimate goal of building more intelligent and proactive supply chain management capabilities within their organizations. If this approach to pedigree data management evolves quickly, so too will the opportunities to move today's *flexibility options* to tomorrow's *quantifiable benefits* and take advantage of the item-level granularity enabled by serialization.

Changes In RFID Technology Performance

UHF Gen 2 standards and corresponding performance have helped promote this technology as the norm for pallet and case tagging. The decision is less clear for item serialization, as the EPCglobal Healthcare and Life Sciences Industry Action Group (HLSIAG) has suggested both the existing UHF Gen 2 standard and an emerging HF standard as viable frequencies (though the HF standard is still under development and will not be commercially available until mid-2008). As these two RFID adoptions evolve, manufacturers must continually evaluate read rates and the effects of frequencies on drug properties as significant risks in their technology decision.

Summary

Understanding the full economic impact of serialization using 2-D bar codes and RFID requires evaluating the costs, benefits, flexibility options, and risks of each technology option. Throughout the course of our research, we were impressed by how tremendously these impact areas vary depending on each manufacturer's unique operating characteristics. In summary, we present an overview of our total economic analysis using estimates of cost/benefits for our hypothetical XYZ Pharmaceutical Company manufacturer, but we stress that these economic categories must be evaluated separately for each manufacturer in light of its specific and unique operations (see Table 3).

Table 3: Hypothetical XYZ Pharmaceutical Corp. Economic Impact Of Item Serialization For 2-D Bar Codes And RFID

	2-D bar codes	RFID
Capital costs (per packaging line)	~$1.3M	~$1.3M
Annual expense costs (per packaging line)	$130K	$810K for UHF Tags $1.5M for HF Tags
Qualitative benefits	Improved patient safety (medium-high)	Improved patient safety (high)
Quantitative benefits (per packaging line)	$220K in the first year $170K in subsequent years	$220K in the first year $180K in subsequent years
Flexibility options	-	▪ Improved supply chain efficiencies ▪ Further improvements in product and financial security
Risks	▪ Changes in laws and/or regulatory requirements ▪ Varying trading partner requirements ▪ Changes in pedigree data management approach	▪ Changes in laws and/or regulatory requirements ▪ Varying trading partner requirements ▪ Changes in pedigree data management approach ▪ Changes in RFID technology performance

Source: Forrester Research, Inc.

Appendix A: Endnotes

[1] This study and its conclusions focus on the state of serialization approaches and technology during the second half of 2007.

[2] Section 913 of the Food and Drug Administration Amendments Act of 2007 (http://www.fda.gov/oc/initiatives/HR3580.pdf).

[3] At the time of this report, it was unclear what level of inference for compliance would be allowed by wholesalers. The strictest scenario would require wholesalers to physically read the unique identifiers of each saleable item (making 2-D bar codes very expensive, given the line-of-sight read requirement), whereas inference would allow wholesalers to read the identifier of an intact case and infer that all the individual serialized items from the manufacturer are still contained within (enabling 2-D bar codes to be a less burdensome alternative).

[4] See footnote 1.

[5] Implementation time includes design, application development and hardware configuration, testing, and deployment. For a typical packaging line, we estimated that five FTEs would require 270 days to perform these tasks, assuming the minimum amount of integration required to pull a master data file from a manufacturing application and encode identification field(s) onto a tag or 2-D bar code. Other integrations between EPCIS repository, middleware, and reader devices are assumed to come standard with the software license. Naturally, individual manufacturers will have varying installation and validation time for the first line as well as subsequent lines that leverage common infrastructure.

[6] This assumption may not equally apply to biotech firms where RFID can potentially affect biologics. The FDA is anticipated to provide guidance on necessary testing protocols and ensure that the protocols can be used.

[7] Figures are based on the average 2005 revenues of the top 20 US pharmaceutical manufacturers by sales. Source: Healthcare Distribution Management Association, "2006-2007 HDMA Factbook: Industry Overview," HDMA Research & Education Foundation, 2006.

The percentage of revenues from prescription drugs is an average based on 19 responses to HDMA Foundational Survey Research Program, 2005, and includes Rx-brand name, Rx-specialty, and Rx-generic.

[8] The average and total packaging line capacities are provided as a representative scenario characteristic of a $10 billion pharmaceutical manufacturer that operates 24-hour days, 250 days of the year. Individual and total line capacities are likely to vary considerably around this scenario estimate based on specific product types (i.e., solid dose, injectables, topicals, biologics, etc.) as well as specific packaging configurations.

[9] Rx inventory levels are based on nine responses to Forrester's PhRMA Benefits Survey.

[10] The analysis of average product recall figures are based on data from the FDA Enforcement Report, which estimates recall costs from 2005, 2006, and 2007 (http://www.fda.gov/opacom/Enforce.html).

[11] The product return average is based on nine responses to Forrester's PhRMA Benefit Survey.

[12] The federal R&D tax credit expired at the end of 2007 and, at the time of this report, has not been renewed.

[13] Notably, manufacturers vary in their self-assessment of the prevalence of the counterfeiting problem. Some manufacturers detected zero counterfeits in the US supply chain during the past several years

[14] The Prescription Drug Marketing Act (PDMA) includes regulations that make drug diversion illegal.

[15] The federal R&D tax credit expired at the end of 2007 and, at the time of this report, has not been renewed.

[16] Source: Interview with Deloitte Touche Tohmatsu conducted November 19, 2007.

[17] Source: Interview with KPMG LLC conducted December 6, 2007.

[18] Source: Healthcare Distribution Management Association, "Adopting EPC in Healthcare: Costs and Benefits," HDMA publications, 2004.

Attachment 3

Pharmacetical Commerce Survey on Readiness to Comply with California's Pedigree Requirements

PHARMACEUTICAL COMMERCE SERIALIZATION SURVEY

Industry speaks: Interest in developing serialization solutions remains high among manufacturers, but low among trading partners *-By Nicholas Basta*

KEY FINDINGS

- Two out of three manufacturers (67%) have serialization projects underway or in planning
- The No. 1 benefit of a serialization project: "to enhance our reputation with customers and the public"
- Eight out of ten manufacturers see business value in serialization; one out of ten do not, and one out of ten have no opinion
- "Uncertainty of legislative deadlines and timing" is the No. 1 organizational challenge to serialization
- Retailers and healthcare providers plan no additional staffing for handling serialized products

OVER THE PAST YEAR OR SO, the ongoing wrangling over pedigree rules, anti-counterfeiting initiatives and industry standards has settled on one technology: serialization. By having a unique serial number on each package of products leaving manufacturer warehouses, brand owners and their trading partners have the potential to address all these issues, as well as business processes like reimbursements (especially in single-payer countries in Europe), chargebacks and rebates and supply chain visibility.

With this in mind, with funding support from data-management firm, Blue Vector, Inc., *Pharmaceutical Commerce* launched a survey in the middle of last month. We now have sufficient responses (just under 200) to paint what we feel is a realistic picture of the serialization mindset.

DEMOGRAPHICS

Fig. 1 shows the breakout by industry, and Fig. 2 by job function. We also asked for size of company, and the results showed that 27% of respondents worked at companies larger than $5 billion in annual sales, and 42% at ones smaller than $250 million in sales, which we interpret to signify that we're getting good representation of both Big Pharma and Little Pharma.

Fig. 1 Respondent industry

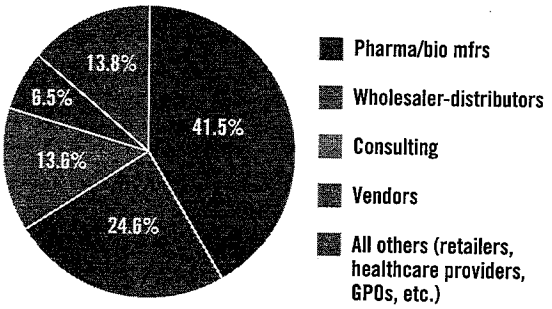


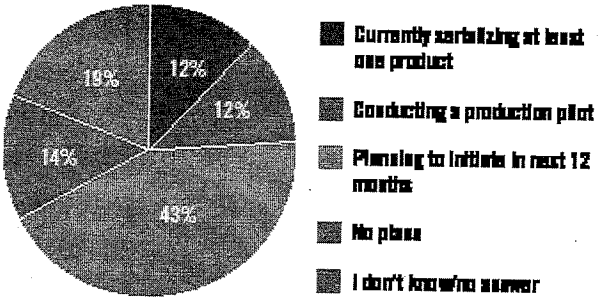
Fig. 2 Job Function

Commercial operations & mfg	42%
DC operations & supply chain	20
IT operations & planning	17
QA and regulatory affairs	11
Other*	10

*Other includes executive management, government, consulting

In a separate breakout, we asked manufacturers only to characterize their level of activity in serialization. Two out of three (67%) said that they had some level of activity going on. How much? See Fig. 3.

Fig. 3 Manufacturer implementation status



We also asked "all other"—wholesale/distributors, retailers, healthcare providers—about implementation plans: 53% indicated that they had a plan or project in place.

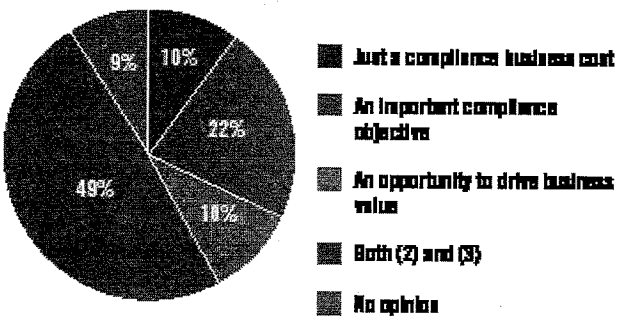
PERCEPTIONS OF BENEFITS/PROBLEMS

Whether or not an actual project is in place, it's valuable to get a sense of how the pharma supply chain looks on serialization. We asked respondents about their perceptions of the technology; 10% believe it to

continued on page 12 >

Support for this survey from blue vector *is gratefully acknowledged*

Fig. 4 Perception of serialization as



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be a business cost to be complied with quickly; 81% see varying degrees of value (Fig. 4).

We asked respondents to check any and all business benefits they thought arose from a serialization system. The No. 1 benefit—chosen by roughly one out of six (17.6%)—is "enhance our reputation with customers and the public." The next highest is "detect and eliminate counterfeits" (15%). There was roughly equal value to detecting gray market activity, higher order fulfillment accuracy, inventory visibility, and improved recall/returns processes (11-12% each). About 4% saw no value whatsoever.

Another perceptional issue is the effect of the California pedigree program delay (the survey was performed just before the California legislature voted to postpone from 2011 to 2015). One out of three respondents says the California schedule has no impact; 23% said they will be delaying, but 4% said they are proceeding with an expanded effort regardless.

We asked whether a serialization project would require "significant" process changes, and 46% said yes, while 11% said no (the rest had no opinion or didn't answer).

Finally, we asked what the organizational challenges are in rolling out serialization. While the No. 1 reason is "uncertainty of legislative mandates and timing," there was no one dominant challenge.

TRADING PARTNER PERSPECTIVES

We were able to slice the data into three categories by type of respondent: manufacturer; wholesaler-distributor and retailer/healthcare provider (including GPOs). We wanted to elicit a sense of how these entities are approaching serialization, given the different tasks each would have (Fig. 5). We think there is a significant message in these data: while roughly 20% of wholesaler-distributors indicated that they would need to add staff, and 10% of manufacturers said the same, retailers/healthcare providers indicated NO additions to staff. If serialization is coming to retail and hospital pharmacies, it is expected to be an all-automatic process. PC

Fig. 5

Most significant process changes	Manufacturer	Wholesaler-Distributor/3PL	Retailer/ Healthcare Provider
Changing mfg line	1		
Changing facility layout	6		
New automation in mfg	3		
New automation in DC/stockroom	2	1	1
Changing DC/stockroom layout	4	2	2
Hire more workers	5	3	3*

*no hiring indicated

Highest Capital Expenditures	Manufacturer	Wholesaler-Distributor/3PL	Retailer/ Healthcare Provider
Drug pedigree system	1	1	1
Device management system	2	2	2
Event management system	4	3	3
Consulting	3	4	4

Attachment 4

Information on Funding Efforts to Enable CURES to Support Near Real Time Data for Practitioners

California Department of Justice
P.O. Box 160447, Sacramento, CA 95816
Telephone: (916) 319-9062
Fax: (916) 319-9448

Patient Activity Report (PAR)

Please complete the following information by typing or printing in the required fields.

PHARMACY INFORMATION			
Pharmacy DEA No.:		Pharmacy License No.:	
Pharmacy Name (As it Appears on CA Pharmacy License)			
Pharmacy Address			
	City:	State:	Zip Code:
Telephone No.:		Fax No.:	

PATIENT INFORMATION			
Last Name		First Name	
AKA (Also Known As)		Maiden Name	
Patient Address			
	City:	State:	Zip Code:
Telephone No.:			
Social Security No.:		Date of Birth	

ADDITIONAL COMMENTS OR INFORMATION

AUTHORIZATION

By signing below, I certify that I am a licensed pharmacist and hereby request the history of controlled substances dispensed to the patient in my care identified above, based on data contained in the Controlled Substance Utilization Review and Evaluation System (CURES). I understand that any request for, or release of a controlled substance history shall be made in accordance with Department of Justice guidelines, that the history shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act (Civil Code §§ 56 et seq.)

Please FAX your request to (916) 319-9448

Or mail to: California Department of Justice, P.O. Box 160447, Sacramento, CA 95816

Pharmacist Signature _____ Date _____

Print Pharmacist Name _____
(as it appears on your CA Pharmacist License)

Pharmacist License No. _____ Pharmacist DEA No. _____

For Department of Justice Use Only	Date Received	Date Completed	Initials
	Comments		

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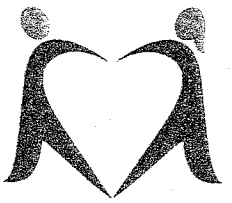

troy and

alana pack

foundation

For our kids' sake

Re: California real-time CURES controlled substance initiative

Dear Gary

On June 4, 2008, California Attorney General- Jerry Brown announced a partnership between the Department of Justice and the Pack Family Foundation. Together we plan to **build a "real-time" accessible web- based technology platform** for controlled substances in California. This platform will allow all doctors and pharmacists in California instant access to patient's controlled substance prescription history maintained in the CURES database. We believe this system will help curb narcotic abuse through the fraudulent means of "doctor shopping."

We are seeking support for this project from the California medical and pharmacy industries through the form of grants and donations. The project will cost $1.5 million to build and operate for the first year. An additional $500K per year is needed or $1.5 million to cover years two, three and four for the project. We are actively seeking to raise the total of $3M for this project. The funding could come in two levels, first the $1.5M for the build out, then an additional $1.5M for the subsequent years.

On October 26, 2003 Troy Pack -10 and sister Alana- 7 were run down and killed while out for a stroll with their mother Carmen Pack to get an ice cream in the town of Danville CA. The driver turned out to be a woman- a professional nanny, who was the ultimate "doctor shopper." She had obtained six prescriptions for Vicodin from six different doctors in just weeks before the accident and numerous prescriptions prior to that. None of the doctors could verify her injuries and none spoke to each other or checked her medical files before prescribing. The day of the crash, she mixed Vicodin, Flexeril and Vodka- and had four prior DUIs on her record. In 2005 she was sentenced, thirty years to life in prison. You can read more about it on the Pack Family Foundation website at www.troyandalana.org

Over four years ago we started working on the plans for the initiative to enhance the CURES system. In 2004 we formed a committee, including members from Senator Torlakson's office, Kaiser Permanente, the DOJ, Board of Pharmacy, Dept. of Consumer Affairs and others to explore the possibilities of what would be needed to develop a real-time PDMP. It was determined that private funding would be the only way to pay for the system, since California has had fiscal problems for several years and the federal government doesn't provide enough funding for new prescription drug control technologies.

In 2005 Senator Tom Torlakson authored SB 734, which provided the authority to build the technology with private funding. The bill passed and became law in January 2006. As part of the bill, the Senate asked for a report on security and privacy in context to the technology system design. A $40K feasibility report, co-funded by Kaiser - Permanente and the Pack Family Foundation was completed and delivered to and approved by the California Senate in July 2007.

In Dec 2007, a volunteer group of Internet technology engineers organized by the Pack Foundation began working with the I.T. Dept at the DOJ to fully design the specifications and cost structure of the search and database technology system to make CURES a real-time accessible system.

We estimate it to take about six - months to build the technology platform once the initial $1.5 million of funds are in place. After the system is complete, **The Pack Foundation will donate the project to the State of California.**

Last year in 2007, there were 34 million prescriptions of controlled substances reported to the CURES database. Shockingly, almost 3 million were obtained through fraudulent means. This represents over $100 million dollars of losses to the California health care system each year. Not to mention the loss of lives and the negative socio-economic impact on all Californians.

Please join us in our efforts to create the real –time accessible CURES platform for all doctors and pharmacists in California. A FAQ sheet is attached to answer further questions. You may contact me directly as I would be happy to make a personal presentation to you or your organization.

Sincerely,

Bob Pack

President

The Troy and Alana Pack Foundation

FAQ

About the Pack Family Foundation

Bob and Carmen Pack created the Pack Family Foundation in 2004 after the loss of their two children. They have worked with Senator Tom Torlakson for over four years on two California DUI bills both of which have become law. The foundation has donated over $250,000 in local and national grants for projects related to reducing drug and alcohol abuse. In 2007 former CBS news anchor Dan Rather joined the Pack Foundation to help create the acclaimed film "Graduation Day" about teen drinking and driving.

Bob Pack has over twenty years in the technology industry along with co-starting NetZero in 1997. He is currently the CEO of Internet search company start-up Sproose, Inc and is on the Board of Directors of the Pharmacy Foundation of California. Bob has a BS Degree in Business from USC.

The committee for real- time CURES

State Senator Tom Torlakson

Attorney General Jerry Brown

Bob Pack

Kathy Ellis DOJ- CURES Manager

Sheri Hofer, Manager DOJ- IT Dept.

Virginia Herold DCA

Steven Gray, Kaiser Permanente

The California DOJ

California Board of Pharmacy

Dept. of Consumer Affairs

How will the system work?

The new technology system will be a web- based portal connected to the CURES database. It will provide real-time access for all California doctors and pharmacists to search a patient's controlled substance prescription history. Each doctor or pharmacist will need to register with the California DOJ to receive a password for logging into the system.

SB 734- Senator Tom Torlakson

In 2005 Senator Torlakson authored SB 734, which among other things allowed for the private funding for the real-time CURES program. It passed and became law in January 2006.

How much will the project cost?

The cost to build and maintain the system for one year will be approximately $1.5 million. For years two, three and four another $1.5 million is needed to maintain and upgrade the system. We have allocated some funds for educational materials and the registration process.

****The immediate goal is to raise the $1.5 million to build and implement the system.**

Who will build and manage the system?

The project will be built by the Calif DOJ IT dept. along with the Pack Foundation. All hardware and software will reside within the DOJ offices in Sacramento. The project will be maintained and upgraded by the DOJ CURES IT department.

Privacy and security

As part of SB 734 feasibility report was required to address privacy and security. The report was submitted in July 2007 and approved. The system will have the highest level of encryption software to maintain security. This is commonly called "Bank Level Security", meaning the type most used by financial institutions. The DOJ will provide each doctor and pharmacists a password to login to the system to maintain patient privacy.

Who has access to the real- time system?

Doctors, pharmacists and some law enforcement officials will be the only ones to have access to the system. The California DOJ will have full authority for who and how the system is to accessed and used. The will be no legal requirements to use the system however, an educational promotion effort will be put into place to encourage the use of the system. Over time, we hope this platform will become "standard practice" for all doctors and pharmacists in the fight to control narcotic and controlled substances abuse in California.

Los Angeles Times

Jerry Brown's Rx for drug abuse: the Internet

VIEWPOINT: Atty. Gen. Jerry Brown says California's prescription monitoring is a "horse-and-buggy" system that needs improvements.

The state attorney general's plan would provide doctors and pharmacists with online access to patients' prescription drug histories.

By Tim Reiterman, Los Angeles Times Staff Writer
June 5, 2008

SAN FRANCISCO -- State Atty. Gen. Jerry Brown unveiled a plan Wednesday to provide doctors and pharmacists with almost instant Internet access to patient prescription drug histories to help prevent so-called doctor shopping and other abuses of pharmaceuticals.

Brown told a Los Angeles news conference that the state's prescription monitoring is a "horse-and-buggy" system that needs significant improvements because it now can take healthcare professionals weeks to obtain information on drug use by patients. That delay can allow some patients to get large quantities of drugs from multiple doctors for personal use or sale.

"If California puts this on real-time access, it will give doctors and pharmacies the technology they need to fight prescription drug abuse, which is burdening our healthcare system," Brown said.

Bob Pack, an East Bay computer company owner, joined with Kaiser Permanente to fund a feasibility study of the project. He then offered to help raise $3.5 million, enough to build and support the computer system for the next several years. Pack's young son and daughter were killed in 2003 by a driver who had recently received multiple prescriptions for drugs and told police that she had taken numerous pills.

State of California • Department of Justice

OFFICE OF THE ATTORNEY GENERAL

Edmund G. Brown Jr.

News Release

June 04, 2008

FOR IMMEDIATE RELEASE

Contact: Gareth Lacy (916) 324-5500

Brown To Launch Online Technology To Fight Prescription Drug Abuse

LOS ANGELES--California Attorney General Edmund G. Brown Jr. today announced a plan to create an online prescription drug database so that authorized doctors and pharmacies can stop drug dealers and addicts who collect dangerous narcotics from multiple doctors.

"Every year thousands of doctors try to check their patient's prescription history information but California's current database is difficult to access," Attorney General Brown told a news conference. "If California puts this information online, with real-time access, it will give authorized doctors and pharmacies the technology they need to fight prescription drug abuse which is burdening our healthcare system."

Brown is working with the Troy and Alana Pack Foundation--founded by Bob Pack whose 7 and 10 year-old children were killed by a driver under the influence of prescription drugs obtained from multiple doctors--to enhance California's current prescription database by providing real-time Internet access for law enforcement and medical personnel.

Since 1940, the California Department of Justice has maintained a state database of dispensed prescription drugs with a high potential for misuse. Today, this prescription information is stored in the state's Controlled Substance Utilization Review and Evaluation System or CURES, which contains 86 million schedule II, III and IV prescriptions dispensed in California. Examples of drugs that are tracked in the state's database include Morphine, Vicodin, Oxycodone, Codeine, amphetamine, and analogs of methadone and opium.

The attorney general currently receives more than 60,000 requests annually from authorized doctors and pharmacies for patient prescription history information. Such requests are currently processed within several days by fax or telephone which makes it difficult for doctors and pharmacists to quickly review a patient's prescription history before dispensing another controlled drug.

California's new online CURES system will make it much easier for authorized individuals to quickly review prescription information to help prevent "doctor shopping," or gathering large quantities of prescription medications by visiting multiple doctors. The new online database, which the state is preparing to launch in 2009, is expected to cost $3.5 million over the next three years.

The new CURES program will give doctors and pharmacists the technology they need to monitor the prescribing and dispensing of controlled medications. Attorney General Brown said that if doctors and pharmacies have real-time access to prescription history information, it will help them make better prescribing decisions and cut down on prescription drug abuse in California.

"If doctors can easily check their own patients' prescription history, it will reduce the number of people who are able to obtain large quantities of narcotics from many different physicians," Brown said.

According to the Drug Abuse Warning Network, there were 598,000 emergency room visits involving non-medical use of prescription or other pharmaceutical drugs in 2005. 55% of these visits involved multiple drugs.

In 2005, Senator Tom Torlakson and the Troy and Alana Pack Foundation authored Senate Bill 734 which authorized new tamper-resistant prescription pads and permitted online access to the CURES system, pending the acquisition of private funding. The Troy and Alana Pack Foundation is working with Kaiser

Permanente, The California State Board of Pharmacy and the California Attorney General's Office to develop the new database.

"As a pioneer in the development of online medical information, Kaiser Permanente is proud to have contributed to the feasibility study and development of the database," said Kaiser Permanente Pharmacy Operations Professional Affairs Leader Steven W. Gray. "With the aid of this database, physicians and pharmacists will have valuable patient history information readily available to make the best and safest patient care decisions."

Virginia Herold, executive officer of the California State Board of Pharmacy said: "The California State Board of Pharmacy has long been a strong supporter of the CURES system. This new system will reduce drug diversion from pharmacies--it is an important enhancement to patient care and law enforcement."

Kentucky was the first state to put all its prescription history information online for authorized doctors, pharmacists and law enforcement. California's new database will be the largest online prescription drug database in the United States.

A Frequently Asked Questions document is attached. For more information on the California Department of Justice Bureau of Narcotic Enforcement and California's current prescription drug monitoring system visit: http://ag.ca.gov/bne/trips.php

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abc NEWS
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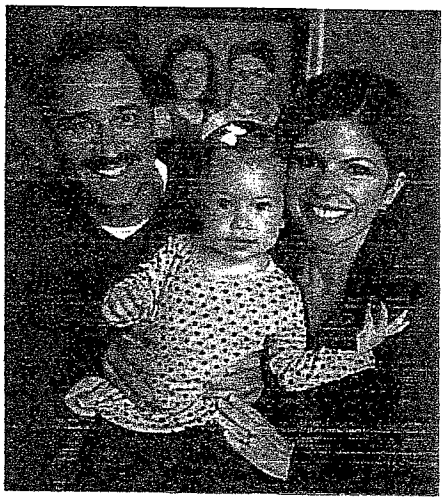
Raids Highlight Prescription Drug Debate

Raids on Home and Offices of Anna Nicole Smith's Doctors Highlight Prescription Drug Debate

By PAUL ELIAS Associated Press Writer
SAN FRANCISCO October 16, 2007 (AP)

The Associated Press

California authorities who raided the homes and offices of two of Anna Nicole Smith's doctors last week made the highest-profile use yet of a controversial state database that can detect suspicious patterns of prescriptions.



Bob and Carmen Pack hold their 17-month-old daughter Noelle, near a painting of their deceased...

But the raids also reignited debate about the technology. Law enforcement officials say it's a useful tool for fighting prescription drug abuse. Many doctors and privacy advocates say patients are suffering because the government crackdown invades people's privacy and interferes with the doctor-patient relationship.

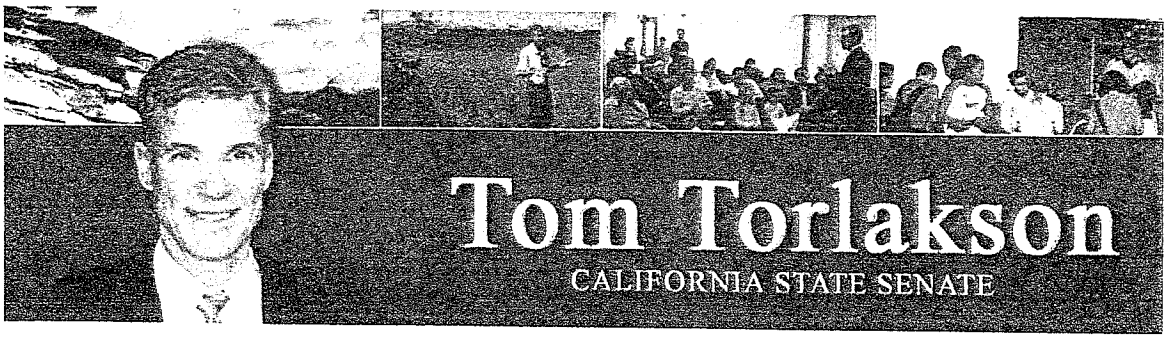
"What we have going on right now is a society wide witch hunt," said Dr. Frank Fisher, who was recently exonerated following a seven-year court battle that included murder charges, malpractice suits and a medical board investigation into the deaths of several patients for whom he prescribed painkillers.

Some patient advocates believe that allowing investigators to track physicians' prescribing habits risks hurting patients who genuinely need the drugs.

California Attorney General Jerry Brown and other law enforcement officials dismiss such claims and contend the system is needed to curb prescription drug abuse.

"There is no evidence that legitimate treatment is being suppressed or being discouraged," Brown said in an interview. "I think there are more cases out there than are being prosecuted."

The number of Americans who abuse prescription drugs nearly doubled, from 7.8 million in 1992 to 15.1 million in 2003, according to the U.N.-affiliated International Narcotics Control Board in its 2006 annual report, issued in February.



System would guard against narcotic abuse

Saturday, December 09, 2006

By Jeanine Benca
Contra Costa Times

California could be the first state with a "real-time" prescription drug monitoring system designed to crack down on narcotics abuse.Kaiser Permanente recently agreed to pay for a study of a proposed computer program to give doctors, pharmacists and some law enforcement officials instant online access to medical records. The state currently requires monthly reports.

The plan raises privacy concerns with some, but supporters -- including the state attorney general's office, state board of pharmacy and state Sen. Tom Torlakson, D-Antioch, -- say it would reduce "doctor-shopping" by drug abusers seeking multiple prescriptions.With just a few mouse clicks, a doctor would be able to find out the most recent time, and from whom, a patient had received Vicodin, OxyContin or other addictive narcotics.

Bob Pack of Danville, father of two children killed in 2003 by a driver who abused alcohol and Vicodin, has pushed for such a system. He said he believes it could prevent tragedies like the crash that took the lives of Troy 10, and Alana, 8.Weeks before Jimena Barreto's car jumped a curb and killed the children, she had received Vicodin from multiple doctors who said they didn't know others had also prescribed it to her.

Many experts say instant reporting would help raise the bar on doctor and patient accountability. And a new national study seems to support the idea.About the same time, Pack began working with Torlakson on SB734, legislation to bolster California's existing drug monitoring program.Kaiser spokeswoman Maureen McInaney said Pack helped convince the health care company's Northern California president, Mary Ann Thode, of the merits of the system.

"I can confirm that we are pleased to work with Mr. Pack to put together the study associated with the online prescription drug program," McInaney said in a statement. Kaiser will also consider contributing to a real-time program when the study is done, she said. She said groups are looking for a vendor to do the research.Once the study is complete, the bill's supporters will have to return to the Legislature with a proposal. One of the biggest hurdles will be long-term funding. It is estimated it could cost from as much as several million dollars to set up a program and hundreds of thousands of dollars per year to operate it.

Attachment 5

Board Comments to the DEA on E-Prescribing of Controlled Substances

California State Board of Pharmacy
1625 N. Market Blvd., Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

September 15, 2008

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

RE: COMMENTS OF THE CALIFORNIA STATE BOARD OF PHARMACY
Docket No. DEA—218: *Electronic Prescriptions for Controlled Substances*

To Whom It May Concern:

I write on behalf of the California State Board of Pharmacy (Board). We are pleased to have this opportunity to respond to a Request for Comments included in Docket No. DEA—218, a Notice of Proposed Rulemaking titled *Electronic Prescriptions for Controlled Substances*. We are encouraged that the Drug Enforcement Administration (DEA) is moving to permit electronic prescribing (e-prescribing) for controlled substances. As you are likely aware, an inability to use e-prescribing for controlled substances has been cited by several studies as a significant barrier to wider adoption of e-prescribing, particularly among prescribers. Widespread adoption is crucial to realize the full demonstrated potential of e-prescribing to reduce medication errors, to improve health outcomes, and to reduce costs. One key to spurring that widespread adoption is the ability to employ e-prescribing for all prescription drugs and devices, including controlled substances.

We therefore welcome this allowance for controlled substance e-prescribing as a vital and long-awaited step forward. We remain somewhat concerned, however, that the spurring effect of this development may be muted if DEA requirements for implementation of controlled substance e-prescribing (and receipt) by prescribers, pharmacies, or others are so onerous or complicated as to reduce the chances of widespread adoption. While as a regulatory body we are sympathetic to and fully understand your stated concerns regarding diversion, prescription authenticity and non-repudiation, and other controlled substance security risks, we urge you to also consider, as part of your decision-making about the requirements for participation, an often counterbalancing interest in encouraging widespread adoption. We believe these interests can be acceptably reconciled.

In what follows, we will comment on just a few specifics in the draft regulations, and will largely leave such specifics to the comments from industry stakeholders. We hope that those few examples we give will illuminate our more general thesis: that any requirement for e-prescribing controlled substances in the draft regulations ought to be reconsidered to assess not only whether it serves vital law-enforcement purposes, but also whether it erects *unnecessary* barriers to wider adoption. We are not sure whether this latter consideration has been given enough weight in the draft regulations, which create requirements for participation in e-prescribing far more weighty and specific than the current requirements for *paper* prescribing of controlled substances.

Our Historical Perspective in California

As you may know, the Board is the agency within California primarily responsible for the enforcement of California's Pharmacy Law (Cal. Bus. & Prof. Code, § 4000 et seq.), and we also share in enforcement of the state's Uniform Controlled Substances Act (Cal. Health & Saf. Code, § 11000 et seq.; see Cal. Bus. & Prof. Code, § 4011). As an enforcement agency, we share your interest in ensuring a safe and secure drug delivery system, particularly for controlled drugs. We are pleased to have a long history of mutual cooperation between the Board and the DEA.

Also from that shared perspective, we are enthusiastic about the potential of e-prescribing to dramatically improve the quality of prescription delivery, and healthcare more generally. That potential has been illuminated by numerous studies and reports, including in recent years the July 2006 Institute of Medicine report titled *Preventing Medication Errors*, and a June 2008 report by the Center for Improving Medication Management in collaboration with eHealth Initiative, titled *Electronic Prescribing: Becoming Mainstream Practice*. These documents have followed others in concluding that e-prescribing has great potential benefits, far outweighing its costs, but that so far adoption has been hindered by, *inter alia*, the inability to e-prescribe controlled substances.

California has its own significant history of studies and reports recognizing this potential value of e-prescribing, among them a November 2001 study titled *E-Prescribing* prepared for the California Healthcare Foundation that similarly identified the values of e-prescribing and barriers to its wider adoption. In 2005, the California Legislature adopted Senate Concurrent Resolution 49 (SCR 49 [Speier]), which created an expert panel to study the causes of medication errors and to recommend changes to the health care system. In March 2007, this "Medication Errors Panel" issued its report, titled *Prescription for Improving Patient Safety: Addressing Medication Errors*, which likewise lauded the benefits of e-prescribing, and which recommended that by 2010 it be a legally mandated requirement that *all* prescriptions be computer-generated or -typed.

California also has a significant history of being legally prepared for e-prescribing. This history demonstrates that California, and this Board, have been waiting for fuller implementation of e-prescribing for at least fourteen (14) years. For instance, since at least 1994, California has defined a legal "prescription" to include electronic transmission prescriptions (e-prescriptions), e.g., those transmitted directly from a prescriber to a pharmacy. (See Cal. Bus. & Prof. Code, § 4040; Cal. Health & Saf. Code, § 11027). Since at least 2001, in case there were any ambiguity about the propriety of direct transmissions of electronic prescription data, California has allowed direct "entry" (including by transmission) of data by a prescriber into a pharmacy's or hospital's computer. (See Cal. Bus. & Prof. Code, § 4071.1; Cal. Health & Saf. Code, § 11164.5). For the same time period(s), California has been awaiting DEA approval for electronic prescriptions for controlled substances. Since at least 2001, California law has specifically said that e-prescribing for controlled substances would be allowed "if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration." (Cal. Health & Saf. Code, § 11164.5, subd. (a).) California is therefore poised to implement these DEA regulations.

Recent Momentum in favor of E-prescribing

Both within California and at the national level, what had been a steady drumbeat solely among some interested constituencies has become a flood of interest in full implementation of e-prescribing. Your agency has obviously experienced that interest recently and directly, with the 2007 requests you received from Congress to permit e-prescribing of controlled substances.

As you know, momentum for wider adoption of e-prescribing was given a boost by the Medicare Modernization Act of 2003 (MMA), which included a requirement that participating Medicare Part D drug plans support e-prescribing (though participation by the prescribers and/or dispensers remained voluntary). Between 2005 and 2008, as required by the MMA, the Centers for Medicare and Medicaid Services (CMS) promulgated regulations containing standards for e-prescribing (and affiliated transactions). Those standards are now in final rule status.

Even more significant to the growing momentum in favor of e-prescribing was the recent (July 2008) passage of the Medicare Improvements for Patients and Providers Act of 2008 (HR 6331). As you are no doubt aware, Section 132 of that legislation provides financial incentives for prescribers participating in Medicare Part D to reach certain e-prescribing thresholds between 2009 and 2013, and beginning in 2012 will financially penalize any prescribers who fail to meet the e-prescribing thresholds. The incentives and penalties will be up to 2% in both directions, a potentially powerful motivator to encourage wider adoption of e-prescribing. Projected savings to Medicare from widespread e-prescribing adoption are in the hundreds of millions of dollars.

California has similarly moved toward a more forceful encouragement of participation in e-prescribing. In the most recent legislative session (2007-2008), the Governor proposed health care reform legislation (AB1x) that, among other things, would have required that by January 1, 2012 all prescribers, prescribers' agents, and pharmacies have the ability to transmit and receive prescriptions by electronic transmission, and given licensing boards the authority to enforce this requirement. The legislation also would have set out standards for such electronic transmissions, including a requirement that the system(s) permit real-time benefit and formulary confirmations.

These legislative exercises at both the state and national level show a clear commitment to e-prescribing. The reasons for this are obvious, including but not limited to the real potential of e-prescribing to dramatically reduce adverse drug events, and thereby reap huge cost savings. E-prescribing is clearly here to stay. Yet despite the overwhelming interest from policymakers and the industry, particularly the pharmacies and other dispensers who have long recognized the value of e-prescribing not only for the safety of their patients but also for their own workflow(s), costs, and technology integration, and who have as an industry been almost universally ready and willing to accept e-prescriptions for a matter of years, the level of participation by prescribers has so far remained stubbornly and shockingly low. Estimates for prescriber adoption rates as of the end of 2007 hovered below 10% of all prescribers. Compare this to the estimate that 72% of all pharmacies were actively prepared for e-prescription receipt by the same date, and 95% of same were "e-prescribing capable." (See *Electronic Prescribing: Becoming Mainstream Practice*.)

Clearly, the incentives and penalties in HR 6331 are intended to have a significant impact on adoption rates by prescribers. California also has some power to affect the motivations of the prescribers serving California patients. However, where it is estimated that approximately 20% of all prescriptions are for controlled substances (*Electronic Prescribing*, *supra*), the inability to e-prescribe controlled substances would remain a significant obstacle to widespread adoption.

We are therefore understandably pleased to see the DEA step forward with an allowance for controlled substance e-prescribing. We only hope that the regulations under which this will be allowed can represent an encouragement, rather than a disincentive, to widespread adoption. We have the following specific suggestions about means to achieve that encouragement, but in general simply urge you to consider that encouragement itself a valid goal for the regulations.

Response to Request for Comments

Again, we will not attempt a comprehensive response to the Request for Comments. The detailed comments on particular provisions will come from industry stakeholders. There are just a few comments we wish to make, to illustrate our larger point about ease of implementation.

For example, we are curious about the requirement of in-person identity proofing before a prescriber may be authorized for e-prescribing by a service provider. According to the proposal, this in-person identity proofing must be done by the credentialing office within a DEA-registered hospital which has granted privileges to the prescriber, by a State professional or licensing board or State controlled substances authority, or by a State or local law enforcement agency. (See 21 CFR §§ 1311.105 and 1311.155.) As far as we are aware, no such in-person identity proofing is presently required for paper or non-controlled substance prescriptions. While we are certainly as concerned as you are about limiting prescribing authority to those appropriately granted same, it is not clear to us that a demonstrably greater risk of impersonation and/or fraudulent use of such authority inheres in e-prescribing than in the use of paper prescriptions. Indeed, the greatest risk for fraudulent use of prescriber authority is probably theft of a prescription pad. Given that this requirement could be a substantial additional burden for a prescriber, particularly for a prescriber not affiliated with a hospital, or in a rural or otherwise remote location distant from any approved identity-proofing entity, we wonder whether the incremental increase in security promised by the in-person identity proof requirement is overbalanced by the possible reduction in participation in e-prescribing this barrier may cause among prescribers. We are also concerned about the ability of hospital credentialing offices, State licensing boards, or State or local law enforcement bodies to expeditiously handle the additional workload required by this provision, as they are suddenly faced with large numbers of prescribers requiring transmission of a verification document, which is then followed by requests for verification from the service provider. (See § 1311.105(c).) We urge you to reconsider the necessity of this requirement, or at least to consider whether it may be possible to streamline this requirement, by for instance increasing the number and type of entities that can perform in-person identity proofing (e.g., perhaps local Post Offices/passport offices).

The regulations also contain numerous other smaller obstacles to prescriber participation in e-prescribing, which cumulatively may discourage the widespread participation that is crucial, and which may be unnecessarily formalistic or burdensome. Among these is the requirement for a minimum two-factor authentication protocol using a hard token, like a PDA or other handheld device. (See § 1311.110.) We agree that it is important to be sure that only the prescriber makes the judgment(s) required for issuance of prescriptions. However, we are concerned that making adoption of e-prescribing dependent on adoption of a PDA or other handheld device will simply further delay adoption of e-prescribing, as many prescribers are resistant to handheld technology. Also, there may be numerous practice settings (e.g., hospitals) where system security forbids the connection of handheld devices to the network, making this authentication protocol implausible.

Other smaller interferences with current prescriber workflow practices that may dampen enthusiasm for participation without obvious benefit include the requirements: that the prescriber be "timed out" after 2 minutes of inactivity (§ 1311.110(c)), even though it may legitimately take more than 2 minutes to research and issue a prescription; that electronic prescriptions always be transmitted immediately (§ 1311.130(a)), which would seem to disallow current DEA-approved practice of writing prescriptions for future furnishing; and that the prescriber conduct and retain for five years a monthly log review of all controlled substance prescriptions (§ 1311.140), with no stated purpose or reporting requirement, perhaps making prescribers into law enforcement.

On the pharmacy side, these regulations may also have the effect of discouraging present enthusiasm for e-prescribing, at least as to controlled substances. The most formalistic addition to present pharmacy workflow processes is the requirement that each pharmacy system, without exception, verify prescribers' DEA registration number(s) for *each* prescription before any such controlled substance prescription is dispensed. (See § 1311.165.) This is a substantial addition to how pharmacies presently process paper prescriptions, where no such verification is required for each prescription, and where (at least as to familiar prescribers) a presumption of validity of registration is made absent some indication to the contrary. It is not clear if this verification can be automated, as we have been informed that the DEA CSA database on which this function will depend is not available in real-time, and this requirement has the real potential to be a significant stumbling block. Though we understand a desire to promote earlier detection of non-legitimate prescribers, it is not clear that this benefit outweighs the possible negative effect on adoption.

We are also concerned about the possible impact that Section 1311.230(d) (with Section 1306.05), and/or the apparent lack of any stated exception to allow for this possibility, may have on generic substitution for brand-name drugs. Section 1311.230(d), understandably, prohibits an "alteration" of an electronically-transmitted prescription. What is less clear, and we do not see in the remaining regulations any explicit mention of this, is whether pharmacies will nonetheless be permitted to substitute generic for brand-name (absent a prescriber indication to the contrary), or whether this would be considered an impermissible "alteration." In California, for instance, our generic substitution statute (Cal. Bus. & Prof. Code, § 4073) contains an explicit allowance for a prescriber to *electronically* include the "Do not substitute" prohibition. We would appreciate an explanation of the interaction of these regulations with ongoing widespread generic substitution. It also appears possible that this "alteration" prohibition is in any event redundant with the digital signature requirement(s), since digital signatures by their nature prohibit alteration(s) of data.

Lastly, these regulations impose a new 5-year retention period for the e-prescriptions and affiliated records. (See, e.g., §§ 1311.170, 1311.180.) Current retention requirements for paper prescriptions are 2 years under federal law or 3 years under California law. It is not clear why an additional 2 years of retention is being required. This is a small point, as data storage can usually be accomplished relatively easily and cheaply, but where the replacement cycle for computers is often less than 5 years, this may be an additional obstacle to widespread adoption. This may be especially the case when combined with the fairly rigorous third-party audit requirements for the pharmacy systems, which are a potentially substantial additional cost. (See § 1311.170). These audit requirements do not seem to allow for the ongoing privacy and security protections that are already in place to comply with HIPAA and other applicable federal and state privacy laws.

Summary and Conclusion

Again, we applaud your efforts in proposing the draft regulations, and emphasize that we view ourselves as joined with you in this task of ensuring a safe and secure prescription delivery system for controlled substances. We are greatly encouraged that the DEA has taken the step of initiating this dialogue about an appropriate system for e-prescribing controlled substances. The document you have produced is impressive in its scope and its complexity. We only hope that its complexity and formalism does not deter potential participants. We think the vital question to be asked with regard to each of the provisions in the proposed regulations is, given the established potential for e-prescribing to improve patient outcomes, public health, public safety, and thus to reduce the costs of health care, whether a barrier or requirement for participation in e-prescribing laid out by these regulations is vital to protection of the public and/or of patient safety.

The Board looks forward to continuing its historical cooperation with the DEA as it sets forth on this rule-making endeavor. The Board is hopeful the DEA can move quickly to permit e-prescribing of controlled substances, and that as it does so the DEA weighs heavily the need to encourage adoption of this technology, along with the need to ensure security and authenticity.

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

Sincerely,

Kenneth H. Schell

KENNETH H. SCHELL
President, California State Board of Pharmacy

Attachment 6

Senate Bill 966 and Draft Guidelines for Take Back Programs for Prescription Drugs

Senate Bill No. 966

CHAPTER 542

An act to amend Section 47200 of, and to add and repeal Article 3.4 (commencing with Section 47120) of Chapter 1 of Part 7 of Division 30 of, the Public Resources Code, relating to pharmaceutical waste.

[Approved by Governor October 12, 2007. Filed with Secretary of State October 12, 2007.]

LEGISLATIVE COUNSEL'S DIGEST

SB 966, Simitian. Pharmaceutical drug waste disposal.

(1) Existing law creates the California Integrated Waste Management Board (board) within the California Environmental Protection Agency.

This bill would, until January 1, 2013, require the board to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of pharmaceutical drug waste. The model programs would be required to include, at a minimum, specific actions and informational elements and would be required to be available to eligible participants no sooner than July 1, 2008, but no later than December 1, 2008.

The bill would provide that its provisions shall not apply to a controlled substance, as defined.

(2) Existing law requires the board to expend certain funds, upon appropriation by the Legislature, for the making of grants, as provided, to cities, counties, and other local agencies with responsibilities for solid waste management, and for local programs to prevent the disposal of hazardous wastes at disposal sites, including, but not limited to, initial implementation or expansion of household hazardous waste programs. The total amount of the grants in any one fiscal year may exceed $3,000,000 but cannot exceed $5,000,000, if sufficient funds are appropriated from the Integrated Waste Management Account for this purpose.

This bill would increase the limit to $6,000,000.

The people of the State of California do enact as follows:

SECTION 1. Article 3.4 (commencing with Section 47120) is added to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, to read:

Article 3.4. Drug Waste Management and Disposal

47120. (a) The Legislature finds and declares all of the following:

(1) The United States Geological Survey conducted a study in 2002 sampling 139 streams across 30 states and found that 80 percent had measurable concentrations of prescription and nonprescription drugs, steroids, and reproductive hormones.

(2) Exposure, even to low levels of drugs, has been shown to have negative effects on fish and other aquatic species and may have negative effects on human health.

(3) In order to reduce the likelihood of improper disposal of drugs, it is the purpose of this article to establish a program through which the public may return and ensure the safe and environmentally sound disposal of drugs and may do so in a way that is convenient for consumers.

(b) It is the intent of the Legislature in enacting this article:

(1) To encourage a cooperative relationship between the board and manufacturers, retailers, and local, state, and federal government agencies in the board's development of model programs to devise a safe, efficient, convenient, cost-effective, sustainable, and environmentally sound solution for the disposal of drugs.

(2) For the programs and systems developed in other local, state, and national jurisdictions to be used as models for the development of pilot programs in California, including, but not limited to, the efforts in Los Angeles, Marin, San Mateo, and Santa Clara Counties, Oregon, Maine, North Carolina, Washington State, British Columbia, and Australia.

(3) To develop a system that recognizes the business practices of manufacturers and retailers and other dispensers and is consistent with and complements their drug management programs.

47121. For the purposes of this article, the following terms have the following meanings, unless the context clearly requires otherwise:

(a) "Consumer" means an individual purchaser or owner of a drug. "Consumer" does not include a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and retailer.

(b) "Drug" means any of the following:

(1) Articles recognized in the official United States Pharmacopoeia, the official National Formulary, the official Homeopathic Pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias.

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(3) Articles, excluding food, intended to affect the structure or function of the body of humans or other animals.

(4) Articles intended for use as a component of an article specified in paragraph (1), (2), or (3).

(c) "Participant" means any entity which the board deems appropriate for implementing and evaluating a model program and which chooses to participate, including, but not limited to, governmental entities, pharmacies, veterinarians, clinics, and other medical settings.

(d) "Sale" includes, but is not limited to, transactions conducted through sales outlets, catalogs, or the Internet, or any other similar electronic means, but does not include a sale that is a wholesale transaction with a distributor or retailer.

47122. (a) (1) The board shall, in consultation with appropriate state, local, and federal agencies, including, but not limited to, the Department of Toxic Substances Control, the State Water Resources Control Board, and the California State Board of Pharmacy, develop model programs for the collection and proper disposal of drug waste. Notwithstanding any other provision of law, the board shall establish, for participants, criteria and procedures for the implementation of the model programs.

(2) In developing model programs the board shall evaluate a variety of models used by other state, local, and other governmental entities, and shall consider a variety of potential participants that may be appropriate for the collection and disposal of drug waste.

(3) No sooner than July 1, 2008, but no later than December 1, 2008, the board shall make the model programs available to eligible participants.

(b) The model programs shall at a minimum include all of the following:

(1) A means by which a participant is required to provide, at no additional cost to the consumer, for the safe take back and proper disposal of the type or brand of drugs that the participant sells or previously sold.

(2) A means by which a participant is required to ensure the protection of public health and safety, the environment, and the health and safety of consumers and employees.

(3) A means by which a participant is required to report to the board for purposes of evaluation of the program for safety, efficiency, effectiveness, and funding sustainability.

(4) A means by which a participant shall protect against the potential for the diversion of drug waste for unlawful use or sale.

(c) The model programs shall provide notice and informational materials for consumers that provide information about the potential impacts of improper disposal of drug waste and the return opportunities for the proper disposal of drug waste. Those materials may include, Internet Web site links, a telephone number placed on an invoice or purchase order, or packaged with a drug; information about the opportunities and locations for no-cost drug disposal; signage that is prominently displayed and easily visible to the consumer; written materials provided to the consumer at the time of purchase or delivery; reference to the drug take back opportunity in advertising or other promotional materials; or direct communications with the consumer at the time of purchase.

(d) Model programs deemed in compliance with this article shall be deemed in compliance with state law and regulation concerning the handling, management, and disposal of drug waste for the purposes of implementing the model program.

(e) (1) The board may develop regulations pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that are necessary to implement this article, including

regulations that the department determines are necessary to implement the provisions of this article in a manner that is enforceable.

(2) The board may adopt regulations to implement this article as emergency regulations. The emergency regulations adopted pursuant to this article shall be adopted by the department in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, and for the purposes of that chapter, including Section 11349.6 of the Government Code, the adoption of these regulations is hereby deemed an emergency and shall be considered by the Office of Administrative Law as necessary for the immediate preservation of the public peace, health, safety, and general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, any emergency regulations adopted by the department pursuant to this section shall be filed with, but not be repealed by, the Office of Administrative Law and shall remain in effect for a period of two years or until revised by the department, whichever occurs sooner.

47123. Notwithstanding Section 7550.5 of the Government Code, no later than December 1, 2010, the board shall report to the Legislature. The report shall include an evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness. The report shall include the consideration of the incidence of diversion of drugs for unlawful sale and use, if any. The report also shall provide recommendations for the potential implementation of a statewide program and statutory changes.

47124. This article shall not apply to a controlled substance, as defined in Section 11007 of the Health and Safety Code.

47125. Nothing in this article shall limit or affect any other right or remedy under any applicable law.

47126. This article shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 2. Section 47200 of the Public Resources Code is amended to read:

47200. (a) The board shall expend funds from the account, upon appropriation by the Legislature, for the making of grants to cities, counties, or other local agencies with responsibility for solid waste management, and for local programs to help prevent the disposal of hazardous wastes at disposal sites, including, but not limited to, programs to expand or initially implement household hazardous waste programs. In making grants pursuant to this section, the board shall give priority to funding programs that provide for the following:

(1) New programs for rural areas, underserved areas, and for small cities.

(2) Expansion of existing programs to provide for the collection of additional waste types, innovative or more cost-effective collection methods, or expanded public education services.

(3) Regional household hazardous waste programs.

(b) (1) The total amount of grants made by the board pursuant to this section shall not exceed, in any one fiscal year, three million dollars ($3,000,000).

(2) Notwithstanding paragraph (1), the total amount of grants made by the board pursuant to this section may exceed three million dollars ($3,000,000) but shall not exceed six million dollars ($6,000,000), in any one fiscal year, if sufficient funds are appropriated from the Integrated Waste Management Account for this purpose.

O

Attachment 1

Criteria and Procedures for Model Pharmaceutical Waste Collection and Disposal Programs

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB) to develop model programs for the collection and proper disposal of unused or expired pharmaceuticals. In developing model programs in California, the CIWMB is also required to evaluate programs used by other state, local, and other governmental entities. The CIWMB provided a survey to those entities that have collection programs and requested that they complete and return it to the CIWMB. The purpose of the survey was to acquire information on existing pharmaceutical waste collection programs in California. From the survey results, the Procedures for Model Pharmaceutical Waste Collection and Disposal Programs were developed that would help organizations or local governments create programs through which the public may return unused or expired pharmaceutical waste (typically a prescription drug dispensed to a consumer, or a non-prescription item, such as over the counter drugs, that are no longer wanted or needed by the consumer) and meet the following minimum criteria and goals of SB 966 and of the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health, Board of Pharmacy, Department of Toxic Substances Control, and the State Water Resources Control Board).

The minimum criteria of SB 966 and of the Pharmaceutical Working Group are listed as follows:

1. Requires, at no additional cost to the consumer, the safe and environmentally sound take back and disposal of unused or expired pharmaceuticals;
2. Ensures protection of the public's health and safety and the environment;
3. Ensures protection of the health and safety of consumers, and employees ;
4. Provides a means to report to the Board the amounts of pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability, and incidents of diversion of drugs for use or sale;
5. Protects against the potential for the diversion of drug waste for unlawful use or sale;
6. Provides notices and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal
7. Persons or businesses are subject to consequences for failure to comply with model programs per SB 966 and related state and federal pharmaceutical and waste management statutes at the point of transportation, deposition, and consolidation;

Additional goals of SB 966 and the Pharmaceutical Working Group include:

1. Provides for the collection of pharmaceuticals that is convenient for consumers
2. Maintains privacy of all participants;
3. Prevents the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;
4. Ensures that medication information is legible, so that it can be identified in case of a poisoning;

5. Develops a sustainable funding source for collection and disposal of pharmaceuticals, such as grants, utility funding, or advanced disposal fees placed on pharmaceuticals and local general funds or via extended producer responsibility funding framework.
6. Strives to develop permanent collection programs rather than one-day events, so they will be more accessible to the public; and
7. Provides recommendations for implementation of a statewide program and recommendations for statutory changes.

The following Procedures for Model Pharmaceutical Waste Collection and Disposal Programs have been extracted from both the Pharmaceutical Collection Programs Survey and collection program information on the internet. These Procedures for Model Pharmaceutical Waste Collection and Disposal Programs are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used to as a model to develop a collection and disposal program for unused/expired pharmaceuticals. The Procedures for Model Pharmaceutical Waste Collection and Disposal Programs are broken down by (I) Ongoing Collection Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

I. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs At Ongoing Collection Programs

As mentioned in the previous section on goals, it is preferable that permanent pharmaceutical collection programs be developed in order to provide the public with consistently accessible and convenient venues to drop off unused or expired pharmaceuticals. Jurisdictions such as the City of Los Angeles, San Mateo County, and Ventura County and nonprofit groups such as the Teleosis Institute are current examples of permanent and ongoing programs utilizing various types of venues. The following are basic steps that can be taken to implement permanent collection programs.

A. Ongoing Collection Program Requirements

The following collection program guidelines should be adhered to at locations collecting pharmaceutical waste from the public:

1. What Will Be Collected - These programs provide for the collection and disposal of prescription drugs dispensed to a consumer, or a non-prescription item, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste. Medical waste such as blood samples, vaccines and serum, and trauma scene waste cannot be accepted. In addition, controlled substances should not be collected by these programs unless a sworn law enforcement officer is onsite to properly collect, document, and dispose of the controlled substances.

2. Controlled Substances - Controlled substances are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples include

opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines and methamphetamines). If a medication is not identifiable, it should be assumed to be a controlled substance and handled accordingly. Controlled substances should not be collected except at police stations or at least in the presence of law enforcement. If controlled substances are brought to a collection location that can't accept controlled substances, staff should provide information as to where they can properly be disposed.

3. How Will Pharmaceuticals Be Collected - Signage or literature informing customers that the program cannot accept controlled substances should be visible and available to the public. The pharmaceuticals should be kept in their original container with personal information removed or marked out. Labels should not be removed. The containers and pharmaceuticals can then be given to the collection program for collection and disposal. The collection location must ensure that the pharmaceuticals are destroyed. In a retail setting, no collected pharmaceuticals can be resold or reused.

a. Packing Pharmaceutical Waste Separate pills from the containers. It is more cost effective to pack pharmaceuticals in this manner.

b. Packing Controlled Substances - This is at the discretion of the law enforcement agency. The signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the pharmaceutical waste is destroyed, the contents are checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

c. Storage - Never store collected pharmaceuticals at a Household Hazardous Waste (HHW) facility or any other setting, other than in the secure sealed containers or in the custody of law enforcement due to the risk of theft or accidents.

d. Sharps - Have sharps containers available, so sharps can be properly disposed of at a sharps consolidation point or via a mail back program. If the sharps are not brought in an approved container, have the resident place them in a sharps disposal container.

4. Security - Containers should be maintained so as to limit diversion opportunities. Some security measures may include a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Other security measures can be taken including video surveillance, limiting access, providing drop-off containers at police stations or utilizing mail-back envelopes. If not accepting controlled substances, provide a flyer as to where they can be disposed.

5. Signage - Provide signage regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.).

6. Data Collection - Data should be kept on the total number of pounds collected, the number of residents utilizing the service, and when possible, the types of materials collected for further

study and analysis. Examples of collection forms can be accessed at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com.

7. Education - Provide educational materials to the community and to customers dropping off pharmaceuticals. Educational materials should include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from pharmaceuticals.

8. Site Visits to Collection Sites - Visit collection locations often to help assure that procedures are being maintained and help maintain lasting relationships. An example of this is the Teleosis Institute that makes routine site visits by the staff person that oversees the Teleosis Institute's pharmaceutical waste take back program.

B. Logistics and Equipment

1. Types of Collection Locations - There is a wide variety of facilities that can collect pharmaceuticals-pharmacies, police stations, retirement and convalescent homes, public health agencies, clinics, and HHW facilities. The best facilities to collect pharmaceutical waste would be those that are convenient to the public, can continue collection for a long period of time, and are willing to collect all pharmaceutical waste.

a. Collection at Law Enforcement Facilities - If collection is at a police station, law enforcement must able to collect the materials, document the amounts collected, place them in an area to be accumulated and destroyed, and have them properly destroyed.

b. HHW Collection Site - If you use a collection site at the HHW facility, there should be room for additional hazardous waste containers for increased material being collected.

2. Government Agency Authorization - Determine if additional permits or approvals are needed for pharmaceutical collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health, local hazardous waste departments, and zoning departments for use permits.
Medical waste generator permits are required for collection programs from the Local Enforcement Agency, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator permit or a large quantity generator permit is required.

3. Budget - A budget estimate should be developed and the program should be free to the public to dispose of unused and unwanted pharmaceuticals at the point of disposal. It needs

to be determined who will be paying for the collection and disposal of pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected. The following list shows collection costs by program type as provided in the Pharmaceutical Collection Survey.

Average Operating Cost by Program Type	
HHW Programs	$7,961
Pharmacy Programs	$8,336
Police Dept. Programs	$8,480
Mail Back Program	Not Given

Average Operating Cost Per Pound	
HHW Programs	$6.58/lb
Pharmacy Programs	$4.15/lb
Police Dept. Programs	$2.82/lb
Mail Back Program	Not Able to Determine

4. Hazardous Waste Hauler/Disposal Arrangements - Advance arrangements should be made with the hazardous waste hauler on the fee schedule, the hazardous waste incineration, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. The transporter shall show the certificate upon demand, to any enforcement agency personnel or authorized employee of the California Highway Patrol.

5. Advertising - Provide advertising which could include the internet, web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating cities, movie theatre ads shown in theaters, ads on buses and at bus stops, print ads in recycling guides, English and Spanish PSAs in video and audio. Advertising may be the most expensive part of the collection program, so for the most effective means for advertising the program, those people that would be disposing of pharmaceuticals should be targeted. These populations could include people at convalescent homes and people that are purchasing new prescriptions or over-the-counter drugs.

6. Essential Equipment and Supplies

a. Pharmacies - Lockable secure containers with a wire cage around them, lockable kiosks, lockable steel bins, refurbished lockable mail boxes, black markers to cover up personal data, signage informing the public about what can and cannot be collected.

b. Police Stations - Refurbished containers with an inside collection container located near the building entrance or in the lobby that allows people to drop off pharmaceuticals and not be able to retrieve them. Refurbished mail boxes, as an example, can be used to prevent theft.
c. Permanent HHW Collection Facility Equipment - 4 container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gallon plastic container for mercury items), gloves, indelible markers, and sharps container and/or mail back sharps disposal kits.

C. Staffing

1. Staffing for Ongoing Collection Programs - The following staff are recommended at collection programs to implement the specified tasks:

a. Pharmacist (at pharmacies) - The pharmacist will determine if a pharmaceutical is a controlled substance, identify non-labeled pharmaceutical waste, inventory controlled substances for law enforcement, witness, and sign the inventory. Another option is to display signage stating that the facility will not accept controlled substances for collection and disposal. This would decrease the time pharmacists would need to spend managing controlled substances.
b. Hazardous Waste Company (for HHW facilities) - The hazardous waste personnel will provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances at a licensed hazardous waste incinerator, provide a certificate of destruction, and provide weight of materials collected. Do not allow pharmaceutical waste that are hazardous waste to be stored longer than 90 days at the facility.
c. Law Enforcement – If an ongoing collection program decides to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances.

2. Recommended Staffing for Programs That Don't Collect Controlled Substances-

A. Pharmacist (at pharmacies) - shown above.
B. Hazardous Waste Personnel (for HHW facilities) - shown above

II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs At One Time or Periodic Collection Events

Although permanent and ongoing collection programs are the preferred way to collect and dispose of pharmaceuticals, there will be instances when conducting one time or periodic

events are necessary. Jurisdictions currently conducting one time/periodic events include Tuolumne County, East Bay Municipal Utility District, and Fresno County. These events are held at local street fairs, festivals, city halls, water district facilities, and household hazardous waste temporary collection events. The following are steps to take in conducting one time/periodic events.

A. Collection Event Operation Requirements

During the collection event, the following requirements need to be adhered to:

1. Critical Information for the Event - The following items are critical to assure that the public and the event staff are safe and that no pharmaceutical wastes are diverted from the collection event:

a. Pharmaceutical wastes stay in their original containers until they can be disposed of by staff. If the pharmaceuticals are removed from their original containers, staff may not be able to determine the source in case of an accidental poisoning by a donator;
b. Personal information can be crossed out, but keep information about medication legible;
c. Do not remove labels;
d. No sharps should be accepted, but probably will be dropped off;
e. No thermometers should be accepted.
f. No medical waste, such as biohazardous waste, sharps waste, or medicinal preparations made from living organisms should be accepted.
g. Pharmaceutical waste should be properly destroyed.
h. If in a retail setting, pharmaceutical waste must not be resold or used.
i. Provide where, when, hours of operation, and who to contact for more information;
j. . Assure that there is no cost to participate in this program.

2. What Will Be Collected - All prescription pharmaceutical waste should be accepted, including veterinary pharmaceutical waste. It is recommended to accept over-the-counter pharmaceutical waste including vitamins and supplements. No controlled substances will be accepted unless a sworn law enforcement officer is present during the entire collection event.

3. Personal Protective Equipment - Wear gloves (latex or non-latex) at all times when handling pharmaceutical waste, because the containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) must be avoided. Wearing facemasks should be considered, especially for the pharmacist who is doing the physical determination of the pharmaceutical waste. Do not eat or drink directly in the area that the pharmaceutical wastes are being collected. Discard used gloves.

4. Packing Pharmaceutical Waste - Controlled and non-controlled substances should be packed separately.

a. Packing of Non-Controlled Substances

1). Loose pills should be placed in a sealed plastic bag to be placed in a secure container.

2). Two additional types of containers must be provided for certain items; items under pressure and certain mercury-containing pharmaceutical waste.

b. Packing Controlled Substances - This is at the discretion of the law enforcement agency. The signed inventory must accompany the pharmaceutical waste and must stay with them in the evidence storage locker and through the point of destruction. Before the pharmaceutical wastes are destroyed, the contents are checked against the inventory to ensure that there has been no diversion. This is federal Drug Enforcement Agency law. If a medication is not identifiable, it should be assumed to be a controlled substance and handled accordingly.

c. Storage - Never store collected controlled substances at a HHW facility or any other setting, other than in the custody of law enforcement due to the risk of theft, accidents, and because it is prohibited by law.

5. Security- Containers with a lockable cage can be purchased for additional security. Containers with pharmaceutical waste should be locked in a closet preventing the public and staff from gaining access. Other security measures can be taken including video surveillance, limiting access, providing drop-off containers at police stations or utilizing mail-back envelopes. If not accepting controlled substances, provide a flyer as to where they can be disposed.

6. Signage - Provide signage regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.).

7. Data Collection - Determine amounts of pharmaceuticals collected along with the number of donators. If time allows, determine the types and amounts of pharmaceuticals collected. This information could be used for further studies and policy recommendations.

8. Medication Containers - Mark out personal information with a permanent marker.

9. Education - Have educational material available to educate the community about unused and expired pharmaceuticals.

10. Site Visits to Collection Sites - Local environmental health or similar program staff should conduct site visits to help assure that procedures are being maintained and help maintain lasting relationships with businesses or organizations collecting pharmaceuticals.

B. Pre-Event Logistics

1. **Government Agency Authorization** - All relevant agencies and programs should have authorized the collection and its procedures for the collection event.
2. Budget - An estimate of the budget should be developed and the program should be free to the public to dispose of unused and unwanted pharmaceuticals.

3. Collection Site - Provide a location that restricts entering and exiting the facility to people dropping off pharmaceuticals. This will allow those in charge to watch people dropping off pharmaceuticals to assure that none of the pharmaceutical wastes are stolen.

4. Agreement With Law Enforcement - A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with law enforcement agency that is providing the law enforcement officer for the event, whether they have requirements or not. The enforcement agency should let you know the type of packaging that the drugs must be contained in to be accepted into their evidence locker, or if the containers the collection event will provide, are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel; this is optional at the discretion of collection organizers and not required for all events.

5. Advertising – Provide advertising which could include the internet, web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings. Multi-lingual flyers distributed in utility bills in participating cities, movie theatre ads shown in theaters, ads on buses and at bus stops, print ads in recycling guides, English and Spanish PSAs in video and audio. Since advertising may be the most expensive part of the collection, people who would be disposing of pharmaceuticals should be targeted. These populations could include people at convalescent homes and people that are purchasing new prescriptions.

6. Pharmacist (if one day event is at a facility other than a pharmacy) - Pharmacists are recommended to be present at the event and must be licensed and in good standing with the California State Board of Pharmacy.

7. Hazardous Waste Hauler/Disposal Arrangements - Advance arrangements should be made with the hazardous waste hauler on the fee schedule, hazardous waste incineration, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers.

8. Dedicated Collection Area at the HHW Facility - If you use a collection site at the HHW facility, provide room for additional hazardous waste containers.

9. Law Enforcement Location - At one time events, due to potential for acceptance of controlled substances, law enforcement must be positioned to be able to see the collection and movement of the pharmaceutical wastes from the public to the collection location. Law enforcement must be able to see the transfer of pharmaceutical wastes from vehicles to the greeter. Determine a good position for law enforcement to be stationed.

10. Essential Equipment and Supplies

a. Tools for counting pharmaceutical waste (pharmacist should provide this);
b. Hazardous waste containers;
c. Gloves (Disposable non-latex preferably; have all sizes available especially extra large);
d. Sealable plastic bags (One-gallon and snack size, with external slide mechanism);
e. Extension cords, grounded;
f. Survey forms (examples can be found at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com);
g. Indelible markers (such as SHARPIE®);
h. Packing tape;
i. Containers-3 types of containers (30-gal cardboard with plastic liner, a 5-gallon plastic container for inhalers, and a 5-gal plastic container for mercury items); and
j. Sharps disposal container, in case some sharps are collected at the event.

11. Informational Instructions for Consumers-Prepare instructions/information for consumers to use as they prepare to bring items to the collection event.

a. List what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste.

b. All pharmaceutical waste must stay in their original containers;

c. Patient name and any other personal information must be rendered unreadable on the prescription label, before turning items in for collection. Blacking out with a Sharpie or other marker is suggested. Leave the name of the drug on the container.

C. Staffing

1. Staffing for Events that Also Collect Controlled Substances - The following staff are recommended at collection sites to implement the specified tasks:

a. Greeter - direct people to the collection location and answer questions. Greeters can also screen incoming people and wastes for problems. If the event is large enough, radios are useful.
b. Law Enforcement Staff - to provide security, take possession of controlled substances after determination by a pharmacist, transport controlled substances to evidence storage locker, document the collection of controlled substance, and arrange for and ensure U.S. Drug Enforcement Agency authorized witnessed destruction of controlled substances. They can also provide crowd control and watch for problem people. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with the law enforcement agency providing an officer for the event, whether they have requirements for the type of packaging the drugs must be contained in to be accepted into their evidence locker, or if containers the collection event will provide are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel. This is optional at the discretion of collection organizers and not required for all events.

c. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled pharmaceutical waste, inventory controlled substances, witness, and sign the inventory.
d. Hazardous Waste Personnel - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste on the same day as the event, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, and provide weight of materials collected.

e. Medical Monitoring Personnel that are handling the pharmaceuticals should be in a medical monitoring program to assure that they have not ingested pharmaceuticals that will be deleterious to their health.

2. Staffing for Events That Don't Collect Controlled Substances -The following staff are recommended at collection sites:

a. Greeter
b. Pharmacist
c. Data Entry Person
d. Hazardous Waste Company

III. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs Through a Mail Back Program

In some jurisdictions mailing back used and unused pharmaceuticals may be the only or most convenient option to disposing of those items. An example is the State of Maine, which uses pre-paid mailing envelopes available at pharmacies, doctors' offices and post offices. In addition, some pharmaceutical companies will take back their own drugs via mail. An example of this is Celgene, who allows patients to return unused drugs purchased from the company, such as thalidomide, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

1. Determine locations where pharmaceuticals can be mailed to for proper management. These facilities must be able to accept controlled substances for destruction. In addition, these facilities must be able to provide data on the amounts of pharmaceuticals received and destroyed.

2. Obtain self-sealing pre-addressed and pre-stamped envelopes that are durable enough to be mailed to a destruction center. The envelopes should also include an instruction sheet on how to package and send the pharmaceuticals.

3. Provide postage-paid envelopes to pharmacies to be provided to customers that will be utilized for the mailing and destruction of unused and expired pharmaceuticals.

4. The envelopes should be tracked to assure that all envelopes are used for their intended purposes and that all of the pharmaceuticals get to the destruction facility.

5. Advertise the program at pharmacies, convalescent homes, and retirement homes to assure the program is not underutilized.

6. As the program's success increases, expand to more age groups and to more sites that distribute the envelopes.

7. Review data on the amounts of pharmaceuticals collected to assure that the amounts are increasing. Make changes as needed to the program to assure continued growth.

Additional Procedures for Model Pharmaceutical Waste Collection and Disposal Programs

For additional procedures, contact the Northeast Recycling Council at www.nerc.org. Additional practices for conducting an event that would be beneficial to other collection programs, and can be provided by e-mail to James Cropper at jcropper@ciwmb.ca.gov.

DRAFT

Appendix I-Definitions

1. Controlled Substance-any substance listed in Chapter 2 (commencing with Section 11053) of Davison 10 of the CA Health & Safety Code.

2. Event – Include programs and one- time events for the collection of pharmaceutical waste to assure appropriate disposal of these items.

3. Collection Programs – include permanent collection programs, temporary collection programs, and mail back collection programs

4. Model Program-CIWMB a[p[proved program through which the public may return unused or expired pharmaceuticals that meets statutory criteria.

5. Over the Counter Drug-a non-prescription drug a defined per CA Business & Professions Code Section 4025.1 which states "non-prescription drugs" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the laws and rules of this state and the federal government.

6. Participant-any entity CIWMB finds appropriate to implement or evaluate a model pharmaceutical waste program. The participant must agree to participate as a model program. Entities that may qualify to participate:
a. Governmental entities,
b. Pharmacies,
c. Veterinaries,
d. Clinics, and
e. Other Medical Settings.

7. Pharmaceutical Waste-In this document it is considered to be a prescription drug dispensed to a consumer or a non-prescription item, no longer wanted or need by the consumer and includes pharmaceuticals in many delivery systems, such as pills, liquids, and inhalers.

8. Prescription Drug-is a dangerous drug as defined per CA Business and Professions Code Section 4022 which means any drug unsafe for self-use in humans or animals, without the oversight of a licensed prescriber and includes the following:

(a) any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription, "Rx only", or words of similar import.

(b) any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to CA Business & Professions Code Section 4006.

Appendix II-Procedural Approaches to the Collection of Pharmaceutical Waste

Approach #1: All Medications Accepted, Segregate Controlled Pharmaceutical Waste

- Need law enforcement and pharmacist
- All flyers, outreach, media and signs should include: "Keep medication in original containers with your name and medical information marked out." (In case of accidental ingestion before event and ease of segregation.)
- All unwanted meds screened by pharmacist to determine whether controlled or non-controlled.

Pharmacist places controlled meds in a container for law enforcement and inventories controlled medication if local law enforcement requires. Pharmacist places non-controlled meds in container to be hauled by medical waste hauler. Non-controlled meds can be handled by event staff, excess packaging can be removed for recycling.

Law enforcement handles all collected pharmaceuticals as they would seize evidence: witnessed incineration.

Pro: all medication is accepted.
Con: law enforcement and pharmacist help may be difficult to obtain.

Approach #2: All Pharmaceutical Waste Accepted and Treated as Controlled Substances

- Need law enforcement participation
- All flyers, outreach, media and signs should include: "Keep medication in original containers with your name and medical information marked out." (In case of accidental ingestion before event.)

All unwanted prescription drugs placed in one container that will be taken by law enforcement. Law enforcement handles all collected pharmaceutical waste as they would seize evidence: witnessed incineration.
Pro: all pharmaceutical waste are accepted.
Con: law enforcement may balk at storing and disposing of large quantities. Some law enforcement may want inventory; if so, you will need a pharmacist, too.

Approach #3: No Controlled Substances Accepted

Approach used if no law enforcement or pharmacist help available. 90% of unwanted medication is not controlled and is acceptable; All flyers, outreach, media and signs advise residents as follows:
"No Controlled Substances (e.g. narcotics, vicodin, ritalin, codeine, oxycodone, valium, etc.)"

"Keep medication in original containers with your name and medical information marked out." (In case of accidental ingestion before event.) Make a list of DEA controlled substances available at event if resident asks what a controlled substance is. If resident advises event staff that (s)he has a controlled substance, event staff may not accept it. Resident places unwanted prescription pharmaceutical waste in a container him/herself. Event staff do not handle prescription meds.

Over-the-counter meds may be removed from packaging by staff to reduce bulk and to recycle packaging.
Do not sort any collected prescription meds and incinerate all prescription and over-the-counter meds through a medical waste hauler.

Pro: does not require law enforcement or pharmacist help.
Con: ~10% of drugs may not be collected.

Approach #4: Permanent Sites - Some local household hazardous waste facilities accept medication and dispose of as poison solids.

Outreach states, "No controlled substances accepted."
San Mateo County: permanent one-way bins at 13 police stations; material consolidated in three locations; medical waste hauler removes collected medication periodically. All medication is accepted.

Teleosis Institute: permanent collection sites at pharmacies and medical offices; incoming medication screened for acceptability – no controlled substances accepted; medical waste hauler removes collected medication. www.teleosis.org

Sources

Rubinstein, Lynn, Northeast Recycling Council, Inc., Operating Unwanted Medication Collection-A Legal and Safe Approach, www.nerc.org, September, 2006.

Bay Area Pollution Prevention Group, Report on the San Francisco bay Area's Safe medicine Disposal Days, August 2006.

Community Medical Foundation for Patient Safety, www.comofcom.com.

Illinois/Indiana Sea Grant, Disposal of Unwanted Medicines: A Resource for Action in Your Community, How to Hold a Successful Unwanted Medicine Collection Event, http://www.iisgcp.org/unwantedmeds/3HTHAC.html

No Drugs Down the Drain, www.nodrugsdownthe drain.org.

Attachment 7

Assembly Bill 501 and Governor's Veto Message

BILL NUMBER: AB 501
VETOED DATE: 09/27/2008

To the Members of the California State Assembly:

I am returning Assembly Bill 501 without my signature.

While I support the safe and proper disposal of home-generated sharps waste, this bill only applies to the disposal of prefilled injection devices. Although the use of these devices is increasing, omitting other types of home-generated sharps from the bill could potentially create an unintentional disincentive for the production and use of these prefilled injection devices. Limiting the types of sharps in this way, making the bill's provisions take effect only upon the request of consumers, and the options provided to the manufacturers of these devices will likely reduce the efficacy of this bill. Lastly, and most importantly, this bill is unclear as to who bears the ultimate cost of these containers. This problem requires a solution that must be shared among all the stakeholders, not just the manufacturers of one type of device.

Sincerely,

Arnold Schwarzenegger

Assembly Bill No. 501

Passed the Assembly August 13, 2008

_____

Chief Clerk of the Assembly

Passed the Senate July 14, 2008

_____

Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2008, at _____ o'clock ____M.

_____

Private Secretary of the Governor

CHAPTER _____

An act to add Section 118288 to the Health and Safety Code, relating to pharmaceutical devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 501, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act prohibits, on or after September 1, 2008, a person from knowingly placing home-generated sharps waste in certain types of containers, provides that home-generated sharps waste is to be transported only in a sharps container, as defined, or other container approved by the department or local enforcement agency, and requires this waste to only be managed at specified locations consistent with existing law.

This bill would require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to arrange to provide, upon request from a consumer, a postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the department or a sharps container for the safe storage and transport of sharps to a sharps consolidation location approved by the department or a clinic, physician, or pharmacy that accepts home-generated sharps waste, as defined, along with concise information on safe disposal alternatives and options for sharps and notice of the act's above described prohibition, that commences September 1, 2008. As a means of meeting these above described requirements, the manufacturer may provide the consumer with a coupon that can be exchanged for, or a toll-free telephone number or Web site that can direct the patient to a supplier of, a qualified sharps container. This bill would also prohibit the manufacturer, or any person or agent with whom the manufacturer contracts, from using information collected for this purpose for any other purpose.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) An estimated 1 million Californians must self-inject prescription medications annually to treat a broad range of serious health problems.

(b) The use of prefilled syringes, prefilled pens, and other prefilled devices with needles is an effective method of prescription drug delivery and is expected to increase significantly in the future. Prefilled syringes, prefilled pens, and other prefilled devices with needles are clearly identified and linked to specific pharmaceutical manufacturers for the provision of their product to California residents.

(c) The increased use of prefilled syringes, prefilled pens, and other prefilled devices with needles will generate millions of home-generated sharps each year. Prefilled pen devices are being used for the treatment of some of the most serious health conditions such as HIV/AIDS, hepatitis C, and many other diseases. If improperly disposed in solid waste and recycling containers these needles will result in significant public health risks.

(d) The Legislature has found that sharps mail-back programs utilizing containers and packaging approved by the United States Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that the cooperative efforts of the pharmaceutical industry are needed to develop a safe needle disposal system for California.

SEC. 2. Section 118288 is added to the Health and Safety Code, to read:

118288. (a) Upon request of a consumer who has been dispensed a prefilled syringe, prefilled pen, or other prefilled injection device for administration at home, a pharmaceutical manufacturer shall arrange to provide the consumer with either of the following:

(1) A postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the State Department of Public Health.

(2) A sharps container for the safe storage of, and transport to, a sharps consolidation location that is approved by the State

Department of Public Health or to a clinic, physician, or pharmacy that accepts home-generated sharps waste.

(3) In addition to providing an appropriate sharps container, the manufacturer shall provide information on safe disposal alternatives and options for sharps and notice to the consumer that effective September 1, 2008, California law prohibits a person from knowingly disposing of home-generated sharps in any container used for the collection of solid waste, recyclable materials, or green waste or for the commercial collection of solid waste or recyclable materials from business establishments.

(b) For purposes of this section, "sharps container" has the same meaning as in Section 117750.

(c) As a means of meeting the requirements of subdivision (a), a manufacturer may do either of the following:

(1) Supply a coupon, either to be delivered to the patient or with the device when it is dispensed, that may be exchanged for a sharps container that meets the requirements of paragraph (1) or (2) of subdivision (a).

(2) Provide a toll-free telephone number or Web site, noted on the packaging containing the device, that directs the patient to a supplier of sharps containers that meets the requirements of paragraph (1) or (2) of subdivision (a).

(d) A manufacturer shall not use or disclose information that it receives in the course of complying with this section for any other purpose, including, but not limited to, marketing, without the written consent of the consumer. This prohibition shall apply to any person or agent with whom the manufacturer contracts or otherwise makes arrangements to carry out the requirements of this section.

Approved _____, 2008

_____

Governor

Attachment 8

List of Drugs Involved in Medication Errors Investigated by the Board of Pharmacy 2007-08

All pharmacy settings July 1, 2007 – July 1, 2008

Common Look-alike Sound-alike Errors

Prescribed	Dispensed
Abilify	Adderall XR
Augmentin	Amoxicillin
Darvocet N	Darvon N
Desipramine	Disopyamide
Felodipine	Feldene
Hydralazine	Hydroxyzine
Lipitor	Lisinopril
Lovastatin	Loratadine
Lumigan	Lotemax
Naproxen	Naproen
Metolazone	Metoclopramide
Rispersal	Requip
Parnate	Paxil
Pepcid	Prilosec
Pravachol	Prevacid
Simvastatin	Sertraline
Trazodone	Tramadol
Zyrtec	Zantac
Zyrtec	Zyprexa
Zetia	Zyrtec

② PRESCRIPTION ERRORS DATA

All pharmacy settings July 1, 2007 – June 30, 2008

Medication Error Category	Number	Percent of Total Citations
Wrong Drug	174	39%
Wrong Strength	72	16%
Wrong Instructions	77	17%
Wrong Patient	46	11%
Wrong Medication Quality	24	5%
Other Labeling Error	25	6%
Compounding/Prearation Error	11	2%
Refill Errors (frequency, timeliness)	1	<1%
Total # Citations for errors (may have more than one category listed)	445	

Attachment 9

First Quarterly Strategic Plan Update 2008-09

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1: Achieve 100 percent closure on all cases within 6 months.

Measure: Percentage of cases closed.

Tasks:

1. Mediate all complaints within 90 days (for cases closed during quarter).

	N	< 90 days	< 120 days	< 180 days	Longer	Average Days
Qtr 1	197	173	6	2	16	47
		88%	3%	1%	8%	
Qtr 2						
Qtr 3						
Qtr 4						

2. Investigate all cases within 120 days (for cases closed during quarter).

	N	< 120 days	< 180 days	< 270 days	Longer	Average Days
Qtr 1	499	378	79	28	14	63
		76%	16%	6%	3%	
Qtr 2						
Qtr 3						
Qtr 4						

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	N	< 180	< 270	< 365	> 365
Closed, no additional action	186	170	10	5	1
Cite and/or fine letter of admonishment	476	447	18	3	8
Attorney General's Office	34	21	6	4	3
Qtr 2	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 3	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 4	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					

Objective 1.2	Manage enforcement activities for achievement of performance expectations.
Measure:	Percentage compliance with program requirements.

Tasks:

1. Administer the Pharmacists Recovery Program.

	Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program
Qtr 1	20	3	0	5
Qtr 2				
Qtr 3				
Qtr 4				

2. Administer the Probation Monitoring Program.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Individuals	108			
Sites	3			
Tolled	18			
Inspections Conducted	41			
Successfully Completed	9			
Petitions to Revoke Filed	1			

3. Issue all citations and fines within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	423	389	29	3	2	15
		92%	7%	1%	.5%	
Qtr 2						
Qtr 3						
Qtr 4						

4. Issue letters of admonishment within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average
Qtr 1	31	22	6	3	0	24
		71%	19%	10%	0%	
Qtr 2						
Qtr 3						
Qtr 4						

5. Obtain immediate public protection sanctions for egregious violations.

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

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

	30 days	60 days	> 60 days	N
Qtr 1	0	0	3	3
Qtr 2				
Qtr 3				
Qtr 4				

Objective 1.3

Achieve 100 percent closure on all administrative cases within 1 year.

Measure:

Percentage of administrative cases closed within 1 year.

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	13	4 30.77%	2 15.38%	5 38.46%	0 0%	2 15.38%	552.62
Qtr 2							
Qtr 3							
Qtr 4							

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.

Tasks:

1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.

	Number of Inspections	Aggregate Inspections This Cycle	Percent Complete
Qtr 1	345	4271	59%
Qtr 2			
Qtr 3			
Qtr 4			

2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.

	Number of Inspections	Number Inspected Late
Qtr 1	59	0
Qtr 2		
Qtr 3		
Qtr 4		

3. Initiate investigations based upon violations discovered during routine inspections.

	Number of Inspections	Number of Investigations Opened	Percent Opened
Qtr 1	345	70	20%
Qtr 2			
Qtr 3			
Qtr 4			

Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California. *Sept. 28, 2006:* *Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.* *Sept. 30, 2006:* *Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.* *Oct. 6, 2006:* *FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 & 8 Meeting.* *Dec. 2006:* *Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.* *Jan. 2007:* *EPCglobal finalizes electronic messaging standards for electronic pedigrees.* *Feb. 2007:* *EPCglobal convenes regional meeting with hospitals to discuss implementation issues of e-pedigree in these facilities. Hospitals are encouraged to join the board's Workgroup on Implementation of E-Pedigree Meetings.* *March 2007:* *Two board members and executive staff meet with nine EPCglobal representatives to walk through EPCglobal's messaging standards and business scenarios. The standard complies with California's e-pedigree requirements although some questions remain about situation-specific criteria.* *Board convenes fifth Workgroup on Implementation of E-pedigree Meeting. Presentations are made by EPCglobal, AmerisourceBergen and SupplyScape.* *May 2007:* *Board presents information at the National Association of Boards of Pharmacy annual meeting on California's electronic pedigree requirements in both a poster session and a full presentation to the full assembly.* *June 2007:* *Board convenes sixth Workgroup on E-pedigree Meeting, with the largest attendance of any prior meeting. Presentations were made by EPCglobal, Pfizer, Walgreens and PhRMA. Hospital pharmacies were specifically invited to attend this meeting.* *Dec. 2007:* *Enforcement Committee Meeting solely dedicated to workgroup on E-Pedigree (an eight-hour meeting). Largest meeting to date involving over 400 individuals representing all members in the pharmaceutical supply chain. Board encourages discussion of grandfathering and inference, and seeks information via a template. Industry seeks delay. Many request board to specify technology. Board releases template for readiness assessment.* *Jan. 2008:* *Board reviews requests for delay until 2011 from members of the pharmaceutical supply chain.* *Feb. 2008:* *Questions and Answers released. Specialized area of the Board's Website is created to consolidate e-pedigree information.* *March 2008:* *Board delays implementation date for e-pedigree requirements from January 1, 2009 until January 1, 2011.*

April 2008:	*Board sponsors legislation that will enhance some of the pedigree requirements, allowing for staggered implementation, as well as provisions for regulations on inference and grandfathering.*
June 2008:	*Board meets as a public meeting rather than an Enforcement Committee meeting to hear discussions and presentations on the status of e-pedigree implementation and to discuss and review the amendments to its e-pedigree legislation, SB 1307.*
Sept. 2008:	*Governor signs SB 1307, which delays implementation until 2015-2017, and makes other modifications.*
Oct. 2008:	*Board convenes workgroup on e-pedigree meeting.*
2.	**Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.**
Sept. 2006:	*Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.*
Oct. 2006:	*Board adds Consumer friendly materials regarding sales of these drugs to its Website.*
July 2007:	*Board hears presentations on EPCglobal standards.*
Sept. 2007:	*Enforcement Meeting has large audience (200 people).* *Presentations by PhRMA, GSK, Bracco, CPhA, EPCglobal, Walgreens, Rite Aid, CVS, rfXcel, and HDMA.* *Federal legislation enacted for the FDA supports California requirements.* *Major presentations made on California's standards to LogiPharma (Philadelphia) and HDMA Subcommittee of board meets with EPCglobal representatives on standards.*
Oct. 2007:	*Major presentations at EPCglobal Conference in Chicago.* *At Board Meeting, presentations made by IBM/Amerisource Bergen, Alien Technology and EPCglobal on readiness of technology.*
3.	**Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances.**
Sept. 2006:	*DEA releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.*
Oct. 2006:	*Board considers proposed rule.*
Nov. 2006:	*Board submits letter supporting change in DEA policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.*
2nd Qtr 07/08:	*DEA agrees to allow a 90-day supply of Schedule II drugs to be prescribed at one time in serial prescriptions.*
June 2008:	*DEA published proposed regulations that would provide physicians and other authorized prescribers with the option of issuing electronic prescriptions for controlled substances.*
July 2008:	*Board to discuss Federal Drug Enforcement Administration's proposed rule to allow e-prescribing for controlled substances at its July board meeting.*
Sept. 2008:	*Board submits comments on DEA proposed requirements for e-prescribing of controlled substances.*

4. Evaluate establishment of an ethics course as an enforcement option.

June 2007	*Subcommittee meets with ethicist trainer for Dental Board.*
Aug. 2007:	*Subcommittee meets with Medical Boards Ethics course provider (Institute for Medical Quality).*
Oct. 2007:	*Institute for Medical Quality provides information to board about program; recommendation of committee is to move forward with the specialized program. Board approves development of program at board meeting.*
Jan. 2008:	*Staff compile resource materials and begin steps to develop framework for program. Board agrees to establish program.*
April 2008:	*Legislation/Regulation Committee to develop draft language for a regulatory proposal. Draft language for a new regulation to be presented and reviewed at July 2008 board meeting.*
July 2008:	*Board moves ethics regulation for 45 day notice and plans action at the October Board Meeting.*
Oct. 2008:	*Board holds regulation hearing on proposed requirements for the ethics class.*

5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.

May 2007:	*Board staff provides presentation at National Association of Boards of Pharmacy annual meeting on California's pedigree requirements.*
June 2007:	*Board works with Center for Medicare and Medicaid Services on security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.*
Nov. 2007:	*Staff meets with FDA officials to discuss California's e-Pedigree requirements and new federal law for FDA's action involving pharmaceutical chain security.*
May 2008:	*The Executive Officer gave a poster presentation on the board's e-pedigree requirements at the annual National Associations of Boards of Pharmacy (NABP) meeting.*
May 2008:	*The Executive Officer attends a drug tracking conference and presents status of California's e-pedigree efforts.*
June 2008:	*Executive staff and supervising inspector provids a presentation via videoconference at the Fourth Global Forum on Pharmaceutical AntiCounterfeiting.*

6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.

Sept. 2007:	*Provided comments on proposed statutory requirements.*
Dec. 2007:	*Sought DCA's support for involvement in e-prescribing by the Administration. Provided comments on proposed e-prescribing initiatives.*

7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.

June - *Oct. 007:* *Board works with the Department of Health Care Services to implement security forms until subsequent federal legislation delays implementation until April 2008.*

Dec. 2007: *Meeting with Department of Health Care Services on issues involving security forms for MediCal prescriptions.*

April 1, 2008: *Requirements that all written prescriptions for MediCal prescriptions be written on security forms containing at least one specified security component takes effect.*

April 2008: *Subscriber alert released with information for contact resources from the California Department of Health Care Services about security forms for MediCal prescriptions.*

Oct. 2008: *Requirements for security forms in place.*

8. Liaison with other state and federal agencies to achieve consumer protection.

1st Qtr 07/08: *Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.*

2nd Qtr 07/08: *Bimonthly meeting with the Department of Health Care Services continue.*
Board inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services.
Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.

3rd Qtr 07/08: *Bimonthly meeting with the Department of Health Care Services continue.*
Board works with the Drug Enforcement Administration on joint investigations and received specialized training.

4th Qtr 07/08: *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.*

9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public.

March 2008: *Second meeting with state agency stakeholders on developing components for model programs that conform with diverse state agency security and safety requirements.*

June 2008: *Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take back programs.*

Aug. 2008: *Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.*

Oct. 2008: *Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps.*
Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.

	10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas. *4th Qtr 07/08:* *Board initiates inspections of 40 California hospitals looking for counterfeit heparin and unlicensed sales but discovers recalled heparin still in 40 percent of hospitals inspected. Board notifies FDA and California Department of Public Health and initiates inspections of 533 hospitals during April-June. Recalled heparin is found in 94 of these facilities. Data reported to board during June Board Meeting.* *June 2008:* *Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take back programs.* *Aug. 2008:* *Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.* *Oct. 2008:* *Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps. Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.* *1st Qtr 08/09:* *The Script highlights problems found in heparin inspections. Citations and fines issued to facilities with recalled heparin. Work with hospitals begins to strengthen drug control within facilities.*

Attachment 10

Enforcement Statistics 2008-09

Board of Pharmacy Enforcement Statistics
Fiscal Year 2008/2009

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 08/09
Complaints/Investigations					
Initiated	466				466
Closed	705				705
Pending (at the end of quarter)	1724				1724
Cases Assigned & Pending (by Team)					
Compliance Team	224				224
Drug Diversion/Fraud	160				160
Probation/PRP	12				132
Mediation/Enforcement	145				145
Application Investigations					
Initiated	81				81
Closed					
Approved	46				46
Denied	10				10
Total*	70				70
Pending (at the end of quarter)	257				257
Citation & Fine					
Issued	424				424
Citations Closed	258				258
Total Fines Collected	$418,500.00				$418,500.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2008/2009

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 08/09
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	37				37
Pleadings Filed	29				29
Pending					
Pre-accusation	73				73
Post Accusation	76				76
Total	153				153
Closed**					
Revocation					
Pharmacist	0				0
Pharmacy	1				1
Other	3				3
Revocation,stayed; suspension/probation					
Pharmacist	3				3
Pharmacy	0				0
Other	0				0
Revocation,stayed; probation					
Pharmacist	0				0
Pharmacy	0				0
Other	1				1
Suspension, stayed; probation					
Pharmacist	0				0
Pharmacy	0				0
Other	0				0
Surrender/Voluntary Surrender					
Pharmacist	2				2
Pharmacy	0				0
Other	1				1
Public Reproval/Reprimand					
Pharmacist	0				0
Pharmacy	0				0
Other	0				0
Cost Recovery Requested	$46,643.50				$46,643.50
Cost Recovery Collected	$25,856.54				$25,856.54

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2008/2009

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 08/09
Probation Statistics					
Licenses on Probation					
Pharmacist	96				96
Pharmacy	2				2
Other	13				13
Probation Office Conferences	10				10
Probation Site Inspections	41				41
Probationers Referred to AG for non-compliance	3				3

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 09/30/08)

Program Statistics					
In lieu of discipline	1				1
In addition to probation	3				3
Closed, successful	5				5
Closed, non-compliant	0				0
Closed, other	1				1
Total Board mandated Participants	59				59
Total Self-Referred Participants*	20				20
Treatment Contracts Reviewed	56				56

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of September 30, 2008

California State Board of Pharmacy Citation and Fine Statistics July 1, 2008 – September 30, 2008

423 Citations were issued this fiscal year

Total dollar amount of fines issued this fiscal year
$ 867,275.00

Total dollar amount of fines collected
$418,500.00*

*This amount also reflects payment of the citations issued before July 1, 2008.

The average number of days from date case is opened until a citation is issued is **156**

Average number of days from date case is routed to Citation Unit to date citation is issued **13**

110 citations are closed. The average number of days from date citation is issued to date citation is closed is **38**

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
423	66	3	48	27	128	3	16	0

Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
12	10	1	7	18	72	3	9	0

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

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	25%	1716 - Variation from prescription	23%	4301(j)/111295/351-Unprofessional conduct - violation of any statutes of this state or of the United States regulation controlled substances or dangerous drugs/t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated/ Adulterated drugs and devices	45%
1732.5(b)- Renewal requirements for pharmacist - Retain certificates of completion for four years	17%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	7%	4319(a)- Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity...	10%
1732.5(a)- Renewal requirements for pharmacist - 30 hours of continuing education	15%	4301(j)/111295/351-Unprofessional conduct - violation of any statutes of this state or of the United States regulation controlled substances or dangerous drugs/t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated/ Adulterated drugs and devices	5%	1716-Variation from prescription	2%
4301(j)/111295/351-Unprofessional conduct - violation of any statutes of this state or of the United States regulation controlled substances or dangerous drugs/t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated/ Adulterated drugs and devices	6%	4104-Procedures to take action when licensed individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity	4%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	2%
1761(a)/11170-No pharmacist shall compound or dispense any prescription, which contains any significant error or omission... /Prohibition on prescribing, etc. controlled substance for self	3%	1707.2 – Duty to consult	3%	4104-Procedures to take action when licensed individual is impaired or known to have diverted or used drugs; Written policies; Report; Immunity	2%
1707.2 – Duty to consult	3%	1709.1- Designation of pharmacist in charge	3%	1304.11-Inventory requirements	1%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	3%	4113(c)- Pharmacy shall notify the board within 30 days of the date a Pharmacist ceases to be pharmacist-in-charge	3%	1715-Self-assessment of a pharmacy by the pharmacist in charge	1%
1761(a)- No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	3%	1711-Quality assurance program	2%	4301(g)- Falsely representing state of fact	1%
1711-Quality assurance program	2%	4125.1711-Pharmacy quality assurance program required/Quality assurance program	2%	1305.13(e)- Purchaser must record on Copy 3 of the DEA Form 222 ...	1%
1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	2%	4115(e)- Pharmacy technician license required	2%	4115(e)- Pharmacy technician license required	1%

Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were six office conferences held so far this fiscal year

Number of requests	116

Number scheduled	116

Number appeared	83

Number Postponed	21**

**Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	10
Failed to appear	3

Office Conference between July 1, 2008 and September 30, 2008

Total number of citations affirmed	33

Decision	Total citations	Total dollar amount reduced
Modified	22	$19,650
Dismissed	10	$9,250.00
Reduced to Letter of Admonishment	0	$0.00

Please note fifteen cases are pending decisions due to additional investigation being required.

Attachment A

Minutes of the Enforcement Committee and WorkGroup on E-Pedigree Meeting of October 6, 2008

Minutes from the Enforcement Meeting on October 6, 2008 will be sent via e-mail prior to the Board Meeting.