



California State Board of Pharmacy

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

NOTICE OF MEETING and AGENDA

**Enforcement Committee and
Work Group On E-Pedigree Meeting**

*Contact Person: Virginia Herold
(916) 574-7911*

Date: October 6, 2008
Time: 9:30 a.m. – 1:00 p.m.
Place: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Leech at (916) 574-7912, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

MEETING AGENDA

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order

9:30 a.m.

I. Workgroup on E-Pedigree

Progress on the Implementation of Electronic Pedigrees Pursuant to the California Business and Professions Code

1. Update of Provisions Contained in SB 1307 (Ridley-Thomas)
2. Presentations and Updates by GS1, Manufacturers, Wholesalers, Pharmacies and Their Associations to Implement Electronic Pedigrees

II. Enforcement Committee

1. Update: CURES Moving to Provide Online, Near Real Time Reports to Practitioners in the Future
2. Comments Submitted to the Federal Drug Enforcement Administration on Its Proposed Rule to Allow E-prescribing of Controlled Substances (Docket No. DEA – 218: Electronic Prescriptions for Controlled Substances)
3. Update on the Implementation of Drug Take Back Programs from Patients (SB 966, Simitian, Chapter 542, Statutes of 2007) and
4. Role of Reverse Distributors in Picking up Medical Waste and Returned Drugs
5. Discussion of Sharps Take Back by Pharmacies

6. E-Prescribing Forum Set for November 20, 2008
7. Medication Errors Made by California Pharmacies 2007-08
8. Discussion: Hospital Pharmacies' Control of Drugs within a Hospital.
9. Public Comment for Items Not on the Agenda*

**(Note: the committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Adjournment

1:00 p.m.

Note: Adjournment time is approximate

Meeting materials will be available from the board's Web site by October 2, 2008



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STATE AND CONSUMERS AFFAIRS
DEPARTMENT OF CONSUMER
ARNOLD SCHWARZENEGGER, GO

Date: September 30, 2008

To: Enforcement Committee

Subject: Workgroup on E-Pedigree

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

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, 3PLs, 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. A copy of this letter is also included in this tab section.

At this E-pedigree Workgroup Meeting, Virginia Herold will provide a PowerPoint presentation of the major provisions enacted to California law by SB 1307.

Thereafter, there will be presentations by those supply chain members who are interested in providing information to the committee. Bob Celeste of GS1 will update the committee of the work of this standards setting organization. There will also be a short PowerPoint presentation on the readiness of the industry by one manufacturer.

There is no formal sign up for these presentations, other than to sign in at the meeting. The committee would welcome comments on how they would like future Workgroup Meetings to be structured.

The committee is interested in hearing from the supply chain participants about what guidance they seek from the board in these meetings in the future.

Lastly, included in this tab section is a recent survey by Pharmaceutical Commerce Magazine regarding the readiness for serialization and e-pedigree.



MEMBERS
Vice Chair – SAM AANESTAD
RON CALDERON
ELLEN CORBETT
JEFF DENHAM
DEAN FLOREZ
TOM HARMAN
JOE SIMITIAN
LELAND YEE

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



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

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

Passed the Senate August 21, 2008

Secretary of the Senate

Passed the Assembly August 18, 2008

Chief Clerk of the Assembly

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

Private Secretary of the Governor

CHAPTER _____

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.

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.

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 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

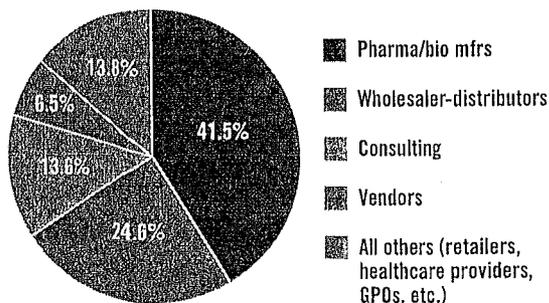


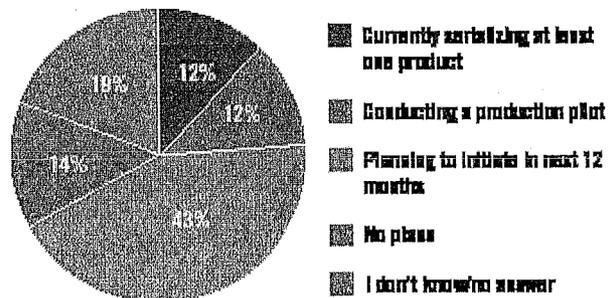
Fig. 2 Job Function

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.

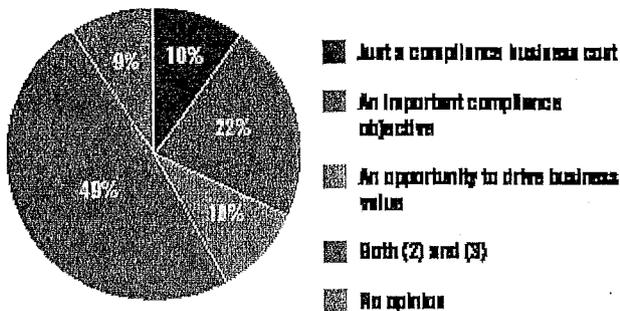
PERCEPTIONS OF BENEFITS/PROBLEMS

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



< continued from page 11

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 perceptual 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	Respondent Type		
	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	Respondent Type		
	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



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

Date: October 2, 2008

To: Enforcement Committee

Subject: Update: CURES Online "Near Real Time" Reports

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 dispensing 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").

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.

Currently Mr. Pack is seeking private donations to pay for this system, which is necessary given the state's fiscal condition. A copy of this material is provided in this tab section. I am aware that 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."

The committee may wish to make a recommendation to continue to support this project.



Patient Activity Report (PAR)

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

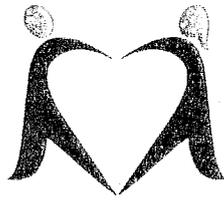
PHARMACY INFORMATION			
Pharmacy DEA No.:		Pharmacy License No.:	
Pharmacy Name (As it Appears on CA Pharmacy License)			
Pharmacy Address			
	City:	State:	Zip Code:
Telephone No.:		Fax No.:	

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
<p>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.)</p> <p style="text-align: center;">Please FAX your request to (916) 319-9448</p> <p style="text-align: center;">Or mail to: California Department of Justice, P.O. Box 160447, Sacramento, CA 95816</p> <p>Pharmacist Signature _____ Date _____</p> <p>Print Pharmacist Name _____ <small>(as it appears on your CA Pharmacist License)</small></p> <p>Pharmacist License No. _____ Pharmacist D EA No. _____</p>

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



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	Virginia Herold DCA
Attorney General Jerry Brown	Steven Gray, Kaiser Permanente
Bob Pack	The California DOJ
Kathy Ellis DOJ- CURES Manager	California Board of Pharmacy
Sheri Hofer, Manager DOJ- IT Dept.	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. There 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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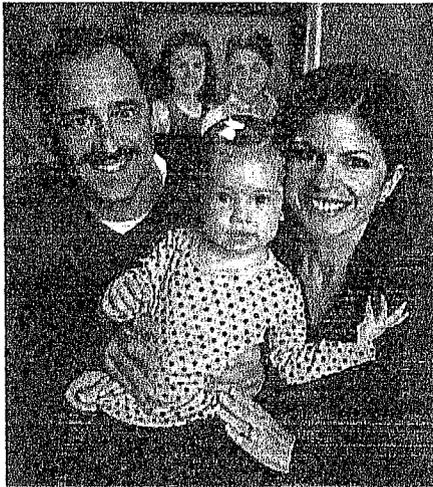
Raids Highlight Prescription Drug Debate

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.

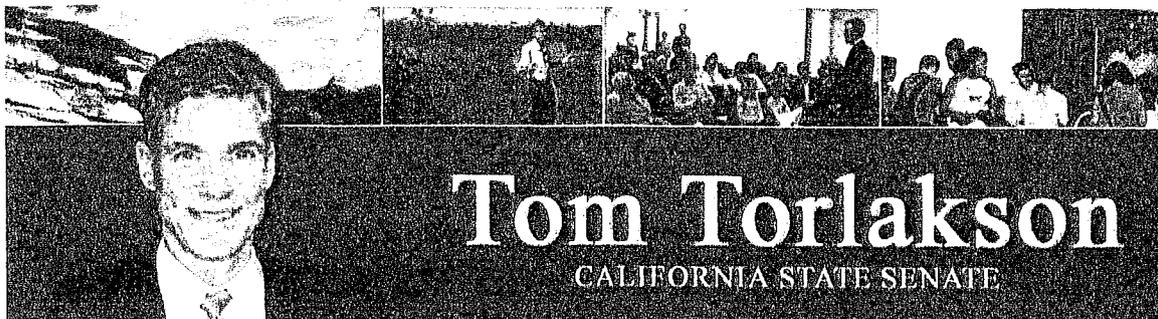
"What we have going on right now is a society wide witch hunt," said Dr. Frank Fisher, who was recently exonerated following a seven-year court battle that included murder charges, malpractice suits and a medical board investigation into the deaths of several patients for whom he prescribed painkillers.

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 Aiana, 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.



California State Board of Pharmacy

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

Date: September 30, 2008

To: Enforcement Committee and Work Group on E-Pedigree

Subject: Comments Submitted to the Federal Drug Enforcement Administration (DEA) on its Proposed Rule to Allow E-Prescribing of Controlled Substances

During the July 2008 Board Meeting, the board discussed the DEA 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.

Since 1994 the board has secured changes in laws to allow for electronic transmission of prescriptions, and since this time, California has been able to e-prescribe. However, because the DEA would not allow e-prescribing for controlled drugs, full implementation of e-prescribing could never be realized.

At the conclusion of the board's discussion, the board voted to prepare comments for the federal DEA in support of the proposed rule to allow e-prescribing of controlled substances.

A letter was sent on behalf of the board and confirmed that the board is encouraged that the DEA is moving forward to permit e-prescribing of controlled substances but 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.

Following is a copy of the letter submitted.



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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 Morrisette 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,

A handwritten signature in cursive script that reads "Kenneth H. Schell".

KENNETH H. SCHELL
President, California State Board of Pharmacy



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

Date: September 30, 2008

To: Enforcement Committee

Subject: Update on Take-Back Drug Programs in Pharmacies

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 follows). 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 regulations 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 dispose 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 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. Individuals from this agency may attend this meeting to respond to questions asked by the committee.

I hope to provide the finalized components of these programs to the board in October, in time for the board to submit comments to the Integrated Waste Management Board in November.

Since late winter, some board staff have been attending meetings with a group of individuals from the Integrated Waste Management Board, Toxics Program and Medical Waste Program, divisions within various state agencies.

The greatest problem for the board with drug take-back programs is the potential for these drugs to be diverted to the streets. 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.

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

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.

The committee may wish to discuss any concerns it has with drug take back programs, and what preferred options it would like to commend to the Integrated Waste Management Board for its decision making in November.

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.

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Best Management Practices for the Collection of Unused and Expired Pharmaceuticals

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 and 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 to the CIWMB. The purpose of the survey was to acquire information on existing pharmaceutical waste collection programs in California. From the survey results, Best Management Practices (BMPs) were developed that would help create model 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 from SB 966 and the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health, Board of Pharmacy, Department of Toxic Substances Control and State Water Resources Control Board):

1. Ensures the safe and environmentally sound disposal of pharmaceuticals;
2. Provides for the collection of pharmaceuticals that is convenient for consumers;
3. Provides the collection of pharmaceuticals at no additional cost to the consumer;
4. Ensures protection of public health and safety, the environment, and the health and safety of consumers and employees;
5. Provides a means to report to the Board the amounts and types of pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability;
6. Protects against the potential for the diversion of drug waste for unlawful use or sale;
7. Provides notice and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
8. Maintains privacy of all participants;
9. Segregates medications into controlled and non-controlled substances;
10. Ensures that medication information is legible, so that it can be identified in case of a poisoning or to determine if it is a controlled substance or not;
11. Develops a sustainable funding source for collection and disposal of pharmaceuticals, such as grants, utility funding, advanced disposal fees placed on pharmaceuticals and local general funds;
12. Strives to develop permanent collection programs rather than one-day events, so they will be more accessible to the public; and

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13. Provides consequences for failure to comply with model programs at the point of transportation, deposition, and consolidation.

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

I. Best Management Practices for the Collection of Unused and Expired Pharmaceuticals 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 and 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 programs.

A. Ongoing Collection Program Requirements

The following collection program requirements need to 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, and veterinary medications. Medical waste such as blood samples, vaccines and serum, and trauma scene waste will not be accepted. In addition, controlled substances should not be collected by these programs unless law enforcement is available to properly collect, conduct inventory, and dispose of them.

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.

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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. Pack pharmaceutical waste (controlled and non-controlled substances) in their original containers.

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

C. Storage - Never store collected pharmaceuticals at a HHW facility or any other setting, other than in the secure containers or in the custody of law enforcement due to the risk of theft or accidents.

D. Sharps - Be prepared for sharps by having sharps containers that can be mailed back to a sharps management company for disposal after the event.

4. 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.

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

6. Data Collection - Itemize amounts and types of pharmaceuticals collected so the information can be used for further study and recommendations for future collection. Examples of collection forms can be accessed at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com.

7. Education - Provide education about the problem of pharmaceutical waste entering waterways and drinking water to the community and customers dropping off pharmaceuticals.

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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 take back program.

B. Logistics and Equipment

1. Type of Collection Location - 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 would be those that are convenient to the public, can continue collection for a long period of time, and are willing to collect.

- A. Collection at Law Enforcement Facilities - If collection is at a police station, law enforcement must be able to collect the materials, document the amounts collected, and place in an area to be accumulated and destroyed.
- B. HHW Collection Site - If you use a collection site at the HHW facility, the site must have access to electricity, room for the hazardous waste containers, and room for workstations.

2. Government Agency Authorization - Determine if additional permits or approval are needed for pharmaceutical collection. All relevant agencies and programs have to authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health agencies, California Department of Public Health, local hazardous waste departments, and zoning departments for use permits.

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.

4. 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.

5. Advertising - Provide advertising which could include internet, web site ads, newspaper ads, fliers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual pictures distributed in utility bills

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in participating cities, movie ads, movie theatre ads shown in theaters, ads on buses and at bus stops, print ads in recycling guides, English and Spanish PSA's 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, 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.

6. Essential Equipment and Supplies

- A. Pharmacies - Lockable secure containers with a wire cage around them, black markers to cover up personal data, a form to track types and amounts of pharmaceuticals collected and signage informing the public about what can be collected. The containers should be located behind the counter.
- B. Police Stations - Refurbished containers with an inside collection container located near the building entrance or in the lobby that allows people to dump off pharmaceuticals and not be able to get them out again. Refurbished mail boxes, as an example, can be used to prevent theft.
- C. Permanent HHW Collection Facilities - 4 container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gal plastic container for mercury items), gloves, indelible markers, and 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 medications, inventory controlled substances, witness, and sign the inventory.
- B. Hazardous Waste Company (for HHW facilities) - The Hazardous Waste Company will provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove medications, 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. Do not allow medications 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 is required to be present to monitor and collect the controlled substances.

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

- A. Pharmacist (at pharmacies)

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B. Hazardous Waste Company (for HHW facilities)

II. Best Management Practices for the Collection of Unused and Expired Pharmaceuticals 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 medications are diverted from the collection event:

- A. Medications stay in their original containers.
- B. Personal information can be crossed out, but keep information about medication legible.
- C. Do not remove labels.
- D. No sharps.
- E. No thermometers.
- F. No medical waste, such as biohazardous waste, sharps waste, or medicinal preparations made from living organisms.
- G. Medications will be destroyed.
- H. If in a retail setting, no refunds and medications will not be resold or used.
- I. Provide where, when, hours of operation, and who to contact for more information.
- J. No cost to participate.

2. What Will Be Collected - All prescription medications should be accepted, including veterinary medications. It is recommended to accept over-the-counter medications.

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

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4. Packing Pharmaceutical Waste - Controlled and non-controlled substances should be packed separately and in their original containers.

A. Packing of Non-Controlled Substances

- 1). No loose pills should be placed in the hazardous waste container. A pharmacist should make a best faith effort to identify the medication. This will include using reference materials. Once identified, put the medication in a Ziploc® bag and mark the bag with an indelible marker indicating the type of medication and dosage. If the tablets remain unidentifiable, mark the bag "unknown."
- 2). Two types of containers must be provided for certain items: items under pressure and certain mercury-containing medications.

B. Packing Controlled Substances-This is at the discretion of the law enforcement agency. The signed inventory must accompany the medications and must stay with them in the evidence storage locker and through the point of destruction. Before the medications are destroyed, the contents are checked against the inventory to ensure that there has been no diversion. This is federal DEA 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 or accidents.

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 - Itemize amounts and types of pharmaceuticals collected so the information can be used for further study and recommendations for future collection.

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8. Medication Containers - These containers can be shredded for recycling. They should have the personal data marked out with a permanent marker.

9. Education - Have educational material available to be utilized by local government 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.

B. Pre-Event Logistics

1. Government Agency Authorization - All relevant agencies and programs should have authorized the collection and its procedures at 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 medications are stolen.

4. Agreement With Law Enforcement - A peace officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a peace officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with law enforcement agency providing peace 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, not required for all events.

5. Advertising - Provide advertising which could include internet, web site ads, newspaper ads, fliers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings. Multi-lingual pictures distributed in utility bills in participating cities, movie ads, movie theatre ads shown in theaters, ads on buses and at bus stops, print ad in recycling guides, English and Spanish PSA's in video and audio. Since

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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, the site must have access to electricity, room for the hazardous waste containers, and room for workstations.

9. Law Enforcement Location - At one time events, law enforcement must be positioned to be able to see the collection and movement of the medications from the public to the workstation. Law enforcement must be able to see the transfer of medications from vehicles to the greeter. Determine a good position for law enforcement to be stationed.

10. Essential Equipment and Supplies

- a. Tools for counting medications (pharmacist should provide this);
- b. Reference documents for researching unknown tablets (book or CD format);
- c. Hazardous waste containers;
- d. Gloves (Disposable non-latex preferably; Have at least two sizes, small and large);
- e. Ziploc® bags (One-gallon and snack size, with external slide mechanism);
- f. Laptop(s) (With spreadsheet software and compatible printer);
- g. Back-up memory (e.g. memory stick, CD);
- h. 1 Printer (Compatible with laptop. Be sure there is enough ink and paper);
- i. Extension cords, grounded;
- j. Survey forms (examples can be found at www.teleosis.org/pdf/Medicine_Return_Form.pdf or www.comofcom.com);
- k. Indelible markers (such as SHARPIE®);
- l. Packing tape;
- m. Containers-3 types of containers (30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gal plastic container for mercury items); and
- n. Mail back sharps disposal kits, in case some sharps do come into the event.

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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.
- B. Law enforcement staff - to provide security, take possession of controlled substances after determination by a pharmacist, transport controlled substances to evidence storage locker, inventory controlled substance, and arrange for and ensure USDEA authorized witnessed destruction of controlled substances.
- C. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled medications, inventory controlled substances, witness, and sign the inventory.
- D. Data Entry Person - Enter inventory of medications into computer.
- E. Hazardous Waste Company - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove medications 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.

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. Best Management Practices for the Collection of Unused and Expired Pharmaceuticals Through a Mail Back Program

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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.

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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 Best Management Practices

For additional best practices, contact the Northeast Recycling Council at www.nerc.org. If you have some additional practices for conducting an event that would be beneficial to other collection programs, please e-mail those practices to James Cropper at jcropper@ciwmb.ca.gov.

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.



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

Date: October 2, 2008

To: Enforcement Committee

Subject: Role of Reverse Distributors in Picking Up Medical Waste and Returned Drugs

During this meeting, if time permits, the committee will hear 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.

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.

If time does not permit a discussion at this meeting, this portion of the agenda will be moved to our December meeting.



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

Date: October 2, 2008

To: Enforcement Committee

Subject: Sharps Take-Back Drug Programs in Pharmacies

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. Pharmacies are listed as one of the disposal locations. However, pharmacy law does not authorize pharmacies to take back sharps.

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. Regrettably, the bill to authorize this was dropped at the end of August by Senator Simitian. The amendment was simple:

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. However, 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. This week, 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 on the following pages.



Household Hazardous Waste Sharps Waste

The CIWMB is working to help develop a safe, convenient, and cost-effective infrastructure for the collection and proper disposal of home-generated sharps waste. Decreasing the number of sharps disposed in landfills will help prevent potential health risks to landfill and material recovery facility workers.

The CIWMB's [Waste Prevention Information Exchange](#) provides more information about how to appropriately manage other health care waste at home, and you may also want to consult the [Medical Waste Management Program](#) of the California Department of Public Health.

The Law

Beginning on September 1, 2008, State law ([Section 118286](#) of the California Health and Safety Code) makes it illegal to dispose of sharps waste in the trash or recycling containers, and requires that all sharps waste be transported to a collection center in an approved sharps container.

Section 117671 of the California Health and Safety Code defines "home-generated sharps waste" as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household.

Sharps Waste Disposal

The following are some of the disposal options available to you for disposal of sharps waste:

- **Pharmacies.** Some drug store chains take back their customers' needles, although large quantities might not be accepted.
- **Mail-Back Service.** A list of sharps waste mail-back services authorized for use in California is available from the [California Department Of Public Health \(CDPH\)](#).
- **Local Household Hazardous Waste Program.** Call your local household hazardous waste agency and ask if they collect needles (sharps) at their collection facilities or on household hazardous waste days. Some do, others do not. There are four places you can look for this information:
 - Look in the Government section of your local white pages for a household hazardous waste listing for your city or county.
 - Call 1-800-CLEANUP (1-800-253-2687), a service of [Earth 911](#).
 - Visit the [Earth 911.org](#) website.
 - See the [Local Enforcement Agency Directory](#) on this website.
- **UPDATED Local Jurisdiction Sharps Collection Programs**, revised September 2008 (Adobe PDF, 345 KB). A file showing a sampling of local jurisdictions' sharps collection programs and containing contacts, email addresses, program summaries, and outreach materials. This spreadsheet could help jurisdictions that don't have collection programs set up their own sharps collection program.
- **Hospital Take Back.** Hospitals might take back needles (sharps) from those patients who go to the hospital for regular outpatient services.
- **Trash.** Please keep in mind that all trash is handled by people both at recycling facilities and at landfills. These people could be stuck by needles or other sharps that poke through their protective clothing, including heavy gloves and boots. This could result in serious injury, including infection by pathogens either from the needle user, or by pathogens that contaminate a needle after it is disposed. After September 1, 2008, home-generated sharps can no longer be thrown in the trash or in recycling containers (see note above).
- **Medical Waste Disposal Directory.** If you are searching for facilities that collect sharps for disposal, this directory enables you to locate one that is near to where you live or work.

Sharps Containers

The California Department of Public Health Medical Waste Management Program is recommending the use of sharps containers approved by the U.S. Food and Drug Administration (FDA). After accessing the FDA website, type "sharps" in the search box. The container names will display alphabetically.

Stakeholder Involvement

- ❖ **Sharps Stakeholders Meetings:** An initial stakeholders meeting took place on March 17, 2008, at the Cal/EPA building.
- ❖ **Surveys:** Sharps surveys were conducted in 2007 to identify current barriers to the proper disposal of home-generated sharps waste. The information will be used to establish more effective collection programs. By participating, survey takers played a part in helping home sharps users find a more convenient and safe way to dispose of sharps. Survey results are now available.

Educational Materials

CIWMB developed a poster and brochure to educate persons on proper sharps disposal. These materials can be downloaded or obtained by emailing a request to jcropper@ciwmb.ca.gov.

- ❖ **Brochure:** Provides more details on where to dispose of sharps, why sharps are dangerous, and how to find locations to properly dispose of sharps. English (Adobe PDF, 152 KB) | Spanish (Adobe PDF, 122 KB)
- ❖ **Mailer:** This mail-back request form is available to have businesses sign up to become a sharps collection location. (Adobe PDF, 3.3 MB)
- ❖ **Poster:** This 18- by 24-inch poster gives general information on where to dispose of sharps properly. (Adobe PDF, 1.9 MB)

For More Information

Stay informed about the latest developments in CIWMB's efforts to promote safe disposal of sharps waste.

- ❖ **Listserv:** To receive periodic information about sharps, subscribe to the Sharps and Pharmaceuticals Listserv.
- ❖ **Contact:** Please contact James Cropper for questions or more information.

Pharmaceutical Drug Waste | Medical Waste Disposal Directory

Last updated: October 1, 2008
Used Oil & Household Hazardous Waste Program <http://www.ciwmb.ca.gov/HHW/>
Contact: UsedOilHHW@ciwmb.ca.gov (916) 341-6457

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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.



California State Board of Pharmacy

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

Date: October 2, 2008

To: Enforcement Committee

Subject: E-Prescribing Forum

On November 20, 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. The Dental Board and Medical Board have joined as partners.

Here is a description of the event:

The California State Board of Pharmacy will host a public forum on e-prescribing on November 20th, from 9:30 to 1230. The forum will focus on what current California law allows with respect to e-prescribing, and will offer speakers who will describe how they are using e-prescribing today, what issues they have encountered and resolved, and the acceptance of e-prescribing by patients, pharmacies, prescribers and third-party payers. The Medical Board and Dental Board are partners of this forum, and other DCA healing arts regulatory boards have been specifically invited to attend.

Interested individuals are encouraged to save the date.



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

Date: October 2 2008

To: Enforcement Committee

Subject: Medication Errors Investigated by the Board of Pharmacy

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.

At this 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.

The following pages provide the information that will be converted into this medication error supplement to the newsletter.

The Communication and Public Education Committee will discuss how it wishes to proceed with respect to educational activities to the profession and consumers about medication errors. Both CPhA and the Institute for Safe Medication Practices have expressed interest in working with us in this area.

One area is the emerging emphasis on using TALL MAN Letters in prescriptions to prevent look-alike drug names from being confused. Attached are several articles from the Institute for Safe Medication Practices, and one expressing the National Association of Boards of Pharmacy policy on this subject.

Also attached are two additional articles on medication errors and ways to prevent them by pharmacies.

2 MEDICATION ERROR DATA

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
	Risperal	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/Preparation Error	11	2%
Refill Errors (frequency, timeliness)	1	<1%
Total # Citations for errors (may have more than one category listed)	445	

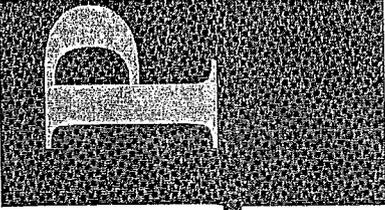
P

RESCRIPTION ERROR CASES

\$500 Fine

Case 1: An 8 month-old child was given a prescription for Novahistine DH (Phenylhist DH), a codeine-containing product. The Pharmacist incorrectly typed the directions on the prescription label as give 1 and 1/2 teaspoonsfuls by mouth every 6 hours instead of the prescribed direction to give 1 and 1/2 cc (ml) by mouth every 6 hours. This resulted in the infant being dispensed seven times the prescribed dose. This infant's mother is a nurse and caught the error; the infant never received any of the medication.

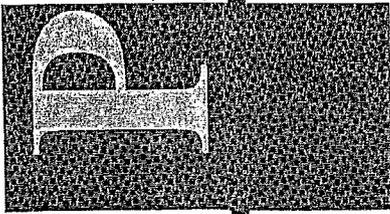
Case 2: A patient being treated for a craniotomy picked up her refill prescription of Hydrocodone/APAP 5mg/500mg (a medication for pain). She spelled out her name for the clerk/technician, who retrieved a prescription. The patient signed and paid for the medication and left the pharmacy. Later that evening the patient took her regular dosage (two pills) of medication, and became nauseated, lethargic, and started to vomit. She then discovered she had received another person's prescription, she received Lexapro 10mg (an antidepressant).



PRESCRIPTION ERROR CASES

\$500 Fine

Case 3: A patient picked up his prescription for Citalopram 40mg. After taking the medication for several days, (four doses total) suffered several incidents of dizziness. The patient noticed the pills looked different and returned to the pharmacy where the pharmacist informed him he had been taking Norvasc 5mg (a low blood pressure medication). The patient recovered without Permanent harm.



PRESCRIPTION ERROR CASES

\$1,000 Fine

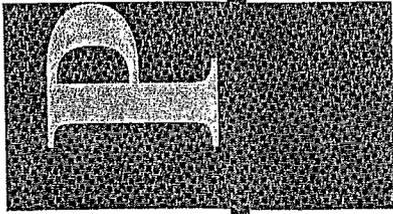
- # **Case 1:** An adult female refilled her Norvasc (5mg once daily) prescription (a drug to lower blood pressure). The pharmacist incorrectly dispensed Lipitor (a drug to lower cholesterol). Five days later the patient suffered a stroke and was hospitalized. After 6 days in the hospital and six major procedures, she was released. One of her discharge medications was Lisinopril 10mg, which the pharmacist incorrectly filled with Lisinopril 20mg. The patient received the corrected medications and her condition stabilized.
- # **Case 2:** An adult female refilled his prescription for Disopyramide 100mg. The pharmacist incorrectly filled with Desipramine 100mg. Within about 5 days the patient began to experience numerous symptoms, difficulty breathing; fainting spells; irregular or fast, pounding heartbeat; stomach pain; unusual weakness or tiredness; anxiety; constipation, or diarrhea; drowsiness or dizziness; and dry mouth, all side effects of Desipramine. The patient contacted the pharmacy and the PIC, stated the tablets were a generic replacement and the symptoms could not be related to the generic drug.
-

P

PRESCRIPTION ERROR CASES

\$1,000 Fine

Case 3: A 53-year-old female patient with diabetes was prescribed Avandia 4mg and Prevacid 30mg. The pharmacist incorrectly filled with Coumadin 4mg and Pravachol 40mg. The patient developed blurred vision and bruising and then went to urgent care. Her blood tests showed a markedly elevated clotting test (INR @ 6.3). She was seen by Ophthalmology and was diagnosed with a bleed (possibly a retinal bleed). She was treated and is better.

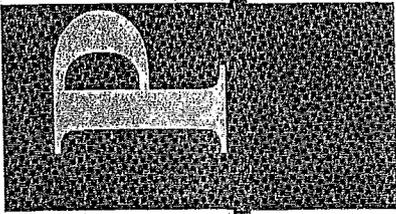


RESCRIPTION ERROR CASES

\$2,500 Fine

Case 1: A mature adult female was prescribed Climata 0.045-0.015mg Pro Patch. The pharmacist incorrectly dispensed Estradiol 0.0375mg patch. The patient took the incorrect medication for 7 months. The patient suffered a uterine build-up requiring a D&C medical procedure as a result of taking this medication.

Case 2: A 58-year-old female patient was prescribed Prednisone 2.5mg tablets as 1 tablet bid (5mg/day). The pharmacist incorrectly dispensed Prednisone 50mg tablets as 1/2 tablet bid (50mg/day). As a result of this error the patient required hospitalization. The patient recovered without permanent harm.



PRESCRIPTION ERROR CASES

\$4,200 Fine

Case 1: A 68-year-old female was receiving prescriptions from three doctors for enormous amounts of Soma and Tylenol with Codeine (both pain medications). In a nine-month period 4,696 doses were dispensed. The pharmacy dispensed all the prescriptions without contacting the prescribers. The patient died of cardiopulmonary arrest.





Medication Safety Alert!®

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Community/Ambulatory Care Edition

Volume 7, Issue 3 • August 2008

Schools need...

Safety Briefs

■ ISMP list of name pairs with tall man letters.

ISMP extends sincere thanks to all who completed our recent survey on the use of tall man letters to differentiate products with look-alike names. Tall man letters are uppercase letters that are used within a drug name to highlight its primary dissimilarities with look-alike drug names. One of the primary reasons for conducting this survey was to use the findings to prepare an unofficial list of look-alike drug name pairs with suggested tall man letters to guide practitioners and healthcare organizations. This is not intended to replace drug name safety testing to prevent name similarities before marketing a product. Many respondents shared their thoughts about other drug name pairs that might benefit from using tall man letters that were not included in our survey. We reviewed each suggestion very carefully, placing emphasis on the potential for patient harm, the frequency of use for each medication, and the need to keep the list short enough to avoid diluting the effectiveness of tall man letters. To help promote standardization, ISMP suggests that the tall man lettering schemes provided by FDA and ISMP be followed consistently. For a fully alphabetized list, please visit: www.ismp.org/Tools/tallmanletters.pdf

FDA and ISMP Lists of Look-Alike Drug Name Sets With Recommended Tall Man Letters

The sets of look-alike drug names in the Tables below have been modified using "tall man" letters to help draw attention to the dissimilarities in their names. Several studies have shown that highlighting sections of drug names using tall man (mixed case) letters can help distinguish similar drug names,¹ making them less prone to mix-ups.²⁻³ ISMP, FDA, The Joint Commission, and other safety-conscious organizations have promoted the use of tall man letters as one means of reducing confusion between similar drug names.

Table 1 provides a list of FDA-approved established drug name sets with recommended tall man letters, which were first identified during the FDA Name Differentiation Project (www.fda.gov/CDER/Drug/MedErrors/nameDiff.htm).

Table 2 provides a list of additional drug name sets with recommendations from ISMP regarding the use and placement of tall man letters. This is not an official list approved by FDA. It is intended for voluntary use by healthcare practitioners and drug information vendors. Any product label changes by manufacturers require FDA approval.

aceto HEX AMIDE - aceta ZOL AMIDE	hydr AL AZINE - hydr OXY zine
bu PROP ion - bus PIR one	medroxy PROG ESTERone
chlorpro MAZ INE - chlorpro PAM IDE	methyl PRED NIsoLone
clom IPH ENE - clomi PRAM INE	methyl TEST OSTERone
cyclo SPOR INE - cyclo SER INE	ni CAR dipine - ni FED ipine
DAUN OR ubicin - DOX OR ubicin	predni SONE - predni SONE
dimenhy DRIN ATE - diphenhy DRAM INE	sulfi ADIAZ INE - sulfi SOXAZ OLE
DOB UT amine - DO PAM ine	TOL AZ amide - TOL BUT amide
gli PIZ IDE - gly BUR IDE	vin BLAS tine - vin CRIS tine

References: 1) Filik R, Purdy K, Gale A, Gerrett D. Drug name confusion: evaluating the effectiveness of capital ("Tall Man") letters using eye movement data. *Social Science & Medicine* 2004;59(12):2597-2601. 2) Filik R, Purdy K, Gale A, Gerrett D. Labeling of medicines and patient safety: evaluating methods of reducing drug name confusion. *Human Factors* 2006;48(1):39-47. 3) Grasha A. Cognitive systems perspective on human performance in the pharmacy: implications for accuracy, effectiveness, and job satisfaction. Alexandria (VA): NACDS; 2000 Report No. 062100.

One of the difficulties with the use of tall man letters is the lack of scientific evidence regarding which name pairs would most benefit from this error-reduction strategy as well as which letters to present in uppercase. Until further evidence is available, ISMP suggests that the tall man lettering scheme provided in these Tables be followed to promote consistency.

ALPRA ZOL am - LO R azepam	metro NIDA ZOLE - met FOR MIN
amLOD IP ine - a MIL oride	morphine - HYDRO MO rphine
azaC IT idine - aza THIO prine	Nex IUM * - Nex AVAR *
ceFA ZOL in - ce TRIAX one	ni MO Dipine - ni FED ipine
Cele BREX * - Cele XA *	Novo LOG * - Novo LIN *
chlorpro MAZ INE - chlordiaze POX IDE	OX car bazepine - car BAM azepine
GI S platin - CAR BO platin	oxy CO DONE - Oxy CONT IN*
clonaze PAM - clo NID ine	PAR OX etine - FLU OX etine
clonaze PAM - LO R azepam	PENT OB arbital - PHEN OB arbital
clo NID ine - Klon OP IN*	Pri LOSEC * - PRO ZAC *
DA CTI nomycin - DA PTO mycin	QUE TAP ine - DLAN ZAP ine
e PHED rine - EPINE PH rine	qui NINE - qui NID ine
fenta NYL - SU FEN anil	ri TUX imab - in FLIX imab
FLU OX etine - DU L oxetine	Sand IMMUNE * - Sand OSTATIN *
guan FAC INE - guan FEN esin	SERO QUEL * - SINE QUAN *
Huma LOG * - Huma LIN *	Solu MEDROL * - Solu CORTEF *
HYDRO CO done - oxy CO DONE	SUM A triptan - sita GLI ptin
ID AR ubicin - DOX OR ubicin	ti ZAN idine - tia GAB ine
INV ANZ * - AV INZA *	tra ZO Done - tra MAD ol
La MIC tal* - Lam SIL *	TREN TAL - TEG RETAL *
lami VU Dine - lami TRI gine	Zy PREXA * - Zy TEC *

* Brand names always start with an uppercase letter. Some brand names incorporate tall man letters in initial characters and may not be readily recognized as brand names. An asterisk follows all brand names in Table 2.

Delegates Approve Eight Resolutions

Delegates from the member boards of pharmacy adopted eight resolutions during the NABP 104th Annual Meeting. Adoption of these resolutions result in actions such as task forces created at the direction of NABP President Rich Palombo, RPh, and NABP and its member boards collaborating with government agencies, health care associations, and other stakeholders. The resolutions are as follows.

Resolution No. 104-1-08
Title: "Tall Man" Letter Utilization For Look-Alike Drug Names
Action: Passed

Whereas, medication dispensing errors continue to occur as a result of look-alike prescription drug product names; and

Whereas, the use of "TALL MAN" letters highlighting the dissimilar letters in look-alike drug name pairs has been shown to assist in reducing these types of dispensing errors;

Therefore Be It Resolved that NABP work with the United States Food and Drug Administration (FDA) and the United States Pharmacopeia (USP), or other standard setting organizations to propose a national standard for "TALL MAN" lettering for look-alike drug names; and

Be It Further Resolved that NABP encourage manufacturers of drug products with look-alike names, as identified by FDA, USP, or other standard-setting organizations, to use "TALL MAN" lettering on applicable product labels and avoid the use of look-alike names; and

Be It Further Resolved that NABP encourage manufacturers of pharmacy data systems and software to recognize "TALL MAN" lettering standards within their systems.

Resolution No. 104-2-08
Title: Standardized Internship Registration
Action: Passed

Whereas, there is an identified need to standardize when interns are recognized and licensed by the boards of pharmacy in order

to accumulate required internship hours while completing the experiential practice requirements noted in the Accreditation Council for Pharmacy Education (ACPE) *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree;*

Therefore Be It Resolved that NABP encourage state boards of pharmacy to uniformly register pharmacy interns and for NABP to work with American Association of College of Pharmacy and ACPE to establish a uniform date within the professional pharmacy curriculum to begin internship registration.

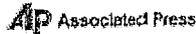
Resolution No. 104-3-08
Title: Task Force On Uniform Prescription Labeling Requirements
Action: Passed

Whereas, concerns have arisen regarding prescription drug label content and format as contributing factors to patient confusion and medication errors; and

Whereas, some prescription drugs are known by several proprietary names (ie, brand name, branded generic name) as well as their established, official, or generic name, and such drugs may be identified on a prescription drug label by multiple different names; and

Karen
Abbe/Pharmacy/DCANotes
09/02/2008 09:00 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc Anne Sodergren/Pharmacy/DCANotes@DCANotes
bcc
Subject AP: Group aims to limit prescription mix-ups



GROUP AIMS TO LIMIT PRESCRIPTION MIX-UPS

Website warns about drugs with similar names

By Lauran Neergaard
Associated Press
September 2, 2008

WASHINGTON - Take the generic drug clonidine for high blood pressure? Double-check that you didn't leave the drugstore with Klonopin for seizures, or the gout medicine colchicine.

Mixing up drug names because they look or sound alike - like this trio - is among the most common types of medical mistakes, and it can be deadly. Now new efforts are aiming to stem the confusion, and make patients more aware of the risk.

Nearly 1,500 commonly used drugs have names so similar to at least one other medication that they have already caused mix-ups, says a major study by the US Pharmacopeia, which helps set drug standards and promote patient safety.

Last week the influential group opened a Web-based tool to let consumers and doctors easily check to see whether they are using or prescribing any of these error-prone drugs, and what they might confuse it with. Try to spell or pronounce a few on the site - www.usp.org - and it's easy to see how mistakes can happen.

Due out later this fall is a more patient-oriented website, a partnership of the nonprofit Institute for Safe Medication Practices and online health service iGuard.org, that will send users e-mail alerts about drug-name confusion.

And the Food and Drug Administration, which rejects more than a third of proposed names for new drugs because they are too similar to old ones, is preparing a pilot program that would shift more responsibility to manufacturers to guard against name confusion. The goal is to spell out how to better test for potential mix-ups before companies seek approval to sell their products.

"There are so many new drugs approved each year, this problem can only get worse," USP vice president Diane Cousins said.

At least 1.5 million Americans are estimated to be harmed each year from a variety of medication errors, and name mix-ups are blamed for a quarter of them.

Rarely does a company change a drug's name after it hits the market, although it has happened twice since 2005. The Alzheimer's drug Reminyl now is named Razadyne, after mix-ups, including two reported deaths, with the old diabetes drug Amaryl. The cholesterol pill Omacor is now named Lovaza, after mix-ups with blood-clotting Amicar.

Doctors' notoriously bad handwriting is not the only culprit. A hurried pharmacist faced with alphabetized bottles on a shelf might grab the wrong one.

Nor are computerized prescriptions a panacea. A doctor who e-prescribes still can click the wrong row on the alphabetized screen, picking the bone drug Actonel instead of the diabetes drug Actos.

Phone or fax a prescription, and static or smudged ink can turn the epilepsy drug Lamictal into the antifungal pill Lamisil.

Harder to measure but perhaps more common: A doctor means to prescribe a new drug but spells out a similar-sounding old one out of habit. Or the patient misspells or mispronounces a drug, and a health worker assumes it's the schizophrenia drug Zyprexa, not the antihistamine Zyrtec.

"We've had cases where a healthcare professional repeats what they think the patient's on, and the patient thinks they must know what they're talking about and agrees," Cousins said.

Enter the new Web tool. Cousins tells consumers to check it against their current medications, so they know to pay more attention to confusing ones at refill time. Question the pharmacist if the tablets look different than last time, said pharmacist Marjorie Phillips, medication safety coordinator at MCGHealth, the Medical College of Georgia's health system. It might just be a new generic, or it might be the wrong drug, she said.

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newsletter

National Association of Boards of Pharmacy®

September 2008 / Volume 37 Number 8

Boards Investigate Regulating Pharmacies for Patient Care Outcomes to Ensure Quality

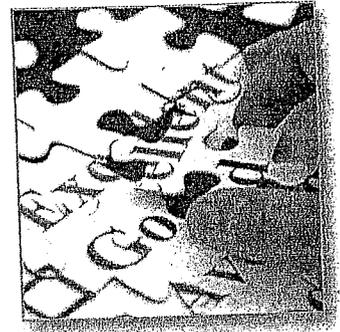
Twelve years ago, David Brushwood, RPh, JD, a professor at the University of Florida College of Pharmacy, advised that the state boards of pharmacy should adjust their policies to begin regulating pharmacies for patient care outcomes. Some in pharmacy regulation also recognized the importance of such an approach. Charles R. "Chuck" Young, RPh, CFE, during his tenure as executive director of the Massachusetts Board of Registration in Pharmacy from 1996 to 2006, initiated several efforts, including creating a board staff position that focused on continuous quality improvement (CQI), the first of its kind in the nation. Today, boards are refocusing on CQI programs and are working to improve or implement their own plans.

In the push for CQI programs in the community pharmacy setting, boards

are looking at methods to evaluate the success of these programs and, subsequently, to establish uniform standards to facilitate uniform success.

NABP and stakeholders from all areas of pharmacy practice and regulation emphasize the importance of looking for the root of "quality-related events" in pharmacy structure and process, or systems, and adjusting those systems as necessary to support CQI programs and prevent the recurrence of medication errors. A necessary part of the process involves measuring changes that actually result from the adjustments to pharmacy systems.

According to CQI reports, health care "outcomes" refer to "changes in a patient's health status that result from the provision of health care." They state, however, "[o]ther



important outcomes are disability, discomfort, and dissatisfaction," and, "[e]xamples in pharmacy of directly measured outcomes would be adverse drug reactions, patient dissatisfaction, and diminished quality of life. Proxy outcomes measures would include the rate of medication-related emergency room visits or blood pressure readings of hypertensive patients."

Brushwood emphasized that measuring such outcomes is the only way

(continued on page 138)

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Communications
Manager

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Regulating for Outcomes

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to reliably determine the relevance and success of system changes. "The importance of outcomes," he said in the August 1996 issue of the *NABP Newsletter*, "is that they can be linked to particular aspects of structure and process, which can be altered to produce improved outcomes. Correspondingly, the importance of structure and process is that they can be linked with outcomes." This cyclical approach is fundamental to effective change.

According to a 2004 article, "Framework for Pharmacy Services Quality Improvement – a Bridge to Cross the Quality Chasm. Part I. The Opportunity and the Tool," in the *Journal of Managed Care Pharmacy*, "[q]uality improvement in health care services in the United States will be made in incremental changes that rely on a structure-process-outcome model. . . . Incremental changes in structure and process will result in the desirable outcome of meeting customer needs for more effective drug therapy and disease management."

Based on this model, pharmacy CQI programs should include looking at the number of errors and, once systems have been modified to reduce the incidence of errors, checking to see if that reduction has actually occurred. Ensuring that appropriate changes are being implemented and leading to

a reduction in quality-related events should be part of inspecting pharmacies for CQI.

By 2001, the momentum was building steam, as noted in the article, "Regulating for Outcomes as a Systems Response to the Problem of Drug-Related Morbidity," in the *Journal of the American Pharmaceutical Association*. "Health care accreditation agencies are moving toward regulation for outcomes," the article states. "Such regulations would clarify pharmacy's role in support of safe and effective pharmacotherapy and would constitute a commitment to pharmaceutical care as public service. A widely adopted system of measuring and improving the quality of medication use and outcomes could eventually lead to quality benchmarks in the community pharmacy setting, which would more firmly establish the value of the pharmacist in pharmacotherapy."

Today, focusing on quality and regulating for outcomes in patient care are consistent with the recommendations of the NABP 2007-2008 Task Force on Continuous Quality Improvement, Peer Review, and Inspecting for Patient Safety (CQI task force). This philosophy is an important aspect of the proposed pharmacy accreditation program that the CQI task force outlines.

To assist the boards with inspecting pharmacies to ensure that CQI practices are in place and operating successfully, the CQI task force recommends that NABP

explore the possibility of developing and implementing a pharmacy accreditation program, in conjunction with the boards, that will ensure pharmacies are operating in a manner consistent with CQI standards, decreasing the occurrence of quality-related events and ultimately increasing patient safety. With many boards facing budget strains and lacking the resources to increase the frequency and complexity of pharmacy inspections, NABP is currently exploring a community pharmacy accreditation program to address this need and to assist those boards in implementing or upholding pharmacy CQI standards in their jurisdictions.

NABP President Rich Palombo, RPh, remarked at the NABP 104th Annual Meeting in May 2008 that "the purpose and desire to develop such a program is to assist the boards and move patient safety forward. . . . Such a program will provide invaluable data to the boards about the pharmacies in their states and across the country." This information would provide useful evidence on which to base future systems and standards. "If we are successful in assisting pharmacists to effectively implement a meaningful definition of patient safety to their practices," President Palombo says, "we will have achieved something that is momentous and that will impact patient care and safety for generations."

To establish a foundation for pharmacy CQI program

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standards, the task force developed a form for use by each pharmacy in conducting a quality self-audit at least quarterly, as well as upon a change of pharmacist-in-charge. The goals of the quality self-audit are to monitor changes in the number of quality-related events over time, as well as to evaluate compliance with CQI procedures, and to develop a plan for improved adherence with the CQI program. This mechanism for measuring outcomes provides pharmacies with a quantifiable means of

assessing, initially, whether system adjustments are needed, and subsequently, whether they have improved patient care outcomes.

The task force used as a basis for its recommendations several aspects of CQI programs established over the past decade by the Massachusetts Board of Registration in Pharmacy. As mentioned earlier, the Board, under the direction of Young, who served as an ex officio member of the task force, initiated several efforts, including the establishment of the "continuous quality improvement coordinator" position. The coordinator position was created to review on-site CQI procedures

established by licensed pharmacies based on "Best Practice Recommendations" implemented by the Board. These efforts assisted the Board in moving forward in its attempt to proactively regulate for outcomes and move away from a reactive, strict disciplinary approach to regulation.

The cyclical approach to outcomes assessment, systems modification, and subsequent outcomes assessment follows the basic philosophy of evidence-based medicine, which has become increasingly pertinent in medical practice. The objective is to make patient care decisions, both on an

individual patient and a pharmacy systems level, based on past experience with and documentation of those systems that have proven successful. Once this assessment process begins and data is collected from multiple pharmacies, the boards may glean information on the most effective systems that lead to the best patient care outcomes, and they may anticipate problems based on previous poor outcomes.

The accumulation of such data will allow the boards to develop and implement uniform quality standards to improve outcomes nationally and, ultimately, enhance patient safety. ®



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

Date: October 2, 2008

To: Enforcement Committee

Subject: Discussion of Hospital Pharmacies' Control of Drugs within Hospitals

During this meeting, the committee will initiate a discussion with interested hospital pharmacists regarding the control of prescription drugs and devices within a hospital.

As you will remember, in late spring, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall. The board has cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. Whereas many of these hospitals and PICs may appeal the citations and fines, the board members cannot discuss the specific parameters of any of these cases without recusing themselves from voting on the specific case in the future.

The recall system is broken and needs fixing, and staff is pursuing this with the California Department of Public Health and the FDA. A list of recommendation changes will be developed by the end of the year.

At this meeting:

This seems an appropriate time to initiate a discussion with hospital pharmacies about the control of drugs within a hospital. This meeting may flow into a series of future meetings on this subject. Pharmacy law in this area has not been updated in years, and this may be the opportunity.