California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Contact Person: Patricia Harris
(916) 445-5014

ENFORCEMENT COMMITTEE MEETING

July 2, 2003

9:30 a.m. - 12 noon

Department of Consumer Affairs

Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 48 hours prior to the meeting.

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

AGENDA

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

A. Discussion Regarding the Reimportation of Prescription Drugs from Canada – Request from Senator Alarcon for Attorney General Opinion 03-601

B. Proposed modification to California Code of Regulations (CCR), title 16, Section 1711, subd. (c) – Notifying the patient and prescriber when an error occurs in an institutional setting (Quality Assurance Regulation)

C. Discussion Regarding the Proposed Addition of CCR, title 16, sections 1784 and 1785 – Wholesale Drug Transactions

D. Request for Prescription Records by Authorized Officers of the Law (B & P Code section 4017)

E. Review of Business and Professions Code Section 4059.5 Regarding the Delivery of Medications After the Pharmacy is Closed and a Pharmacist is Not Present

F. Off-Site Order Entry of Hospital Medication Orders (Bus. & Prof. Code Section 4071.1) – Presentation by Cardinal Health

G. Report on the MBC/Board of Pharmacy Joint Task Force on Prescriber Dispensing - May 27, 2003

H. Implementation of the federal HIPAA Requirements

I. Pharmacists Recovery Program – New Contract Vendor - Maximus

J. Review of Strategic Objectives for 2003/04

K. Adjournment **12 noon**

Committee materials will be available on the board's website on June 20, 2003.

Agenda Item A

110 WEST A STREET, SUITE 1100
SAN DIEGO, CA 92101
P.O. BOX 85266
SAN DIEGO, CA 92186-5266
Public: (619) 645-2400
Facsimile: (619) 645-2489
Direct Dial: (619) 645-2210
E-Mail: Rodney.Lilyquist@doj.ca.gov
June 2, 2003

TO WHOM IT MAY CONCERN:

RE: Opinion No. 03-601

We have received a request from Senator Richard Alarcon for an opinion of the Attorney General on the following questions:

1. Will the State of California be subject to Food and Drug Administration sanctions if it purchases prescription drugs in Canada for its Medi-Cal beneficiaries?

2. Will a California buying co-operative created to purchase prescription drugs in Canada be subject to prosecution by the Food and Drug Administration if it limits the sale of such drugs to its members?

3. Will a California non-profit corporation importing prescription drugs from Canada be subject to prosecution by the Food and Drug Administration if the distribution of such drugs is limited to its members and their families or those certified by the state or federal government as living at or below the poverty level?

4. Will a sovereign Indian nation in California be subject to prosecution by the Food and Drug Administration if it imports prescription drugs from Canada for its members or for other Indian nations where sovereignty has been recognized by the United States?

5. May such an Indian nation sell Canadian prescription drugs on its reservation or through its Internet website to other residents of California?

6. Will residents of California who take chartered bus trips to Canada to purchase prescription drugs be subject to prosecution by the Food and Drug Administration?

7. Will a city or county in California be subject to prosecution by the Food and Drug Administration if it passes legislation legalizing the importation of prescription drugs from Canada for the use of its residents or those living at or below the poverty level?

8. May the federal government successfully challenge the constitutionality of an initiative measure adopted in California legalizing the importation of prescription drugs from Canada?

9. May public pension funds such as CALPERS or CALSTRS negotiate for Canadian prescription drug prices for their members?

It is the policy of our office to solicit the views of all interested parties prior to issuing an opinion. If you would like to submit comments, a response by July 2, 2003, would be most helpful; materials received after such date will nonetheless be considered. Please address your views to: Deputy Attorney General Gregory Gonot, Post Office Box 944255, Sacramento, CA 94244-2550; telephone (916) 324-7860; or via e-mail Gregory.Gonot@doj.ca.gov.

Issued opinions may be found on the Internet at www.caag.state.ca.us/opinions.

Sincerely,

RODNEY O. LILYQUIST
Senior Assistant Attorney General
Chief, Opinion Unit

For BILL LOCKYER
Attorney General

ROL:jmn

RECEIVED BY CALIF. BOARD OF PHARMACY
2003 MAY 28 PM 4:08

News Release

FOR IMMEDIATE RELEASE

May 22, 2003

For more information contact:
Courtney M. Karzen, Communications and Services Senior Manager
847/698-6227; custserv@nabp.net

NABP, NAPRA Finalize Position Statement to Work Together to Protect Citizens

On May 4, 2003, the National Association of Boards of Pharmacy® (NABP®) announced the finalization of a position statement between the Association and the National Association of Pharmacy Regulatory Authorities (NAPRA) whereby NABP and NAPRA pledge to work together to protect the citizens that each are mandated to serve and to promote compliance with the federal, state, and provincial laws and standards of Canada and the United States, to ensure the safety and integrity of the prescribing drug supply in their respective jurisdictions.

Both associations share the common responsibilities in the regulation of the practice of pharmacists, ensuring public safety, and are committed to working together to advocate the ability and effectiveness of individual member organizations in executing their regulated mandates. Due to an immediate need to address the cross-border movement of prescription drugs, both associations signed an agreement stating in part that "illegal international movement of prescription drugs between Canada and the United States undermines the regulatory systems established in each country to protect consumers. . . ."

(— more —)

"It is important for the American public to understand that there are numerous risks involved with purchasing prescription medications from countries other than where the patient lives including adverse reactions between other prescription medications, over-the-counter drugs, and/or nutritional supplements that could have been recognized had the patient gone to his or her regular pharmacist." warned NABP Executive Director/Secretary Carmen A. Catizone. "Another danger in the illegal purchasing of prescription medications lies in not fully knowing where the medications originated from, ie, these drugs bought via illegal methods could contain incorrect dosages, or be contaminated and/or counterfeit."

NABP is pleased to announce that Barbara A. Wells, executive director of NAPRA, and Carmen A. Catizone formally executed that agreement at NABP's 99th Annual Meeting, May 3-7, 2003, in Philadelphia, PA.

Catizone stated, "We [NABP and NAPRA] believe that due to the explosion of foreign prescription drug importation, it is imperative that we work closely with NAPRA and their provincial and territorial members to tackle the challenges pharmacy regulators face on both sides of the border and protect public safety."

Wells agreed and added, "This joint resolution signals our [both associations'] commitments to work together to support the ability and effectiveness of our member organizations in protecting the citizens each are mandated to serve . . . ."

NABP and NAPRA have worked closely with US Food and Drug Administration on this issue. For more information about the position statement, please contact NABP at 847/698-6227.

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

- 30 -

Agenda Item B

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: June 19, 2003**

From: **Patty Harris**
Executive Officer
Board of Pharmacy

Subject: Proposed Modification to the Quality Assurance Regulation

At the April Board meeting, the Enforcement Committee discussed the proposed language that was submitted to amend CCR 1771(c) regarding the notification of the patient and prescriber when a prescription error has occurred. It was requested that this issue be returned to the Enforcement Committee with direction to the stakeholders to develop language to address those situations when a patient has not ingested the medication. No additional proposals have been submitted.

Background
At the Enforcement Committee meeting in March 2003, the California Society of Health-System Pharmacists (CSHP) requested that the Enforcement Committee consider its proposal to amend the regulation. They stated that while the current version may work well in an ambulatory setting, it presents some logistical issues in the inpatient setting. It was noted the California Code of Regulation section 1711 requires the pharmacist to notify the patient and the prescriber that a medication error has occurred and the steps required to avoid injury or mitigate the error.

During this meeting, Kaiser Permanente then provided language modifications in support of CSHP's request. The modification required that the patient be notified only if the wrong medication was administered or ingested. The committee expressed concern that there are situations where a patient has received the wrong medication, has not taken the medication, but it is still important that the patient and the patient's prescriber be notified, especially if it means that the patient has not received the appropriate medication thus delaying therapy.

Following the meeting, the board received proposed modifications from Albertsons. Based on the discussions at the meeting and subsequent comments, the following amendment was submitted to the board by the Enforcement Committee.

> (c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless ~~the~~ a pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall ~~immediately~~ as soon as possible, and working in collaboration with the prescriber or, if unavailable, another prescriber then treating the patient, communicate to the patient, or the patient's representative or care provider the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

Agenda Item C

Board of Pharmacy
Proposed Additions
Title 16 - California Code of Regulations

1784. Wholesale Drug Transactions

~~(a) A wholesaler shall not sell, distribute, transfer, or otherwise provide more than 10 percent of the total annual dollar volume of sales of dangerous drugs dangerous drugs to another wholesaler, distributor or manufacturer.~~

~~(b)~~ (a) A pharmacy that sells, trades, or transfers more than ten percent of its total annual dollar volume of sales of dangerous drugs to a person other than the final consumer is acting as a wholesaler and shall obtain a license as a wholesaler from the board. For the purposes of this section, prescriptions refilled for another pharmacy as authorized by section 1707.4 shall not be considered to have been sold, traded or transferred to a person other than the final consumer.

~~(c)~~ (b) A wholesaler may not purchase or otherwise receive a dangerous drug from a pharmacy except that a wholesaler may receive a dangerous drug from a pharmacy that was originally purchased by the pharmacy from the wholesaler. A wholesaler may not receive back from a pharmacy more of a dangerous drug than was originally sold by the wholesaler to the pharmacy nor may a wholesaler pay more to the pharmacy, either in cash or credit, than the pharmacy originally paid to the wholesaler for the dangerous drug.

1785. Statement of Prior Sales

(a) If a wholesaler purchases a dangerous drug from a person other than the manufacturer of the dangerous drug, a wholesaler shall provide a "Statement of Prior Sales" identifying each sale, trade or transfer of a dangerous drug when a dangerous drug is sold, traded or transferred to any other person. If a pharmacy sells a drug to any person that is not the final consumer, the pharmacy shall provide to the person acquiring the dangerous drug a "Statement of Prior Sales" identifying each sale, trade or transfer of a dangerous drug. Sale, trade or transfer of a dangerous drug between licensees with a common ownership are not subject to this section.

(b) The "Statement of Prior Sales" shall:
- (1) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or wholesaler.
- (2) Accompany all dangerous drugs purchased from a wholesaler, even if they are resold to another distributor.
- (3) Include the business name and address of the person from whom the dangerous drug was purchased.
- (4) Include the date of the sale.
- (5) Include the:
  - (A) Name of the dangerous drug.
  - (B) Strength of the dangerous drug.
  - (C) Size of the container.
  - (D) Number of containers.
  - (E) Lot number of the dangerous drug.
  - (F) Name of the manufacturer of the finished dosage form.

(c) Each statement shall be:
- (1) Maintained by the buyer and the wholesaler for 3 years.
- (2) Available for inspection or removal upon a request of an authorized officers of the law.

Paul Riches

06/04/2003 04:40 PM

To: RArell10@dhs.ca.gov@DCANotes, Virginia Herold/Pharmacy/DCANotes@DCANotes, Patricia Harris/Pharmacy/DCANotes@DCANotes, Ron.Diedrich@doj.ca.gov, Dana Winterrowd/EXEC/DCANotes@DCANotes, JArellano@dhs.ca.gov

cc:

Subject: fyi

WASHINGTON (AP) -- Federal investigators discovered more than 30,000 additional bottles of fake Lipitor, a top-selling anti-cholesterol pill, as they worked Tuesday to crack a huge case of medical counterfeiting.

Also Tuesday, the manufacturer of real Lipitor, Pfizer Inc., filed suit to stop a pharmaceutical repackaging company and distributor from selling any more fake pills -- and to get more information to track the counterfeit's source.

Repackager Med-Pro Inc. and Albers Medical Distributors both denied involvement in the counterfeiting.

The Food and Drug Administration first uncovered three batches of fake Lipitor almost two weeks ago, and ordered Kansas City-based Albers to recall 100,000 bottles. Tuesday, the FDA announced it had turned up three more batches containing counterfeit pills.

The FDA warned Lipitor users and pharmacists Tuesday to carefully check their bottles before using Lipitor. To spot the fake version, look for the words "Repackaged by MED-PRO Inc., Lexington, NE 68850" on 90-tablet bottles that bear any of the following lot numbers:

- 20842V, expiration 09-2004
- 16092V, expiration 07-2004
- 20722V, expiration 09-2004
- 04132V, expiration 01-2004
- 16942V, expiration 09-2004
- D270481, expiration not available.

All but that last batch are 10-milligram tablets; the last one includes 20-milligram tablets.

Many patients taking Lipitor buy it in smaller quantities dispensed in different bottles by their local drugstore. So patients not sure if they have the counterfeit version should call their pharmacist, who can check the pills' source, the FDA advised.

"We want consumers, if there's any doubt at all, to call their pharmacist," said FDA Associate Commissioner John Taylor.

Pfizer says the fake Lipitor pills bear a close resemblance to real Lipitor,

although they may be slightly thicker. Consumers have reported that the fake pills dissolve faster and have a slightly bitter taste. In fact, a handful of consumer complaints about the taste prompted the FDA's probe.

Drug manufacturers typically sell their products to a wholesaler that can in turn send tablets directly to pharmacies, or to a distributor and repackager before they arrive at drugstores.

Pfizer sued Med-Pro and Albers on Tuesday, saying it has no relationship with either of the companies so far identified as handling the fake pills.

"We're suing to get the product off the market and to identify the source," said Pfizer spokeswoman Vanessa McGowan.

Both Med-Pro and Albers denied involvement.

"Med-Pro acted at all times in good faith and was never knowingly involved in counterfeit Lipitor," said company attorney J.R. Hobbs.

Albers attorney Kathy Dean said the fake pills never came to the distributor's warehouse but were directly shipped from Med-Pro to a small number of wholesalers.

"We are cooperating fully with the FDA and are willing to work with Pfizer to identify the true source of the counterfeit product," she said.

Counterfeit medicine is increasingly turning up in the United States. In the last year, the FDA has investigated more than half a dozen cases. Just last month, three men were charged in Miami with a counterfeiting scheme that sold bacteria-tainted water in the guise of the anti-anemia medicine Procrit.

Paul Riches, Legislative Analyst
CA Board of Pharmacy
(916) 445-5014 ext. 4016

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By facsimile to (916) 327-6308 and U.S. Mail

January 17, 2003

California Board of Pharmacy
Attn: Patty Harris, Executive Officer
400 R Street, Suite 4070
Sacramento, CA 95814

Re: California's Proposed Wholesale Drug Transactions Regulations, Title 16, Sections 1784 and 1785

Dear Board Members:

This is in response to your request that Albertsons provide written comment on the proposed regulations pertaining to Wholesale Drug Transactions. We contend that section 1784, as currently proposed, would significantly impede legal trade and commerce in our industry and would directly and significantly hinder our ability to compete in the marketplace. While we understand and appreciate the core purpose of the proposed language and the desired result, we believe that its effect will go far beyond the Board's purpose and will negatively impact patient care in the areas of supply and cost.

We submit that adoption of the language proposed for section 1785 with one minor change (as indicated on the attached) is adequate to carry out the Board's purpose in that it provides a sufficient audit trail for enforcement purposes without the significant impact on trade and commerce. We propose that the Board modify section 1785, as indicated, to provide consistency with standard industry terminology, and that section 1784 be stricken in its entirety.

As always, we would be happy to answer questions or provide additional information or testimony, as necessary. We appreciate the Board's consideration.

Respectfully submitted,

ALBERTSON'S, INC.

Rich Mazzoni / lb

Rich Mazzoni, Director
Pharmacy Professional Services
and Government Relations

RM:lb
Enclosure
cc: David Vucurevich

~~1784. Wholesale Drug Transactions~~

~~(a) A wholesaler shall not sell, distribute, transfer, or otherwise provide more than 10 percent of the total annual dollar volume of sales of dangerous drugs dangerous drugs to another wholesaler, distributor or manufacturer.~~

~~(b) A pharmacy that sells, trades, or transfers more than ten percent of its total annual dollar volume of sales of dangerous drugs to a person other than the final consumer is acting as a wholesaler and shall obtain a license as a wholesaler from the board. For the purposes of this section, prescriptions refilled for another pharmacy as authorized by section 1707.4 shall not be considered to have been sold, traded or transferred to a person other than the final consumer.~~

~~(c) A wholesaler may not purchase or otherwise receive a dangerous drug from a pharmacy except that a wholesaler may receive a dangerous drug from a pharmacy that was originally purchased by the pharmacy from the wholesaler. A wholesaler may not receive back from a pharmacy more of a dangerous drug than was originally sold by the wholesaler to the pharmacy nor may a wholesaler pay more to the pharmacy, either in cash or credit, than the pharmacy originally paid to the wholesaler for the dangerous drug.~~

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(b) The "Statement of Prior Sales" shall:

- (1) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or wholesaler.
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- (3) Include the business name and address of the person from whom the dangerous drug was purchased.
- (4) Include the date of the sale.
- (5) Include the:
  - (A) Name of the dangerous drug.
  - (B) Strength of the dangerous drug.
  - (C) Size of the container.
  - (D) Number of containers.
  - (E) Lot number of the dangerous drug.
  - (F) Name of the manufacturer of the finished dosage form.

(c) Each statement shall be:

- (1) Maintained by the buyer and the wholesaler for 3 years.
- (2) Available for inspection or removal upon a request of an authorized officers of the law.

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
Phone 614.757.5000
www.cardinal.com

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2003 MAR 5 PM 12: 48

CardinalHealth

VIA AIRBORNE:

February 24, 2003

Paul Riches
Legislative Analyst
California State Board of Pharmacy
400 R. Street, Suite 4070
Sacramento, CA 95814-6237
Dear Paul:

It was a pleasure having an opportunity to meet with Patty, John and you last week at the California Drug Wholesalers Association (CDWA) meeting in Sacramento. Per our discussions, please find attached some comments we have to the preliminary draft rules your organization had drafted (copy attached of §§ 1784 and 1785).

As I mentioned to both John and Patty, I would be happy to participate in any Committee(s) or group you may be forming which are charged with working on these wholesaler regulations. Given our experience in this area, we believe we could provide value to the process. Please let me know if this is something the Board would be interested in our doing.

Lastly, as per your request regarding a "surveillance program," we would be interested in helping the Board as you move towards evaluating and developing such a program in California. To the extent you are still interested in this regard, please let Steve Reardon (614-757-7101) or me know (614-757-7721).

Sincerely,

Robert P. Giacalone
Vice President, Regulatory Affairs

CC: Ms. Patricia J. Harris (Executive Director, California State Board of Pharmacy)
Mr. John Jones (President, California State Board of Pharmacy)
Mr. Steve Reardon (Cardinal Health, Inc.)
Ms. Cassi Baker (Cardinal Health. Inc.)

Comments to
Board of Pharmacy
Proposed Additions
Title 16 – California Code of Regulations

1784. Wholesale Drug Transactions

~~(b)~~ (a) A pharmacy that sells, trades, or transfers more than ten percent of its total annual dollar volume of sales of dangerous drugs to a person other than the final consumer is acting as a wholesaler and shall obtain a license as a wholesaler from the board. For the purposes of this section, prescriptions refilled for another pharmacy as authorized by section 1707.4 shall not be considered to have been sold, traded or transferred to a person other than the final consumer.

Comments: The 10% rule as envisioned here is logical given that if pharmacies are to act as wholesale distributors, then they should be licensed accordingly.

~~(c)~~ (b) A wholesaler may not purchase or otherwise receive a dangerous drug from a pharmacy except that a wholesaler may receive a dangerous drug from a pharmacy that was originally purchased by the pharmacy from the wholesaler. A wholesaler may not receive back from a pharmacy more of a dangerous drug than was originally sold by the wholesaler to the pharmacy nor may a wholesaler pay more to the pharmacy, either in cash or credit, than the pharmacy originally paid to the wholesaler for the dangerous drug.

Comments: This provision while attempting to address certain issues, actually creates further problems for wholesalers and especially those pharmacies they service. Specifically, as the provision is currently written, a wholesaler can only receive/purchase dangerous drugs from a pharmacy that originally purchased those drugs from that wholesaler. This requirement prevents wholesalers from receiving returns from those pharmacies with which the wholesaler does not have a prior history. For example, Pharmacy A opens on January 1, 2002 and is serviced by Wholesaler One. On January 1, 2003, Pharmacy A switches wholesalers so that now it is serviced by Wholesaler Two. Perhaps Pharmacy A would like to make returns to Wholesaler Two due to overstock, etc. Technically, Wholesaler Two cannot take those returns since they would be purchases of dangerous drugs from Pharmacy A which originally purchased those drugs from a different wholesaler (i.e., Wholesaler One). In addition, any subsequent stock purchased from Wholesaler Two by Pharmacy A would also have to be segregated (form that bought from Wholesaler One) in the event that Pharmacy A would want return drug product it purchased to Wholesaler Two. At this point, Pharmacy A may be left in a position that no returns are possible for a significant amount of its product since Pharmacy A no longer has a relationship with Wholesaler One.

Similarly, the same situation would arguably occur if Pharmacy A was subsequently purchased by another person or entity. For example, Pharmacy A is currently owned and operated by Mr. Jones who is also the pharmacist-in-charge. The pharmacy is serviced by Wholesaler One. Mr. Jones subsequently sells Pharmacy A to Ms. Smith. Ms. Smith, also a registered pharmacist, assumes the role of the pharmacist-in-charge and the state issues Pharmacy A a new license. In this case, Pharmacy A is technically a new licensed entity. As such, any returns to Wholesaler One would be prohibited since those dangerous drugs were originally by a different licensed pharmacy (e.g., Pharmacy A owned by Mr. Jones as opposed to Ms. Smith).

Another issue arises where Pharmacy A is serviced by both Wholesaler One (as the primary supplier) and Wholesaler Two (as a secondary supplier). As written, the proposed rules would require that Wholesaler One only "receive" product it sold to Pharmacy A. Likewise, Wholesaler Two could only receive product it sold to Pharmacy A. To be able to facilitate returns, Pharmacy A would have to segregate stock or take other steps to definitively identify which product was provided to it by which wholesaler. Arguably, this may entail more work especially since stock in pharmacies is typically commingled (e.g., all of the Zocor® purchased is generally placed together into the pharmacy's inventory regardless of where it is sourced).

Lastly, the provision which provides that the wholesaler may not ". . . pay more to the pharmacy, either in cash or credit, than the pharmacy originally paid to the wholesaler for the dangerous drug." also poses another problem. This provision does not take into account the issue of returns and the ongoing appreciation of the price of such goods. For example, on January 1, 2002, Pharmacy A purchases Zocor® from Wholesaler One. On January 1, 2003, Pharmacy A realizes it has a surplus of product due to lack of prescriptions and chooses to return that product to Wholesaler One. Pharmacy A originally purchased the product for $100 and bottle. However, today due to the manufacturer's price increase that same bottle lists for $120. Under the current proposed rules, Pharmacy A could only receive $100 for that bottle. In addition, Pharmacy A would have to keep all invoices which specifically list product purchased and price paid so as to validate that the pharmacy originally purchased that product from that wholesaler and what price should be paid by the wholesaler for that returned product. Typically, neither the pharmacies nor the wholesalers, keep track what prices a product was sold or purchased for many years prior. Rather, both pharmacies and wholesalers focus upon the current value of the drugs products at issues for purposes of sales and returns. As written, the proposed rules tend to penalize pharmacies for market conditions which arguably may benefit them due to the appreciation of drug inventory costs.

1785. Statement of Prior Sales

(a) *If a wholesaler purchases a dangerous drug from a person other than the manufacturer of the dangerous drug, a wholesaler shall provide a "Statement of Prior Sales" identifying each sale, trade or transfer of a dangerous drug when a dangerous drug is sold, traded or transferred to*

any other person. If a pharmacy sells a drug to any person that is not the final consumer, the pharmacy shall provide to the person acquiring the dangerous drug a "Statement of Prior Sales" identifying each sale, trade or transfer of a dangerous drug. Sale, trade or transfer of a dangerous drug between licensees with a common ownership are not subject to this section.

Comments: As currently written, the proposed rule appears to make no distinction between sales by wholesalers who are "authorized distributors of record" of the manufacturers versus those wholesalers who are not. Under the Prescription Drug Marketing Act of 1987 (PDMA), accompanying regulations and guidance documents, the FDA has made a distinction wholesalers who are authorized distributors and those who are not. Specifically, wholesalers who are designated as authorized distributors of a manufacturer's products are not required to provide a "Statement of Prior Sales" when that product is sold to another party. Thus, wholesalers such as Cardinal Health, McKesson Corp. and AmeriSource Bergen who have established, ongoing relationships with drug manufacturers have not traditionally been required to have this additional documentation (but do so when they purchase product from unauthorized distributors). This new proposed requirement fails to recognize this "authorized distributor" relationship and lumps all wholesalers in the same group regardless of this distinction.

(b) The "Statement of Prior Sales" shall:

(1) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or wholesaler.

(2) Accompany all dangerous drugs purchased from a wholesaler, even if they are resold to another distributor.

(3) Include the business name and address of the person from whom the dangerous drug was purchased.

(4) Include the date of the sale.

(5) Include the:

(A) Name of the dangerous drug.

(B) Strength of the dangerous drug.

(C) Size of the container.

(D) Number of containers.

(E) Lot number of the dangerous drug.

(F) Name of the manufacturer of the finished dosage form.

Comments: As in the case of our prior comment, the requirement for a "Statement of Prior Sales" does not reflect the fact that certain wholesalers are "authorized distributors" for drug manufacturers' products. As such, the need for a "Statement of Prior Sales" or drug pedigree for product sold by non-authorized distributors has typically been limited information concerning each sale when it originates from either the manufacturer or the authorized distributor. As such, an authorized distributor,

like the manufacturer, is not required to produce a drug pedigree given its unique relationship with the manufacturer. Again, this distinction is not reflected in this provision.

General Comments

While we commend the Board of Pharmacy for trying to establish rules which attempt to address the issue regarding the legitimacy of wholesaler transactions and ensuring the integrity of their product, we believe that the rules as currently drafted pose greater obstacles and do not necessarily succeed in accomplishing their intended goal. To that effect, we would suggest that perhaps the Board consider an alternative approach towards addressing this matter. That approach would be similar to the approach currently under consideration in Florida. A copy of that draft regulation in enclosed.

The Florida approach would envision a situation where rather than changing the overall way in which products are sold by wholesalers, it would focus upon identifying those potential products which are more susceptible to inappropriate activity. Specifically, products more prone to counterfeiting or diversion such as Procrit®, Serostim®, Trizivr®, Epogen® and Neupogen® would be designated as a "specified drug." For those "specified drugs," the invoice or transfer document accompanying the product would be required to carry the statement that the product was purchased from the manufacturer by the wholesaler which is an authorized distributor of record for that manufacturer. In the alternative, if this is not the case, a drug pedigree must be provided with the product which identifies each individual purchaser of that drug back to the manufacturer. In this way, the party receiving the pedigree (as well as law enforcement) could validate the authenticity of each transaction back to the manufacturer.

The goal of this rule would be to discourage the sale and purchase of "specified drugs" from sources other than from the product's manufacturer. However, in the event there is a need for such products due to shortages, back orders, or otherwise, there would still be in place a system, albeit a more stringent system, to allow for this to occur.

As to the selection criteria for "specified drugs," a group comprised of the wholesale industry and board members should be formed so as to make that determination on a product-by-product basis. The criteria used to designate a specified drug should include factors such as a history of counterfeiting or diversion associated with the product. In addition, another potential factor might include a determination as to whether a product is more susceptible to counterfeiting such as high dollar volume injectable drugs used for the treatment of disease states such as AIDS/HIV or cancer.

Agenda Item D

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: June 19, 2003**

From: **Patty Harris**
Executive Officer
Board of Pharmacy

Subject: **Request for Pharmacy Records by Authorized Officers of the Law**

It was brought to the board's attention that pharmacies are choosing not to provide prescription records when requested by an authorized officer of the law engaged in an official investigation. Whether to provide the record or not, is a decision that the licensee must make. The board does not advise licensees in this regard.

However, there is some misinformation that is being given to the officers as to why the pharmacy will not release the records without an investigative subpoena. One reason is that the Board of Pharmacy requires an investigative subpoena to document the release of the records and without it, the pharmacy will be cited for violation of pharmacy law.

This is not true. When an officer takes prescription record(s), the pharmacy should be given a receipt identifying the records. If a board inspector should ever ask for the same records, the pharmacy should be able to produce the receipt to document release of the records to an authorized officer of the law.

(Amended Stats. 1997, Chapter 549)

4006. Regulations Restricting Furnishing of Particular Drug

The board may adopt regulations consistent with this chapter and Section 111485 of the Health and Safety Code or regulations adopted thereunder, limiting or restricting the furnishing of a particular drug upon a finding that the otherwise unrestricted retail sale of the drug pursuant to Section 4057 is dangerous to the public health or safety.

4007. Limitations of Rules

(a) Nothing in Section 4005 shall be construed as authorizing the board to adopt rules of professional conduct relating to price fixing or advertising of commodities.

(b) Nothing in Section 4005 shall be construed as authorizing the board to adopt any rule or regulation that would require that a pharmacist personally perform any function for which the education, experience, training, and specialized knowledge of a pharmacist are not reasonably required . However, rules and regulations may require that the function be performed only under the effective supervision of a pharmacist who shall have the overall responsibility for supervising all activities that take place in the pharmacy.

(Amended Stats. 1997, Chapter 549)

4008. Inspectors; Authority as Public Officers

(a) Except as provided by Section 159.5, the board may employ inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places in which drugs or devices are compounded, prepared, furnished, dispensed, or stored. Any board inspector of pharmacy whose principal duties include either (1) the inspection and investigation of pharmacies or pharmacists for alleged violations of this act, or (2) the supervision of other inspectors of pharmacy, shall be a pharmacist. For purposes of inspecting or investigating nonpharmacies or nonpharmacists pursuant to this chapter, a board inspector of pharmacy is not required to be a pharmacist.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c)(1) Any pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated any provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code. If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, any person, acting pursuant to subdivision (a) and within the scope of his or her authority, for false arrest or false imprisonment arising out of any arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. No inspector shall be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest or to prevent escape or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(Amended Stats. 2001, Chapter 728)

4009. Board Rules; Exemption From Coverage Under Industrial Welfare Commission Rules

The board may not adopt or amend any rule or regulation that thereby would conflict with Section 1186 of the Labor Code.

(Added Stats. 1999, Chapter 190)

4010. Immunity of Officers

All authorized officers of the law, while investigating violations of this chapter in performance of their official duties, and any person working under their immediate direction, supervision, or instruction are immune from prosecution under this chapter.

4011. Administration and Enforcement of Uniform Controlled Substances Act

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

4012. Board to Provide Copy of Laws or Regulations

The board shall upon request furnish any person with a copy of the laws or regulations relating to dangerous drugs, the furnishing or possession of which is restricted by this article or by further rules of the board.

Article 2. Definitions

4015. Definitions to Govern Construction

For purposes of this chapter, the definitions of the terms in this article shall govern the construction of this chapter, unless otherwise indicated.

4016. Administer

"Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(Repealed and Added Stats. 1997, Chapter 549)

4017. Authorized Officers of the Law

"Authorized officers of the law" means inspectors of the California State Board of Pharmacy, inspectors of the Food and Drug Branch of the State Department of Health Services, and investigators of the department's Division of Investigation or peace officers engaged in official investigations.

(Amended Stats. 1997, Chapter 549)

4018. Board

"Board" means the California State Board of Pharmacy.

(Amended Stats. 1997, Chapter 549)

Agenda Item E

Sav-on™
An Albertson's Company

Albertsons

Osco®
An Albertson's Company

RECEIVED BY CALIF. BOARD OF PHARMACY
2003 MAR 20 AM 10:50

March 17, 2003

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

Re: After Hours Receiving of Pharmaceuticals
Albertsons, Inc. (Albertsons/Sav-on/Osco)

Dear Ms. Harris:

With approval from the Board, Albertsons intends to initiate a secure procedure for receiving pharmaceutical deliveries during periods in which the pharmacy is closed and there is no pharmacist on duty.

Each of our stores is equipped with a receiving area that is located outside the licensed pharmacy area. This area will house a steel cage. Access to the cage will be controlled by a padlock to which a pharmacist will have the only key.

The transfer of pharmaceuticals into and out of the cage will take place as follows.

The padlock will remain disengaged until a delivery person ("driver") places parcels containing pharmaceuticals ("totes") inside the cage. The driver shall indicate on a manifest the number of totes being placed into the cage. The employee of Albertsons who is responsible for the management of the receiving area ("receiver") will witness the totes being placed into the cage and will also record the number of totes on the manifest. In an effort to ensure that the totes are not tampered with, the condition of the seals on the totes shall be noted on the manifest.

After being signed by both the driver and the receiver, a copy of the manifest shall be placed inside the cage with the totes and the driver shall engage the padlock. At the start of business the next day, a pharmacist will use the key to unlock the cage. The pharmacist will review the manifest, relocate the totes into the pharmacy, and leave the cage unlocked in anticipation of the next delivery.

Albertsons respectfully requests a written response to this proposal. Please address all correspondence to Richard B. Mazzoni at the address indicated below. Should you have questions or comments in this regard, or if the Board requires anything further, please call me at (480) 767-4572.

Sincerely,
ALBERTSONS, INC.

Richard B. Mazzoni, R.Ph.
Director, Pharmacy Professional Services
and Government Relations

Walgreens

RECEIVED BY CALIF.
BOARD OF PHARMACY
2003 MAY 12 PM 2:37

May 9, 2003

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

Re: After Hours Receiving of Pharmaceuticals

Dear Ms. Harris:

Walgreens Co. seeks the approval from the Board to implement a new procedure for receiving pharmaceuticals outside the business hours of the pharmacy, in the absence of a pharmacist.

Each of our stores is equipped with a secure room that is located outside of the pharmacy department. This room is secured by two methods, a lock and a door seal that is marked with a serial number.

The delivery of pharmaceuticals after hours would be placed into this secure room. The delivery person and a member of Walgreens' management would secure the delivery, record the serial number of the door seal on a log sheet, along with the date and time received, and the number of parcels received. The following business day, the pharmacist would receive the delivery by checking that the unbroken seal on the door matches the serial number indicated on the log sheet and account for the proper number of parcels delivered. The pharmacist would be the only person with possession of the key to this secure room.

We believe that this proposed procedure would ensure safe delivery of pharmaceuticals to our pharmacies during the absence of a pharmacist. The majority of our deliveries are during business hours of the pharmacy and this policy would only be implemented in a small number of stores where deliveries are made outside the business hours of the pharmacy.

Thank you for your consideration. If there are any questions or comments on our proposal, please feel free to contact me.

Sincerely,

Philip P. Burgess, R.Ph.
National Director, Pharmacy Affairs
(847) 914-3241
Phil.Burgess@Walgreens.com

PPB/sr

(i) This section shall become operative on July 1, 2001.
(Amended Stats. 2001, Chapter 159)

4059.5. Who May Order Dangerous Drugs or Devices: Exceptions; Compliance With Laws of All Involved Jurisdictions

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

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

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

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

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to any person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the drugs or devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the drugs or devices are to be delivered shall include, but not be limited to, determining that the recipient of the drugs or devices is authorized by law to receive the drugs or devices.
(Added Stats. 1997, Chapter 549)

4060. Controlled Substance - Prescription Required; Exceptions

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, or veterinarian, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section 3502.1. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, physician, podiatrist, dentist, veterinarian, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, or a physician assistant to order his or her own stock of dangerous drugs and devices.
(Amended Stats. 2001, Chapter 289)

4061. Distribution of Drug as Sample; Written Request Required

(a) No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, or veterinarian. However, a certified nurse -midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to a protocol described in Section 3502.1, may sign for the ***request and receipt of complimentary samples of a dangerous drug or dangerous device that has been ***identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725 or 3502.1, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, or physician assistant shall be defined within the standardized procedure, protocol, or practice agreement.

(b) Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, or physician assistant, if applicable, receiving the samples pursuant to this section, the date of receipt, and the name and quantity of the dangerous drugs or dangerous devices provided. These records shall be preserved by the supplier with the records required by Section 4059.

(c) Nothing in this section is intended to expand the scope of practice of a certified nurse-midwife, nurse practitioner, or physician assistant.
(Amended Stats. 2002, Chapter 263)

4062. Furnishing Dangerous Drugs During Emergency

Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name and address of the person to whom the drug or device is furnished, and the name, strength and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.
(Amended Stats. 1997, Chapter 549)

4063. Refill of Prescription for Dangerous Drug or Device; Prescriber Authorization

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.
(Amended Stats. 1997, Chapter 549)

4064. Emergency Refill of Prescription Without Prescriber Authorization

(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the

Agenda Item F

CardinalHealth

Off-Site Order Entry of Hospital Medication Orders

Gary Cacciatore, Pharm.D., J.D.
Director of Regulatory Affairs

May 8, 2003

Background

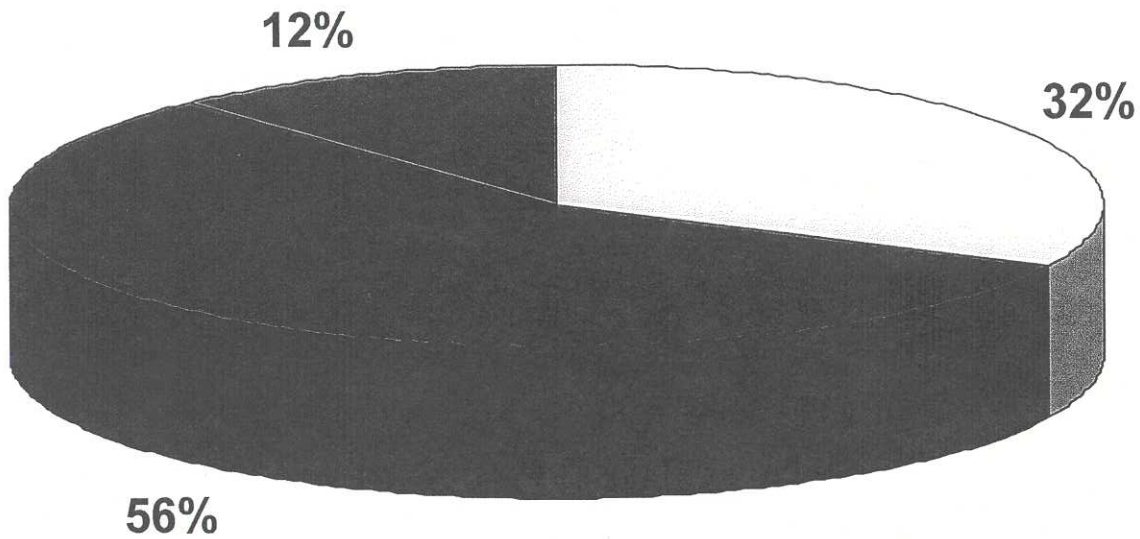
- Focus on medication safety
  - Institute of Medicine "To Err is Human" report demonstrates medication errors lead to 7,000 deaths/year
    - Lazarou J, JAMA 1998;279:1200-5.
  - "Better patient monitoring and review of orders before the drug was administered to the patient were major mechanisms for preventing fatal ADEs."
    - Kelly WN, Am J Health Syst Pharm. 2001;58:1317-24

Background

- Accreditation /Regulatory Standards
  - JCAHO standards
    - TX 3.5.2 Pharmacists review each prescription or order for medication and contact the prescriber or orderer when questions arise.
    - TX 3.5.4 Pharmacy services are available when the pharmacy department is closed or not available.
  - Regulatory Standards
    - Many state boards have regulations regarding review of orders by pharmacist prior to dispensing
  - CMS (Centers for Medicare & Medicaid Services)
    - Consistent level of care

Background

Only 12% of hospitals have 24/7 pharmacy services
88% of hospitals have at least some gap in coverage



□ Weekdays, no night shift ■ Weekdays, weekends, no night shift ■ 24/7

Source: Pharmacy Management Survey

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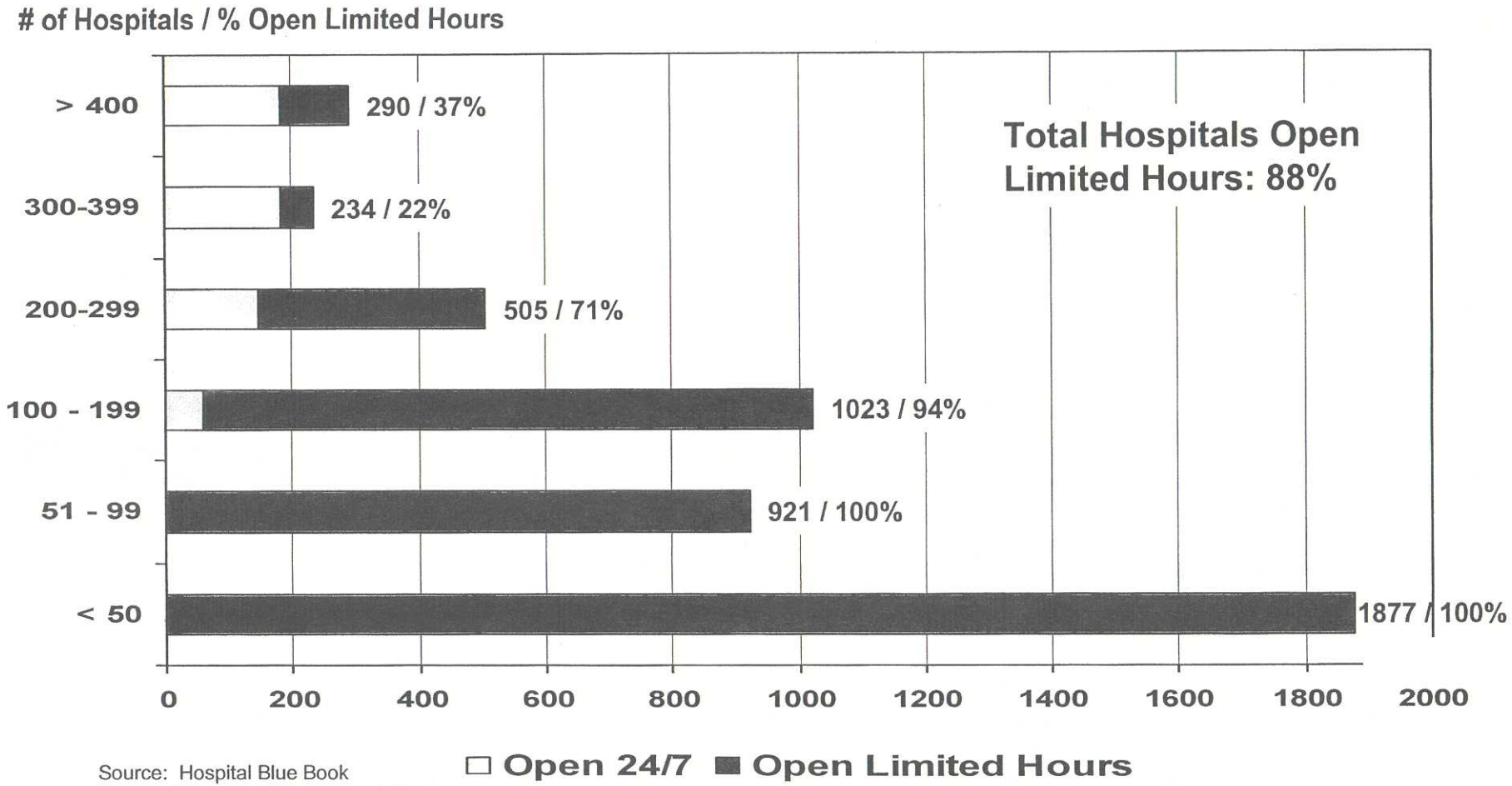
Background



Source: Hospital Blue Book
Source: Pharmacy Management Survey

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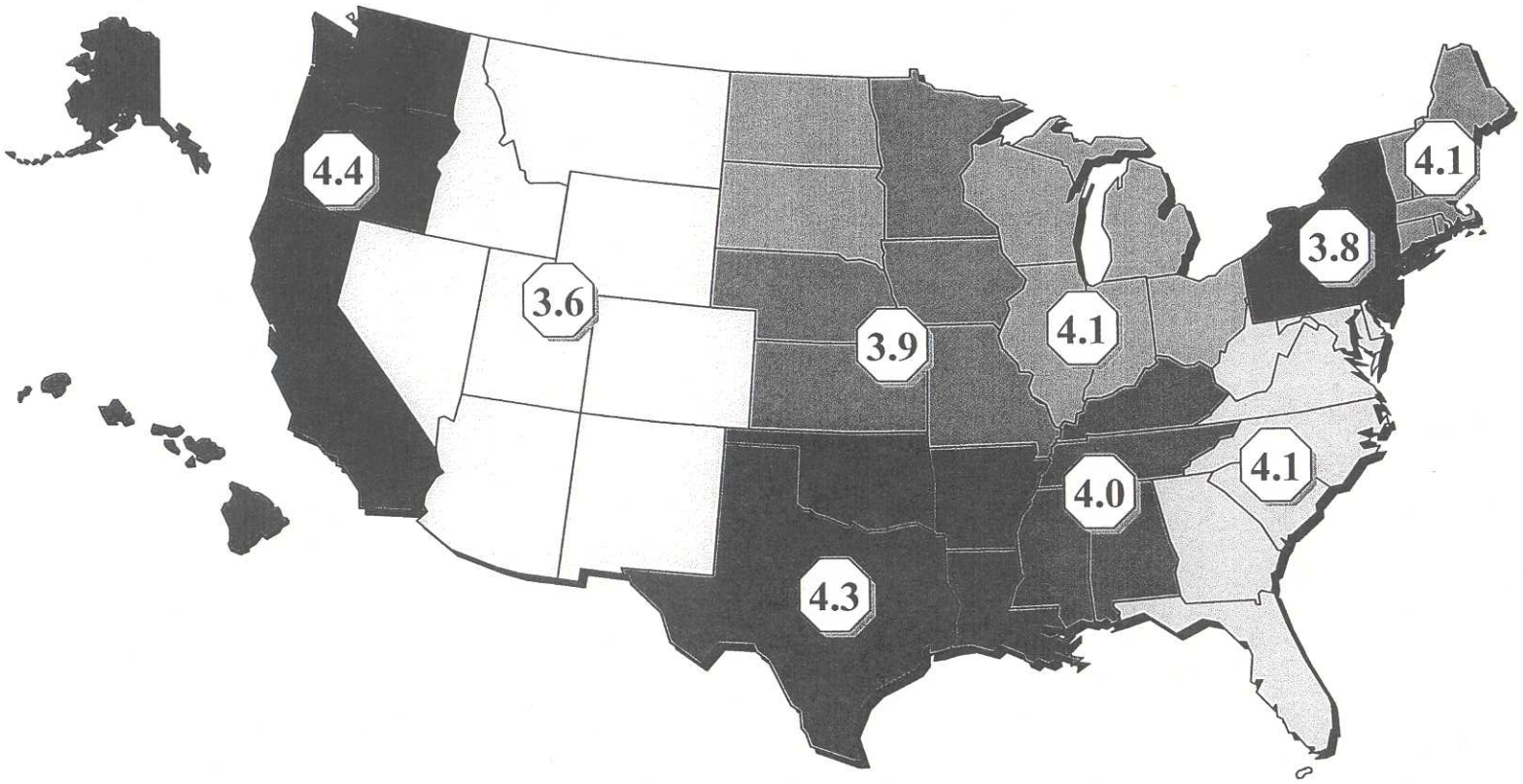
Pharmacist Demand Index



1= Pharmacist Supply Adequate

5 = Severe Pharmacist Shortage

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R_xe-source℠

- Pharmacy Service Center, an office-based, licensed pharmacy staffed with experienced hospital pharmacists established by Cardinal Health.
- Hospitals transmit new orders to the Pharmacy Service Center after the hospital pharmacy closes or when needed via fax or digital imaging system.
- Pharmacists at the Pharmacy Service Center remotely access the hospital pharmacy computer system and review orders, perform prospective drug use review, and approve orders within 60 minutes.
- Pharmacists are also available via toll free number to answer medication questions from nursing and medical staff.

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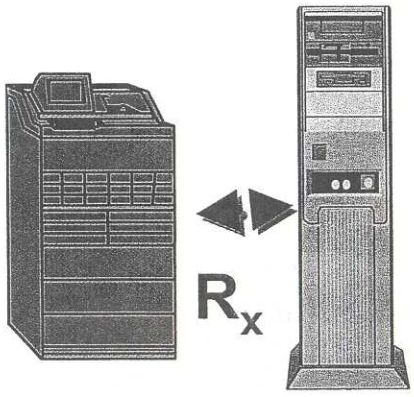
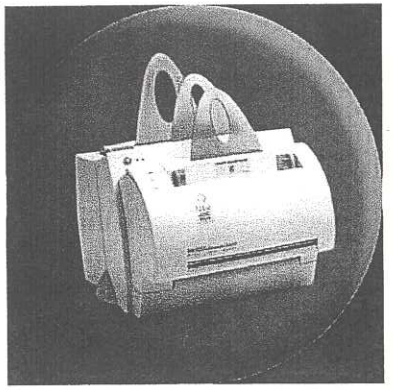
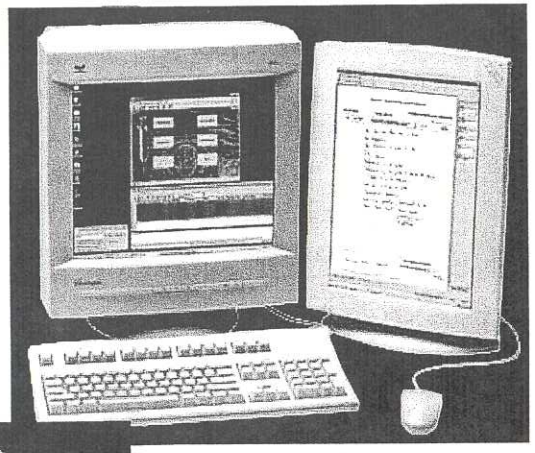
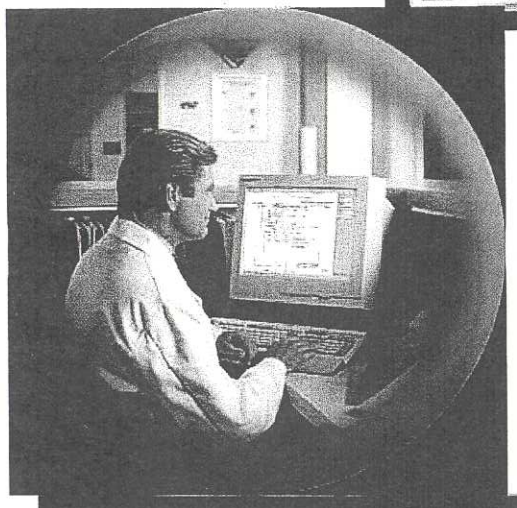
Hospital





Pyxis Connect, Fax, or Scan





Pharmacy Service Center

CardinalHealth

R_xe-*source*℠

- Training
  - Pharmacists are trained on each hospital's policies, procedures, and protocols prior to initiation of the service.
  - Copies of hospital pharmacy's policies and procedures are kept on site at the Pharmacy Service Center.
  - Pharmacy Service Center is staffed with pharmacists experienced in hospital pharmacy.
- Recordkeeping
  - System is able to identify each individual who processes an order.

R_xe-source℠

- Measurements and Reports
  - Pharmacy Service Center staff document all interventions such as interaction avoidance, illegible order clarification, incomplete order clarifications, dosing changes, therapy duration changes, drug information provided, adverse drug reaction reporting, therapeutic interchange, etc.
- Confidentiality and Security
  - Remote access to hospital pharmacy computer system is through a secure, virtual private network.
  - Pharmacy Service Center enters into a Business Associate agreement with hospital and is in full compliance with HIPAA and state privacy laws.

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Service Benefits

- Patients
  - Improved continuity of patient care
  - Avoidance of adverse medication events
- Pharmacist
  - Ease staffing pressures
  - Focus on professional patient care functions
- Nurses
  - Safety of order authorization
  - Drug Information Resource

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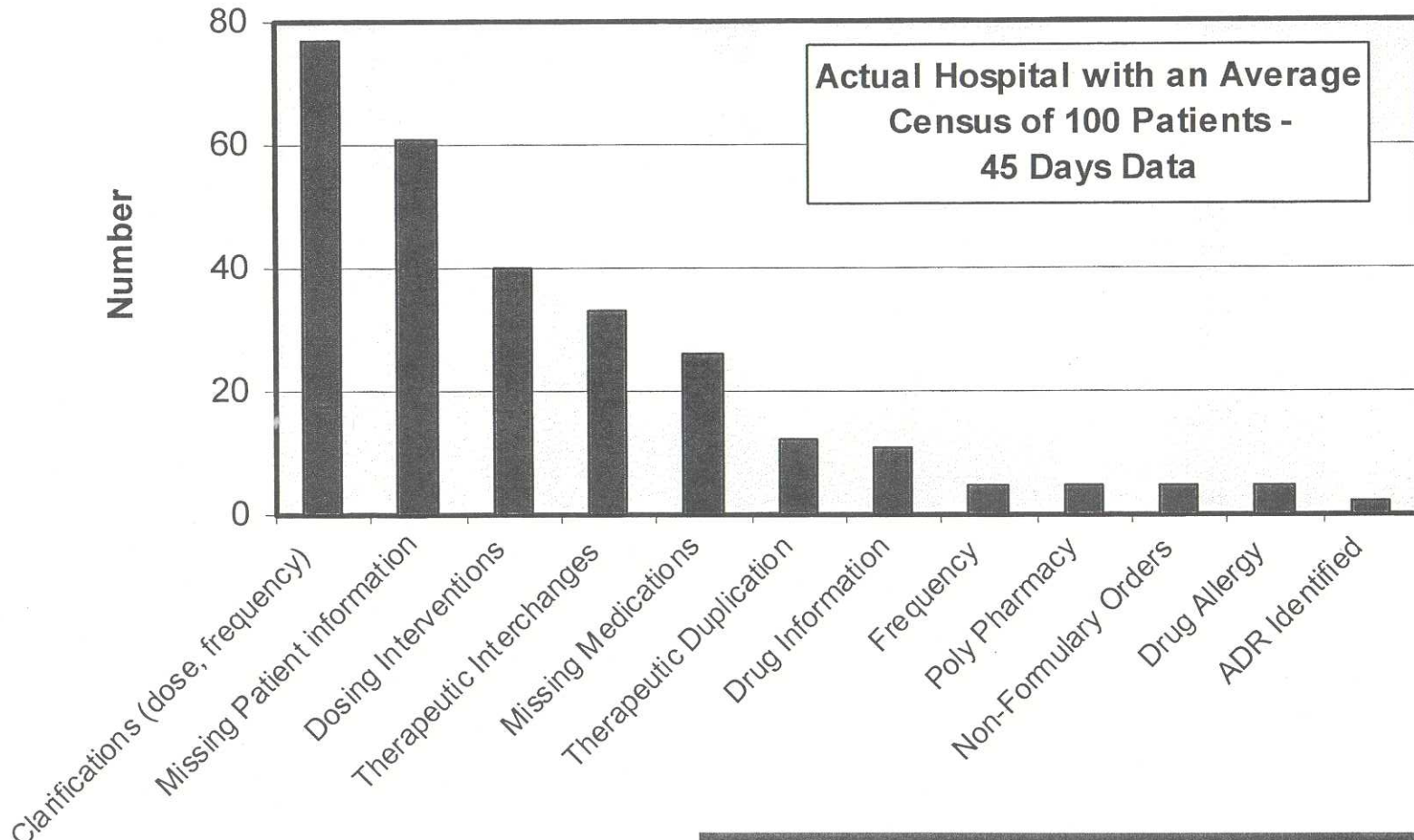
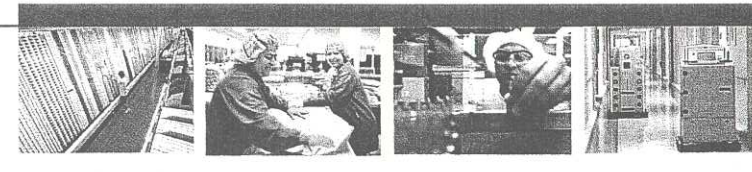
Texas Pharmacy Service Center





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California Law

- Business and Professions Code 4071.1
  - "A prescriber, a prescriber's agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital….This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, <u>except as permitted pursuant to Section 11164.5 of the Health & Safety Code."</u>

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California Law (cont'd)

- Health and Safety Code 11164.5
  - "Notwithstanding Section 11164, with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration. The California Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision."

Next Steps

- Location of Pharmacy Service Center already identified.
- Application for pharmacy license.
- Request for approval to include controlled substances.

CardinalHealth

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

MAY 23 2003

Mr. Gary Cacciatore
Director of Regulatory Affairs
Cardinal Health
1330 Enclave Parkway
Houston, Texas 77077

Dear Mr. Cacciatore:

This is in response to your correspondence dated May 16, 2003, requesting the Drug Enforcement Administration (DEA) to review Cardinal Health's Rx-E-Source system for compliance with our regulations. Rx-E-Source is an Internet based remote order entry system utilized by hospitals for in-patient medication orders. Personnel at hospital locations enter orders for in-patients into the system and pharmacists at Cardinal Health's support center, located at a separate location, will review the orders prior to the medications being administered to the hospital patients. Rx-E-Source provides pharmacist services to hospitals that may not have on-site pharmacist coverage available 24 hours a day, seven days a week.

The DEA has no regulatory authority over entities that do not possess or handle controlled substances. Under the circumstances described above, the pharmacists at Cardinal Health's support center do not have access to controlled substances and the centers do not stock controlled substances. The only activity taking place at the support center is pharmacists performing drug utilization reviews of medication orders for patients that are located in hospitals. The hospitals where the controlled substances are actually being administered to the patients must remain registered with the DEA and comply with federal controlled substance laws and regulations.

I trust this information addresses your concerns. The DEA appreciates the opportunity to assist registrants in their efforts to comply with our controlled substance regulations. If you have additional questions, please contact Vickie B. Seeger, R.Ph. at (202) 307-7297.

Sincerely,

Robert C. Williamson

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

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

(Added Stats. 2000, Chapter 681)

Article 4. Requirements for Prescriptions

4070. Reduction of Oral or Electronic Prescription to Writing

(a) Except as provided in Section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in subdivision (c) of Section 4040 shall as soon as practicable be reduced to writing by the pharmacist and shall be filled by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy.

(b) A pharmacy receiving an electronic transmission prescription shall not be required to reduce that prescription to writing or to hard copy form if, for three years from the last date of furnishing pursuant to that prescription or order, the pharmacy is able, upon request by the board, to immediately produce a hard copy report that includes for each date of dispensing of a dangerous drug or dangerous device pursuant to that prescription or order: (1) all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040, and (2) the name or identifier of the pharmacist who dispensed the dangerous drug or dangerous device. This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(c) If only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's computer system shall not permit the received information or the dangerous drug or dangerous device dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law once the information has been received by the pharmacy and once the dangerous drug or dangerous device has been dispensed. Once a dangerous drug or dangerous device has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall impair the requirement to have an electronically transmitted prescription transmitted only to the pharmacy of the patient's choice or to have a written prescription. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

(Amended Stats. 2000, Chapter 293)

4071. Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded

Notwithstanding any other provision of law, a prescriber may authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher. The furnisher shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent of the prescriber who transmits the order.

This section shall not apply to orders for Schedule II controlled substances.

(Amended Stats. 1997, Chapter 549)

4071.1. Electronic Prescription Entry Into Pharmacy or Hospital Computer

(a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's authorized agent" is a person licensed or registered under Division 2 (commencing with Section 500). This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(b) Nothing in this section shall reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.

(c) No dangerous drug or dangerous device shall be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.

(Added Stats. 2000, Chapter 293)

4072. Oral or Electronic Transmission of Prescription - Health Care Facility

(a) Notwithstanding any other provision of law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

(b) In enacting this section, the Legislature recognizes and affirms the role of the Department of Health Services in regulating drug order processing requirements for licensed health care facilities as set forth in Title 22 of the California Code of Regulations as they may be amended from time to time.

(Amended Stats. 1997, Chapter 549)

4073. Substitution of Generic Drug - Requirements and Exceptions

(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark.

this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) In addition, the prescription shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber. The information required by this paragraph shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand. Notwithstanding any provision in this section, the prescriber's address, telephone number, category of professional licensure, or federal controlled substances registration number need not appear on the prescription if that information is readily retrievable in the pharmacy.

(3) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(c) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be reduced to writing by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. The date of issue of the prescription and all the information required for a written prescription by subdivision (b) shall be included in the written record of the prescription. The pharmacist need not reduce to writing the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient if that information is readily retrievable in the pharmacy. Pursuant to authorization of the prescriber, any employee of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the employee of the prescriber transmitting the prescription.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Notwithstanding any provision of subdivisions (b) and (c), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(f) In addition to the prescriber's record required by Section 11190, any practitioner dispensing a controlled substance classified in Schedule II in accordance with subdivision (b) of Section 11158 shall prepare a written record thereof on the official forms issued by the Department of Justice, pursuant to Section 11161, and shall transmit the original to the Department of Justice in accordance with any rules that the department may adopt for completion and transmittal of the forms.

(Amended Stats. 2002, Chapter 536)

11164.5. Electronic Prescriptions or Orders to Pharmacies and Hospitals

(a) Notwithstanding Section 11164, with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration. The California State Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision.

(b) Notwithstanding Section 11164, if approved pursuant to subdivision (a), a pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance classified in Schedule II, III, IV, or V shall not be required to reduce that prescription or order to writing or to hard copy form, if for three years from the last day of dispensing that prescription, the pharmacy or hospital is able, upon request of the board or the Department of Justice, to immediately produce a hard copy report that includes for each date of dispensing of a controlled substance in Schedules II, III, IV, and V pursuant to the prescription all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040 of the Business and Professions Code and the name or identifier of the pharmacist who dispensed the controlled substance.

(c) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

(Added Stats. 2000, Chap. 293)

11165. Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. CURES shall be implemented as a pilot project, commencing on July 1, 1997, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies between the two systems.

(b) The CURES pilot project shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or crimi-

Agenda Item G

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Medical Board of California
California State Board of Pharmacy

Joint Task Force on Prescriber Dispensing

Meeting Summary

DATE: May 27, 2003

TIME: 2:00 p.m. – 5:00 p.m.

LOCATION: Embassy Suites – Granada Room
El Segundo, CA 90245

Joint Task Force Members:
Steven B. Rubins, M.D., Co-Chair, MBC
John Jones, R.Ph., Co-Chair, Board of Pharmacy
Lorie Rice, Public Member, MBC
Stan Goldenberg, R.Ph., Board of Pharmacy

Staff Present:
Ron Joseph, Executive Director, MBC
Patricia Harris, Executive Officer, Board of Pharmacy
Ronald Diedrich, Liaison Deputy Attorney General for the Board of Pharmacy
Paul Riches, Legislative Analyst, Board of Pharmacy

Call to Order/Introductions:

Chairs Rubins and Jones called the meeting to order at 2:00 p.m. Each task force member introduced himself or herself as did the audience participants.

Purpose and Goals of the Task Force

It was stated that the purpose and goals of the task force was to evaluate the prescriber dispensing law (Business and Professions Code section 4170) to determine if it is still relevant to today's practice and to identify those areas of law that needed to be clarified or updated to ensure public protection. Specific areas that should be addressed were the commingling of drugs by physician groups for common use, potential conflicts of interest and the jurisdictional authority of the Medical Board of California and the Board of Pharmacy.

***Park Medical Pharmacy v. San Diego Orthopedic Associates, Inc.* (2002) 99 Cal. App.4th 247**

As background information, the task forced reviewed this decision. In 1992, Park Medical Pharmacy brought action for declaratory and injunctive relief against San Diego Orthopedic

Associates, Inc., a physicians' corporation, alleging violation of the statute (Bus. & Prof. Code sec. 4170) prohibiting physicians from keeping pharmacies. The Superior court in San Diego County granted summary judgment for the physicians' corporation and the pharmacy appealed. The Court of Appeal held that the physicians did not violate pharmacy law by dispensing drugs to their patients on a for-profit basis.

Review of Business and Professions Code Section 4170

It was explained that current law allows an individual prescriber to dispense prescription drugs to his/her own patient from the prescriber's own stock. The drugs must be necessary for the treatment of the condition for which the prescriber is attending the patient, and a nurse or physician attendant cannot furnish the prescription drugs. However, a nurse may assist, at the prescriber's direction, in the dispensing of such drugs, including handing them to the patient, under the direct supervision and control of the prescriber provided that the prescriber verifies each step performed by the nurse. (57 Op. Attorney Gen.93 (1974)) The law does allow a certified nurse-midwife, a nurse practitioner, or a physician assistant functioning pursuant to a protocol to hand to a patient of the supervising physician and surgeon a properly labeled prescription drug that has been properly prepackaged.

There was agreement that the dispensing prescriber must comply with all the labeling requirements of section 4076, and the recordkeeping requirements of the Pharmacy Law. The pharmacy's dispensing process was explained, including the safeguards established to prevent prescription errors, quality assurance evaluations and the review of every prescription by a pharmacist. The law does allow a prescriber to use a dispensing device as long as the prescriber owns the device and personally dispenses the prescription drugs.

Current law does not authorize a group of physicians to purchase prescription drugs for group dispensing. Only clinics permitted by the Board of Pharmacy may directly purchase drugs for common use.

Recommendations

There was considerable discussion regarding the conflict of interest when a physician dispenses prescription drugs for profit. However, it was noted that the dispensing prescriber is required to offer the patient the option of having the prescription filled at a pharmacy of the patient's choice.

It was suggested that physicians be allowed to dispense from a commingled drug supply if a permit process was established modeled after the Board of Pharmacy's clinic permit (Business and Professions Code sections 4180 and 4190). Another example to this permit process is the licensure of laboratories by Department of Health Services. These laboratories are owned by medical groups and are located in their office. Another proposal was to authorize a pharmacy to place in the prescriber's office an automated dispensing device consistent to what is allowed now in clinics that would provide the patient with increased access to prescription drugs and oversight by a pharmacist.

The task force reached consensus on the following issues: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the recordkeeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, recordkeeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

The task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004.

Adjournment

The meeting of the Joint Task Force on Prescriber Dispensing was adjourned at 5:00 p.m.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

MEDICAL BOARD OF CALIFORNIA
CALIFORNIA STATE BOARD OF PHARMACY

Joint Task Force on Prescriber Dispensing

Steven B. Rubins, M.D., Co-Chair, Medical Board of California
John Jones, R.Ph., Co-Chair, Board of Pharmacy
Lorie Rice, Public Member, Medical Board of California
Stan Goldenberg, R.Ph., Board of Pharmacy

May 27, 2003

Embassy Suites
Granada Room
1440 East Imperial Avenue
(LAX Airport – courtesy shuttle available)
El Segundo, CA 90245
(310) 640-3600

2:00 p.m. – 5:00 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 48 hours prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item.

A. Call To Order 2:00 p.m.

B. Introductions

C. Purpose and Goals of Task Force

D. *Park Medical Pharmacy v. San Diego Orthopedic Associates, Inc.* (2002) 99 Cal.App. 4th 247.

E. Review of Business and Professions Code sections 4170- 4175 – Purchase of Dangerous Drugs for Communal Use and Dispensing by Medical Group Practices

F. Next Meeting

G. Adjournment 5:00 p.m.

Agenda Item H

Statement of Authority

(Title 45, Code of Federal Regulations (C.F.R.) § 164.514, subdivision (h), (2), (iii).)

Recent federal regulations recognize the propriety of longstanding California law that enables the California State Board of Pharmacy ("Board of Pharmacy") to protect consumers through inspections and investigations related to the practice of pharmacy. Specifically, federal regulations implementing the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") define a *health oversight agency*, in relevant part, as follows:

> "*Health oversight agency* means an agency or authority of . . . a State . . . or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant. (45 C.F.R. §164.501.)

A *covered entity* may disclose *protected health information* to a *health oversight agency* for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of: (i) The health care system; (ii) Government benefit programs for which health information is relevant to beneficiary eligibility; (iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or (iv) Entities subject to civil rights laws for which health information is necessary for determining compliance. (45 C.F.R. § 164.512, subd. (d).)

Protected health information means individually identifiable health information: (1) Except as provided in paragraph (2) of this definition, that is: (i) Transmitted by electronic media; (ii) Maintained in any medium described in the definition of *electronic media* at section162.103 of this subchapter; or (iii) Transmitted or maintained in any other form or medium. (2) *Protected health information* excludes individually identifiable health information in: (i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g; (ii) Records described at 20 U.S.C. section 1232g(a)(4)(B)(iv); and (iii) Employment records held by a covered entity in its role as employer. (45 C.F.R. § 164.501.)

Covered entity means a health care provider who transmits any health information in electronic form in connection with a transaction covered by the federal regulations. (45 C.F.R. § 160.103.)

Health information means any information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. (45 C.F.R. § 160.103.)

California laws provide authority for the Board of Pharmacy's oversight activities, as a *health oversight agency*, within the meaning of HIPAA regulations. See, for example, Business and Professions Code, Division 2, Chapter 9, section 4000, *et seq* ., including the following sections, together with some related regulations.

General Authority

The California State Board of Pharmacy may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations for the proper and more effective enforcement and administration of chapter 9. (Bus. & Prof. Code, § 4005.)

Pharmacy Records

All prescriptions filled by a pharmacy and all other records required by Business and Professions Code section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a California State Board of Pharmacy-licensed facility for at least three years. (Bus. & Prof. Code, § 4333.)

Controlled Substances Inventories

The controlled substances inventories required by Title 21, C.F.R., section 1304 shall be available for inspection upon request

for at least 3 years after the date of the inventory. (16 Cal.Code Regs., § 1718.)

Pharmacies, Wholesalers, Dispensaries, Stores, or Places
Inspectors may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places in which drugs or devices are compounded, prepared, furnished, dispensed, or stored. (Bus. & Prof. Code, § 4008.)

Records of Manufacture and of Sale, Acquisition, or Disposition of Dangerous Drugs or Dangerous Devices
All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law. (Bus. & Prof. Code, § 4081.)

Any person who fails, neglects, or refuses to maintain the records required by Business and Professions Code section 4081 or who, when called upon by an authorized officer or a member of the California State Board of Pharmacy, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor. (Bus. & Prof. Code, § 4332.)

Physician's Office or Clinic without Permit under Business and Professions Code sections 4180 or 4190
Any California State Board of Pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Business and Professions Code sections 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Business and Professions Code sections 4080 or 4081. (Bus. & Prof. Code, § 4008.)

Hypodermic Syringes or Hypodermic Needles
The book containing the record of furnishing of a hypodermic syringe or hypodermic needle without a prescription shall be available for inspection by any authorized officer of the law. (Bus. & Prof. Code, § 4146.)

Non-Profit or Free Clinics
The following described clinics must keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel:
(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of section 1204 of the Health and Safety Code.
(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of section 1206 of the Health and Safety Code.
(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of section 1206 of the Health and Safety Code.
(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of section 1206 of the Health and Safety Code.
(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of section 1206 of the Health and Safety Code.
(F) A nonprofit multispecialty clinic as referred to in subdivision (*l*) of section 1206 of the Health and Safety Code.
And the California State Board of Pharmacy shall have the authority to inspect any such clinic at any time in order to determine whether the clinic is, or is not operating in compliance with Article 13, of Division 2, of Chapter 9 of the Business and Professions Code. (Bus. & Prof. Code, §§ 4180 & 4185.)

Surgical Clinics
A surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code must keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel. The California State Board of Pharmacy shall have the authority to inspect such a clinic at any time in order to determine whether the clinic is, or is not, operating in compliance with Article 14, of Division 2, of Chapter 9 of the Business and Professions Code and all other provisions of the law. (Bus. & Prof. Code, §§ 4190 & 4195.)

Customs Broker or Carrier
All stock of any dangerous drug or dangerous device or of shipments through a customs broker or carrier shall be, at all times during business hours, open to inspection by authorized officers of the law. (Bus. & Prof. Code, § 4080.)

Agenda Item I

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: June 20, 2003**

From: **Anne Sodergren**
Board of Pharmacy

Subject: Changes in the Pharmacists Recovery Program

As a result of state's competitive bidding process, a new contractor has been awarded oversight of the Pharmacists Recovery Program (PRP) effective July 1, 2003.

The PRP program was the direct result of legislation requiring the board to seek ways and means to identify and rehabilitate pharmacists whose competency may be impaired due to the abuse of alcohol or other drugs, or due to mental illness, so that pharmacists and interns so afflicted may be treated and returned to the practice of pharmacy in a manner which will not endanger the public health and safety.

The new contractor will be Maximus, Inc, and Leslie Hanover will be the case manger assigned to the PRP. Ms. Hanover is a licensed Marriage Family Therapist with experience in mental health and substance abuse since 1986.

The phone number for the program 1-800-522-9198 will be transferred to the new contractor effective July 1, 2003.

The board would like to thank the dedicated staff from Managed Health Network, the previous contractor, for their commitment to the PRP.

Agenda Item J

California State Board of Pharmacy
Strategic Plan

Enforcement

Goal: 1: Exercise oversight on all pharmacy activities.
Outcome: Improve consumer protection.

Objective 1.1:	**To achieve 100 percent closure on all cases within 6 months by June 30, 2005:**
Tasks:	1. Mediate all consumer complaints within 90 days. 2. Investigate all other cases within 120 days. 3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days. 4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public. 5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports). 6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations. 7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public. 8. Improve public service of the Consumer Inquiry and Complaint Unit. 9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.
Objective 1.2:	**To achieve 100 percent closure on all administrative cases within one year by June 30, 2005:**
Tasks:	1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases. 2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs. 3. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.

	4. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. 5. Review and update disciplinary guidelines.
Objective 1.3:	**Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004:**
Tasks:	1. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. 2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. 3. Seek legislation to mandate that periodic inspections of all board-licensed facilities.
Objective 1.4:	**Develop 4 communication venues in addition to the inspection program to educate board licensees by June 30, 2005:**
Tasks:	1. Develop the board's website as the primary board-to-licensee source of information. 2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations. 3. Update pharmacy self-assessment annually. 4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.
Objective 1.5:	**To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2005:**
Tasks:	1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program). 2. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.

Objective 1.6:	**Respond to 95 percent of all public information requests with 10 days by June 30, 2005:**
Tasks:	1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions. 2. Establish on-line address of record information on all board licensees. 3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests.