California State Board of Pharmacy
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www.pharmacy.ca.gov

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

Enforcement Committee Report

John Jones, Chair
Stan Goldenberg, Member
Don Gubbins, Jr.

Report of March 5, 2003

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy agree to amend California Code of Regulation section 1771(c) to allow the pharmacist to work in collaboration with the prescriber when notifying a patient of an error and that the notification take place "as soon as possible" instead of "immediately."

Discussion

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. **(Attachment A)**

Kaiser Permanente also 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, but 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.

The following amendment is being recommended.

> (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.

RECOMMENDATION 2 (Not a Committee Recommendation)

That the Board of Pharmacy consider its enforcement options regarding the importation of prescription drugs from Canada through storefront facilities.

Discussion

Recently, storefront operations such as Rx Depot, Rx Canada, and American Drug Club have opened in California for the primary purpose of facilitating the illegal shipment of prescription drugs from Canadian pharmacies to California patients.

The importation of prescription drugs is illegal and the federal Food and Drug Administration (FDA) is responsible for enforcing the federal law. However, until last month, the FDA had not taken any such action. Obtaining discounted prescription drugs from Canada has become a booming Internet and mail-order business that attracts more than 2 million Americans per year. Some patients claim they can save up to 80% on their prescription drug costs. It is a practice that has been vigorously endorsed by the Congress and other elected officials. For many seniors it is their only option for obtaining their much needed prescription medication. So far, there has been no documented evidence of any patient being harmed from receiving prescription medications from Canada.

Last month, the FDA in collaboration with the Arkansas State Board of Pharmacy issued a warning letter to the storefront operations advising that the FDA considers the firms operations to be illegal and a risk to the public health. FDA is concerned that the firms are making misleading assurances to consumers about the safety of their drugs. FDA acted in conjunction with the Arkansas board, which also issued a letter instructing the firms to cease violating state law immediately. The Okalahoma Board of Pharmacy in conjunction with its the Attorney General also sought injunctive relief against a storefront operation.

FDA is very concerned that foreign medications purchased by U.S. consumers from unregulated drug outlets pose a growing potential danger. This is true because many of these storefront companies often state incorrectly to consumers that the FDA condones their activities and even that their prescriptions are FDA approved, which may lead consumers to conclude mistakenly that the prescription drugs sold by the foreign pharmacies have the same assurance of safety as drugs actually regulated by the FDA.

FDA believes that these storefront operations expose the public to the significant potential risks associated with unregulated imported prescription medications. Because the medications are not subject to FDA's safety oversight, they could be outdated, contaminated, counterfeit, or contain too much or too little of the active ingredient. In addition, foreign dispensers of drugs to

American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. Consumers are at a higher risk because these medications are not subject to the FDA labeling or California's pharmacy requirements. **(Attachment B)**

Enforcement Options
Legal Citations – Possible Violations

1. Only an U.S. manufacturer can import drugs into the U.S. [(21 U.S.C. sec. 381(d)(1)] Obtaining prescription drugs from Canada violates federal law and should be enforced by the FDA.

2. These storefront facilities are operating without a license issued by the Board of Pharmacy. (As to what state license would be required, e.g. pharmacy, nonresident pharmacy, or wholesale license still needs to be determined.). If an application is made for that license, it would then be denied for engaging in illegal activity.

3. These storefront operations may be unlawfully using the Internet to dispense prescriptions to patients (Business and Professions Code section 4067). Further investigation would be required to determine if this is true.

4. Misleading use of the "Rx" by these storefront operations in violation of Business and Professions Code section 4343.

5. Untrue and misleading statements used by the storefront operations that indicate that the prescription medications from Canada are FDA approved [(Business and Professions Code section 17500)].

Possible Remedies

1. The Board of Pharmacy with the approval of the Director of the Department of Consumer Affairs could seek an injunction pursuant to Business and Profession 125.5 to prohibit the storefront firms from operating. (The AG's Office would represent the board. Cost to pursue an injunction up to the Court of Appeal is estimated at $25,000 - $50,000).

2. The board could file a complaint pursuant to Business and Professions Code 17200 and 17500. The board then must request the Attorney General's office, the District Attorney, or County Counsel (in the county where the storefront operation is located) to file a complaint on behalf of the board. If the AG agreed to bring forward the complaint on behalf of the board, estimated cost again would be $25,000 - $50,000. Amount of civil penalty is $2,500 per violation (per prescription) up to $10,000.

3. The board could issue a citation and fine against the storefront operation for unlicensed activity and misuse of "Rx" signage. AG's office would represent the board in an appeal. (Maximum amount of fine would be $2,500.)

4. The board could issue a citation and fine against the storefront operation for misuse of the Internet for dispensing prescriptions. Further investigation would be required to determine if this is a viable option.

5. Do nothing. Issue a statement that the reimportation of drugs from Canada and any foreign country is illegal and that it is the responsibility of the FDA to enforce the law.

NO ACTION

Implementation of the Federal Health Insurance Portability and Accountability Act (HIPAA).

Discussion

At the last board meeting, it was reported that licensees were seeking clarification about their obligation to account for the disclosure of protected health information (PHI) when an inspector reviews this information during a routine inspection. Licensees stated that they were unclear as to the threshold of when such a release must be documented. Inspectors may skim through hundreds of hard copy records and/or computerized files in one inspection. Concern was expressed that the time to document each viewing will add a significant amount of time to the inspection process, increasing the burden and impeding the ability of boards to perform a thorough inspection.

It was noted that the National Association of Boards of Pharmacy wrote to the Director of the Office of Civil Rights requesting guidance in this area. NABP expressed concern that such a requirement would adversely affect patient care as pharmacies divert time away from patient care activities in an attempt to comply with this accounting requirement, without a resulting enhancement of the confidentiality of patient records. NABP asked for a supporting position that a standard investigatory review of prescription files (quick viewing of or skimming) would not constitute disclosure for which an accounting is then required.

Richard Campanelli, the Director of the Office of Civil Rights responded to NABP on April 1, 2003. He concluded that the "skimming" of patient files by state investigators is a disclosure of protected health information, and such disclosures must be included in an accounting of disclosures if requested by the patient. **(Attachment C)**

Under the guidance of Staff Counsel Dana Winterrowd, the board will be revising its inspection form to include a written statement advising licensees of the board's authority to perform an inspection. Upon the completion of an inspection, the inspector will provide to the licensee

those patient records that were reviewed so that the licensee can make a proper accounting of the disclosure. When the inspector is performing an investigation, either the inspector will provide a medical release for the protected patient information, an investigative subpoena, or an investigative demand. The investigative demand will include a statement of facts demonstrating why the information is relevant and why de-identified information cannot reasonably be used. The receipt that the inspector provides for the records can be used by the licensee to account for the disclosure.

Task Force with Medical Board of California on Prescriber Dispensing

As reported at the October board meeting, a task force has been formed with the Medical Board of California on the issue of prescriber dispensing. The boards agreed to the task force after a meeting on this issue last September with the Department Director Kathleen Hamilton and other interested parties.

The purpose of the meeting was to discuss a recent Court of Appeal decision that concluded that Pharmacy Law does not prohibit a physician from dispensing or selling drugs on a for-profit basis to his or her patients for the condition for which the patient sought treatment. CMA requested that the following issues also be addressed regarding dispensing by physician groups: accountability, ordering of drugs, common storage, and the use of an assistant for dispensing. It is the board's position that there is no authority for a group of physicians to purchase prescription drugs for communal use, except as specifically authorized by law. There is disagreement with this interpretation and thus the request from CMA to address the commingling of drugs by physician groups.

For background information, the Enforcement Committee drafted a Compliance Guide on prescriber dispensing that was discussed at its public meetings in July 2000 and September 2001. Essentially the Compliance Guide stated that the issue of prescriber dispensing for-profit was the jurisdiction of the Medical Board of California and that the dispensing of drugs by physicians groups (where the drugs are commingled) is the practice of pharmacy and falls within the jurisdiction of the Board of Pharmacy. The Board of Pharmacy has yet to take a formal position on this compliance guide.

Board of Pharmacy representatives will be John Jones and Stan Goldenberg. The Medical Board representatives will be Steve Rubins, M.D. and public board member Lorie Rice (Associate Dean at the UCSF, School of Pharmacy and former executive officer for the Board of Pharmacy).

The meeting date and location has not been finalized. However, when it has, the meeting will be noticed. **(Attachment D)**

Proposed Strategic Objectives for 2003/04

While the proposed strategic objectives will be formally adopted during the board's strategic planning session, please review them for priority and clarity. **(Attachment E)**

Enforcement Committee Meeting Summary of March 5, 2003 (Attachment F)

Enforcement Team Meeting Summary of March 5, 2003 (Attachment G)

Report on Enforcement Actions (Attachment H)

Quarterly Status Report on Committee Goals for 2002/2003 (Attachment I)

Attachment A

CSHP | CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

February 18, 2003

Patricia Harris
Executive Officer
California Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814-6237

RE: Request for amendments to California Code of Regulations, Title 16, Division 17, Section 1711 (Quality Assurance Programs)

Dear Patty,

The purpose of this letter is to request, on behalf of the California Society of Health-System Pharmacists, that the Enforcement Committee consider this proposal to amend Section 1711 of the California Code of Regulations (Title 16, Division 17). (Full text of 1711 is attached).

While Section 1711 as written might work well in an ambulatory environment, it presents some logistical issues in the inpatient setting. To address these logistical challenges, we request that you consider the following changes to Section 1711 (c):

(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[1], and working in collaboration with the prescriber[2], communicate to the patient ~~and the prescriber~~ the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

Rationale for proposed changes

(1) *Change the notification requirement from "immediately" to "as soon as possible" (or "as soon as reasonable".)* Our members have expressed grave concerns about the potential for being cited for lack of compliance because a patient was not *immediately* notified of a medication error. We'd like to provide a practical example to illustrate the logistical challenges associated with implementation of such a process:

Example #1: A pharmacist dispenses Dalmane 15 mg (for sleep) instead of Dalmane 30 mg for a patient in a hospital. The nurse administers the dose without realizing the dispensing error. By definition, an error has occurred and we agree the patient should be notified.

In the meantime, the patient is feeling the effects of the medication and is sleeping peacefully. Waking the patient up to *immediately* notify them they received 15 mg of their sleeping

medication, instead of 30 mg, (as currently required by law), seems counter productive when the situation could be addressed just as well, and more appropriately, in the morning.

(2) **Our second suggestion is to add a statement that requires that the pharmacist work "*in collaboration with the prescriber*" when notifying a patient of a medication error**.

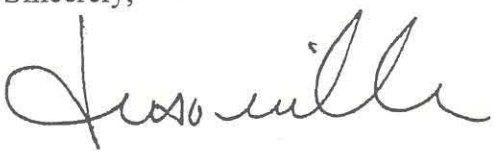
Medication errors do occur. We wish this was not the case; however, it is. We also believe that a collaborative approach is critical to reducing the level of medication errors –and therefore recommend that notification of the patient should be done *"in collaboration with the prescriber"*.

Under current regulations, if a medication error were to occur, the patient and the prescriber must be notified immediately, but there is no requirement that the pharmacist and the prescriber collaborate in notifying the patient, or in proposing the next step(s). This may actually do the patient a disservice, by not requiring a collaborative effort in solving the problem. Here's another practical example to illustrate our point:

Example #2
A chemotherapy-related medication error occurs -- the patient receives a dose due to be infused over four days, in one day. The error is not discovered until the next day. The patient may best be served by having the pharmacist **and** the physician (or, if the physician deems most appropriate, the physician alone) discuss the error with the patient at the soonest possible time. Our proposed change provides the flexibility for an either/or scenario, and most importantly, assures that the pharmacist and the prescriber work collaboratively in the patient's best interest.

Thank you for considering our request. Please feel free to contact CSHP President, Dr. Robert Mowers, Coordinator, Managed Care Pharmacy Services, UC Davis Health System (916) 734-3305, or me if you need additional information.

Sincerely,



Teresa Ann Miller, Pharm.D.
Executive Vice President, Chief Executive Officer
California Society of Health-System Pharmacists
725 30th Street, Suite 208
Sacramento, California 95816
(916) 447-1033

cc: CSHP Board of Directors

PROPOSED AMENDMENTS TO

CALIFORNIA CODE OF REGULATIONS
TITLE 16, DIVISION 17
Section 1711

February 18, 2003

1711:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(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, communicate to the patient ~~and the prescriber~~ the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c)
3. the findings and determinations generated by the quality assurance review; and,
4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

(i) This section shall become operative on January 14, 2002.

KAISER PERMANENTE®

When a drug dispensed in error has been taken or administered a pharmacist shall assure that the prescriber is notified and, as appropriate, that the patient or the patient's representative or care provider is notified and that steps are taken to avoid injury or mitigate the error.

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By e-mail and U.S. Mail

March 11, 2003

RECEIVED BY CALIF. BOARD OF PHARMACY 2003 MAR 13 AM 10:58

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

Re: Proposed Revisions to California's Code of Regulations, Title 16, Division 17, Section 1711, Quality Assurance Programs

Dear Ms. Harris:

On behalf of Albertsons, I'd like to add our support to the changes proposed by the California Society of Health-System Pharmacists to California's Quality Assurance regulations. In addition to the benefits described by CSHP, this proposed change would eliminate the requirement that the physician be contacted unnecessarily when the error is discovered before ingestion or other use has occurred.

Albertsons would also appreciate the Board's consideration of one minor addition to the proposed language, discussed in the last Enforcement Committee meeting and indicated in bold below:

(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 practitioner then treating the patient,** communicate to the patient ~~and the prescriber~~ the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

I would be happy to answer questions or provide any additional information or comment necessary. Thank you.

Respectfully submitted,

ALBERTSONS, INC.

Rich Mazzoni

Rich Mazzoni, Director
Pharmacy Professional Services
and Government Relations

RBG:lb
cc: Mary Staples – NACDS
Bruce Young - CA Retailers
Teresa Ann Miller - CSHP

Attachment B

FOR IMMEDIATE RELEASE MEDIA INQUIRIES: 301-827-6242
P03-19 CONSUMER INQUIRIES: 888-INFO-FDA
March 21, 2003

FDA COLLABORATES WITH ARKANSAS STATE BOARD OF PHARMACY IN ENFORCEMENT ACTION AGAINST STOREFRONT OBTAINING UNAPPROVED DRUGS FROM CANADA

The Food and Drug Administration (FDA) today issued a warning letter to Rx Depot, Inc., of Lowell, Ark., notifying that firm that the agency considered the firms operations to be illegal and a risk to public health. FDA accused Rx Depot of running a storefront operation that illegally causes the shipment of prescription drugs from a Canadian pharmacy into the U.S. FDA is particularly concerned because Rx Depot is making misleading assurances to consumers about the safety of their drugs. FDA is acting today in conjunction with action by the Arkansas State Board of Pharmacy, which also issued a letter to Rx Depot instructing the firm to cease violating state law immediately.

FDA is very concerned that foreign medications purchased by U.S. consumers from unregulated drug outlets pose a growing potential danger. This is particularly true because Rx Depot and similar companies often state incorrectly to consumers that the FDA condones their activities and even that their prescriptions are FDA approved, which could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by the FDA.

State pharmacy boards are responsible for determining whether pharmacies operating within the state are doing so in compliance with state law. In all states, it is a violation to sell prescription drugs in the state without proper licensing by the state.

FDA believes that operations such as this one expose the public to the significant potential risks associated with unregulated imported prescription medications. Because the medications are not subject to FDAs safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient.

In addition, foreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. For example, some prescription medications advertised by Rx Depot have potentially serious side effects, contradictions, and drug/food interactions. Since these medications are not subject to FDA labeling or state board of pharmacy medication information requirements, consumers are at higher risk.

As this action indicates, the FDA intends to work closely with its partners in the individual states in support of their efforts to curtail illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety. The National Association of Boards of Pharmacy (an umbrella group representing state pharmacy boards) which is urging FDA to assist in acting against these schemes stated, allowing unlicensed practitioners to dispense non-FDA approved medicines without regard for patient health and safety sets a dangerous precedent that puts Americans at risk. FDA has been working closely with states on illegal Internet pharmacy issues over the past four years, to protect the public health. While many internet pharmacies provide safe and possibly more convenient access to prescription services, foreign internet pharmacies selling to the U.S. operate outside the law. FDA provides guidance to consumers on buying prescription drugs safely over the Internet at http://www.fda.gov/oc/buyonline/default.htm.

FDA is taking many actions to help American consumers get safe

access to low-cost prescription drugs. For example, FDA is about to issue a final rule that will address issues in the implementation of the Hatch-Waxman law that will support more timely access to lower-cost generic drugs, and the FDA is significantly expanding its generic drugs program to approve safe and effective generic drugs more quickly. These steps will result in billions of dollars in prescription drug savings each year. FDA is also improving its prescription drug regulatory process, with the goal of reducing the cost of developing new drugs. However, despite continued efforts to identify ways to assure the safety of reimported drugs, the FDA for many years has stated that it cannot assure the safety of prescription drugs that are obtained outside its comprehensive regulatory system.

FDA's action follows the agency's recent notifications that businesses engaging in practices like those used by Rx Depot are at risk for legal action (see http://www.fda.gov/ora/import/kullman.htm). Rx Depot has fifteen working days to respond to FDAs warning letter. FDA will take appropriate action, including collaborative actions with individual states and foreign governments, to stop similar illegal activities by this or other similar firms.

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APR - 1 2003

nabp

National Association of Boards of Pharmacy

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Web Site: www.nabp.net

FOR IMMEDIATE RELEASE

March 25, 2003

For information contact:
Reneeta "Rene" Renganathan, Editorial Manager
847/698-6227; custserv@nabp.net

Arkansas State Board of Pharmacy, FDA Issue Warning Letters to Internet Pharmacy for Illegal Drug Importation

On Friday, March 21, 2003, Food and Drug Administration (FDA) issued a warning letter to Rx Depot, Inc, of Lowell, AR, notifying the firm that the agency considered the firm's operations to be illegal and a risk to the public health. FDA accused Rx Depot of running a "storefront" operation that illegally causes the shipment of prescription drugs from a Canadian pharmacy into the United States. FDA is particularly concerned because Rx Depot, through its Web site and written materials, is misleading consumers about the safety of their drugs. FDA action corresponds with action taken by the Arkansas State Board of Pharmacy, which also issued a letter to Rx Depot instructing the firm to cease violating state law immediately.

"The cooperative efforts of the state boards of pharmacy with the FDA and other federal agencies is the best means for addressing the illegal distribution and reimportation of medications from Canada and other foreign sources," said John A. Fiacco, president of the National Association of Boards of Pharmacy® (NABP®).

(— more —)

Halting the illegal distribution and importation of medications from foreign sources is a major priority of the NABP Executive Committee, which recently released a 12-page position paper on the issue that can be found on the Association's Web site at www.nabp.net. The NABP Executive Committee has been working with the state boards and FDA to enhance communication and coordinate the provision of information regarding the illegal distribution of medications from foreign sources. These actions are the most recent examples of the ongoing cooperative efforts between the state boards of pharmacy and FDA to address the multifaceted issue of illegally operating Internet pharmacies.

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.

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nabp

National Association of Boards of Pharmacy

700 Busse Highway • Park Ridge, IL 60068
Tel: 847/698-6227 • Fax: 847/698-0124
Web Site: www.nabp.net

To: **EXECUTIVE OFFICERS - STATE BOARDS OF PHARMACY**

From: Melissa Madigan, Professional Affairs Manager

Date: February 25, 2003

RE: **Importation of Foreign Prescription Medications**

Enclosed please find a recent letter from William K. Hubbard, Associate Commissioner for Policy and Planning, of the US Food and Drug Administration, that discusses the illegal importation of foreign prescription drugs and addresses a factual scenario involving health plans that include coverage for foreign drugs.

If you have any comments or questions, feel free to contact me at 847/698-2612 x306 or mmadigan@nabp.net.

cc: NABP Executive Committee
Carmen Catizone, Executive Director/Secretary

Food and Drug Administration
Rockville MD 20857

February 12, 2003

Via Facsimile (504-524-4162)
and U.S. Mail
Robert P. Lombardi, Esq.
The Kullman Firm
P.O. Box 60118
New Orleans, LA 70160

Dear Mr. Lombardi:

I write in response to your letter to Mr. Harold Davis of this agency, dated November 8, 2002. In your letter, you state that your firm represents a number of sponsors and/or administrators of employer-sponsored health plans. You raise many questions about potential civil and criminal liability of various parties involved in importing prescription drugs from Canada.

For public health reasons, FDA is very concerned about the importation of prescription drugs from Canada. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.- approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA.

From a legal standpoint, businesses and individuals that are involved in shipping prescription drugs to consumers in the U.S. must take many steps to ensure compliance with the Federal Food, Drug, and Cosmetic Act (the Act). Practically speaking, it is extremely unlikely that a pharmacy could ensure that all of the applicable legal requirements are met.

If parties are involved in violations of the Act, there are many potential avenues of liability. A court can enjoin violations of the Act. A person who violates the Act can also be held criminally liable. Those who can be found civilly and criminally liable under the Act include all who cause a prohibited act. Those who aid and abet a criminal violation of the Act, or conspire to violate the Act, can also be found criminally liable.

353(b)(1)). Thus, their shipment into the U.S. from Canada violates the Act. See, e.g., 21 U.S.C. 331(a), (d), (t).[2]

The reason that Canadian or other foreign versions of U.S.-approved drugs are generally considered unapproved in the U.S. is that FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Frequently, drugs sold outside of the U.S. are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved. 21 U.S.C. § 355.

Virtually all shipments of prescription drugs imported from a Canadian pharmacy will run afoul of the Act, although it is a theoretical possibility that an occasional shipment will not do so. Put differently, in order to ensure compliance with the Act when they are involved in shipping prescription drugs to consumers in the U.S., businesses and individuals must ensure, among other things, that they only sell FDA-approved drugs that are made outside of the U.S. and that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. They must also ensure that each drug meets all U.S. labeling requirements, including that it bears the FDA-approved labeling. 21 C.F.R. § 201.100(c)(2). The drug must also be dispensed by a pharmacist pursuant to a valid prescription. 21 U.S.C. § 353(b)(1).

Your letter mentions that 21 U.S.C. § 384 would allow drug wholesalers and pharmacists to import prescription drugs from certain countries under certain circumstances. As noted in your letter, however, that section is not in effect. That section would only become effective if the Secretary of Health and Human Services were to certify to Congress that the section's implementation will "pose no additional risk to the public's health and safety" and will "result in a significant reduction in the cost of covered products to the American consumer." 21 U.S.C. § 384(l). HHS Secretary Tommy Thompson and former HHS Secretary Donna Shalala both declined to make such findings.

FDA'S PERSONAL IMPORTATION POLICY

There has been some confusion about whether FDA's Personal Importation policy changes the law with respect to personal imports of pharmaceuticals. This confusion is reflected in your letter. The Personal Importation policy is used to guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal

[2] Shipping prescription drugs to consumers in the U.S. may also violate state law because, among other things, many U.S. states require that a pharmacy that ships drugs to a consumer within that state be registered with, or licensed by, the state. Obviously, we cannot analyze state law issues for you.

CONCLUSION

I hope that the above discussion is helpful to you. From a public health standpoint, FDA is very concerned about the kind of scenario described in your letter. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA.

Thank you for your interest in this matter. If you need additional information, please feel free to contact me.

Sincerely yours,

William K. Hubbard
Associate Commissioner for Policy and Planning

Enclosures:
Personal Import Policy

Attachment C

DEPARTMENT OF HEALTH & HUMAN SERVICES
Voice - (202) 619-0403 TDD - (202) 619-3257 Fax - (202) 619-3818
Http://www.hhs.gov/ocr/

OFFICE OF THE SECRETARY

Director
Office for Civil Rights
200 Independence Ave., SW Rm 506F
Washington, DC 20201

April 1, 2003

Dr. Carmen Catizone
National Assoc. of Boards of Pharmacy
700 Busse Highway
Park Ridge, Illinois 60068

Dear Dr. Catizone:

Thank you for your letter regarding the requirements of the health information privacy regulation (Privacy Rule) issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA). The Secretary and I are committed to protecting the privacy of health information through implementation of the Privacy Rule. At the same time, the Department is undertaking a broad range of efforts to assist covered entities in voluntarily complying with their obligations under HIPAA.

We have considered your request that we interpret the definition of disclosure to exclude the standard investigatory quick viewing or skimming review of prescription files, as well as the regular filing of certain designated controlled substances. We are must advise that the definition of disclosure at 45 CFR section 164.501 clearly encompasses the provision of access to protected health information, even when that access is only to skim the file. The "skimming" of patient files by state investigators is a disclosure of protected health information, and such disclosures must be included in an accounting of disclosures if requested by a patient.

The accounting requirements are designed to permit individuals to learn the non-health care purposes for which their protected health information was disclosed by covered entities. The Privacy Rule excepts from the accounting certain disclosures, including those authorized by the individual and disclosures for treatment, payment, and health care operations purposes, because individuals already know of these disclosures, or typically expect that those disclosures occur. By contrast, individuals are less likely to have similar knowledge or expectations about disclosures that covered entities may make to comply with law.

With respect to the accounting standard, we note that, like other privacy standards, it is designed to be flexible and scalable. Thus, the Rule does not require that disclosures be tracked individually; rather, a covered entity is free to design a system that efficiently permits an accounting to be provided upon an individual's request. It would be sufficient to prepare a standard checklist of such disclsoures, which could then be completed and provided to those individuals who request an accounting. The Rule permits this or other simplified means of providing the required accounting.

We thank you for your thoughtful suggestion on how to improve the operation of the Privacy Rule and hope our comments are helpful in assisting your members with their compliance efforts. Additional information, guidance, and technical assistance materials to facilitate compliance with the Privacy Rule are available on our web site: http://www.hhs.gov/ocr/hipaa/. As the Privacy Rule is implemented, the Department will continue to carefully monitor its impacts to assure that the Rule does not have any unintended negative effects on patient access to quality health care. If we find that the Privacy Rule is indeed causing problems in this regard, we will consider proposing modifications to the Rule. In addition, we will continue to publish guidance and technical assistance materials to ensure covered entities have the tools they need to implement the Privacy Rule in an effective and efficient manner.

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

Sincerely,

Richard M. Campanelli, J.D.
Director
Office for Civil Rights

National Association of Boards of Pharmacy
700 Busse Highway • Park Ridge, IL 60068
Tel: 847/698-6227 • Fax: 847/698-0124
Web Site: www.nabp.net

December 9, 2002

Richard M. Campanelli, JD
Director, Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F, HHH Building
Washington, D.C. 20201

RE: HIPAA Privacy Rule: Impact on State Board of Pharmacy Inspections and Prescription Monitoring Programs

Dear Mr. Campanelli:

The National Association of Boards of Pharmacy (NABP) is the professional organization that represents state boards of pharmacy in all regions of the United States, the Virgin Islands, Puerto Rico, eight provinces of Canada, four states in Australia, and New Zealand. NABP was established in 1904 to develop uniform standards and procedures for pharmaceutic licensure and for the transfer of licensure. Over the past 98 years, NABP has been repeatedly called upon to develop programs and services to assist the state boards in their charge to protect the public health, safety, and welfare.

It is in this capacity that we write to you asking how Section 167.528 of the final privacy rule (45 CFR §167.528) will impact inspections conducted by state boards of pharmacy, as well as controlled substance prescription monitoring programs run by state boards of pharmacy or other designated state agencies. Section 164.528 reads as follows:

> *Section 164.528: Accounting of disclosures or protected health information*
> *(a) Standard: right to an accounting of disclosures of protected health information.*
> *(1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:*
> *(i) To carry out treatment, payment and health care operations as provided in §164.506;*
> *(ii) To individuals of protected health information about them as provided in §164.502;*
> *(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in §164.502;*
> *(iv) Pursuant to an authorization as provided in §164.508;*
> *(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in §164.510;*
> *(vi) For national security or intelligence purposes as provided in §164.512(k)(2);*
> *(vii) To correctional institutions or law enforcement officials as provided in §164.512(k)(5);*
> *(viii) As part of a limited data set in accordance with §164.514(e); or*
> *(ix) That occurred prior to the compliance date for the covered entity.*

Although it seems clear that covered pharmacies must account for disclosures made of protected health information to pharmacy board inspectors, it is unclear as to the threshold of when such a release must be documented. Inspectors may skim through hundreds or even thousands of hard copy prescriptions and/or computerized files in one inspection. The amount of time it would take to document each viewing will add a significant amount of time to the inspection process, increasing the burden and impeding the ability of boards to conduct thorough inspections. Furthermore, such a requirement will adversely affect patient care as pharmacies divert time away from patient care activities in an attempt to comply with this accounting requirement, without a resulting enhancement of the confidentiality of patient records. Guidance from your office supporting the position that a standard investigatory review of prescription files (quick viewing of or skimming) would not constitute a disclosure for which an accounting is then required would be appreciated to alleviate these concerns.

On a similar note, many states now have prescription monitoring programs, which require pharmacies to report to a designated state agency, oftentimes the board of pharmacy, the filling of certain designated controlled substances on a monthly or twice-monthly basis. Again, the documentation of each reporting does not enhance the patient confidentiality provisions but could, in fact, hamper investigatory operations to curb or stop drug diversion. The required documentation would also adversely affect patient care as pharmacies divert time away from patient care activities to complying with this accounting requirement.

If we can provide any background information to assist you in supporting the position that these health oversight activities should not be included in the accounting of disclosures requirement found in Section 164.528 of the final privacy rule, please feel free to contact me at 847/698-6227 or ceo@nabp.net.

Sincerely,
NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh
Executive Director/Secretary

CC/mm

cc: NABP Executive Committee
2002-2003 Task Force on Privacy

Attachment D

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

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 Date
Meeting Time
Meeting Location

This meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Opportunities are provided to the public to comment on each agenda item.

A. Call To Order

B. Introductions

C. Purpose of Task Force – To Review Prescriber Dispensing Laws

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. Adjournment

Attachment E

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.

Attachment F

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

ENFORCEMENT COMMITTEE MEETING

Meeting Summary
March 5, 2003

Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento, CA 95814

Present: John Jones, Chair and Board President
Stan Goldenberg, Board Member
Don Gubbins, Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Board of Pharmacy Inspectors
Ron Diedrich, Liaison Deputy Attorney General
Dana Winterrowd, DCA Staff Counsel

Call to Order

Enforcement Committee Chair John Jones called the meeting to order at 9:30 a.m.

Identification of Where Pharmacy Practice Has Changed – But Pharmacy Law Has Not

- **Drug Addiction Treatment Act (DATA) of 2000**

It was noted that under this new law, Schedule II medications for the treatment of opiate dependence are subject to less restrictive controls and can be prescribed in a doctor's office by specially trained physicians. Subutex and Suboxone (two new formulations of buprenorphine) are the first narcotic drugs available for the treatment of opiate dependence pursuant to this new federal law. It was stated that the provisions of DATA also includes limits on the number of patients individual physicians are allowed to treat in their office and a special DEA registration for the use of these drugs.

It was requested that the Board of Pharmacy provide information to its licensees on this new federal law and the filling of prescriptions for Subutex and Suboxone. It was agreed that an article would be written for the July newsletter.

- ***Pharmacy leaders offer new practice paradigm – PCT***

Committee Chair John Jones stated that an article on Pharmaceutical Clinical Technology (PCT) appeared in Drug Topics last December. He stated that the article is for informational purposes.

The article argues that the role of the pharmacists should go beyond that of managing drugs. The pharmacist should be the healthcare professional in charge of the safe, effective and economical use of devices, instruments, and diagnostics.

- **Long Term Care – Cycle Fills/Bubble Packs**

It was unclear as to what the issue is regarding long term care facilities and cycle fills that the profession would like the board to address. It was suggested that for the committee to address issues that are brought to it, a "white paper" should be prepared that states the problem, the impact to patient care and the proposed solution.

- **Schedule III and IV Prescriptions**

It was recommended that Health and Safety Code section 11164 be revised to eliminate the requirement that the prescriptions for schedule III and IV drugs must be in the handwriting of the prescriber. Therefore, when a prescription is electronically transmitted or faxed, it doesn't have to be treated as an oral prescription and rewritten by the pharmacist.

- **Interim Pharmacist-in-Charge (PIC)**

Clarification was sought on the interpretation of the regulation that allows an interim PIC. Concern was expressed that some inspectors require that an interim PIC be at the pharmacy a required number of hours. It was clarified that the regulation does not require a specific number of hours that an interim or permanent PIC be at a pharmacy.

- **Transfer of Prescriptions**

It was requested that the board consider modifying its regulations to allow a pharmacy technician to transfer prescriptions electronically to another pharmacy. This is allowed in other states. It would be done under the supervision of the pharmacist and when there has been no change to the prescriptions.

- **Automation – Checking by a Pharmacy Technician**

It was suggested that the pharmacy technician be allowed to check prescriptions in an automated process when there are quality assurances checks and reviews in place.

Request to Amend California Code of Regulations (CCR) title 16, section 1711(c)
Notification of the patient and the prescriber when an error occurs

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. CSHP requested that the following amendments be considered:

(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, communicate to the patient the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

Concern was expressed that the pharmacist should have the authority to determine when it was appropriate to notify the patient and that notification be done in collaboration with the prescriber. Examples were provided when an "immediate" notification of the patient would not be in the patient's best interest.

After further discussion, Steve Gray, representing Kaiser Permanente, also provided amendments to this section. He suggested the following language:

(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 pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall immediately communicate to the patient the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.~~ When a drug dispensed in error has been taken or administered, a pharmacist shall assure that the prescriber is notified and, as appropriate, that the patient or patient's representative or care provider is notified and that steps are taken to avoid injury or mitigate the error.

The committee expressed concern that there are situations where a patient has received the wrong medication, but 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.

California Code of Regulation (CCR), title 16, section 1707.3 – Duty to Review a Patient's Profile

Current regulation requires that a pharmacist review a patient's profile prior to providing patient consultation. This regulation essentially requires the drug utilization review on new prescriptions. However, it has been the experience of the Citation and Fine Committees that patients have been substantially harmed when the pharmacist has failed to review the profile especially on refill prescriptions. It has been evident that pharmacists are not using their professional judgment in determining if the dispensing is appropriate especially for controlled substances.

For optimal patient care, the committee discussed the importance of the pharmacist's professional responsibility to review the profile. They also discussed the definition of "review" and agreed that there are tools that the pharmacist uses to perform this review. One such tool is technology, which plays a critical role. However, it was noted that not all computer systems provide the same quality of information and often times, it is the ancillary personnel that is reviewing the patient information and is making a judgment call as to when a pharmacist should intervene. Other options would be for the board to review the computer systems and determine the quality of such systems.

Comments were also made that if a pharmacist was required to review a patient record for every refill, the cost would be prohibited. Moreover, it has not been demonstrated that any benefit to the patient would outweigh the cost.

Implementation of the Federal Health Insurance Portability and Accountability Act (HIPPA) Requirements

It was noted that on April 14, 2003, the new HIPPA requirements take effect. Implementation issues were discussed. At the last Enforcement Committee meeting, licensees sought clarification regarding the accountability of licensees for the disclosure of protected health information to pharmacy board inspectors; however, licensees stated that they are unclear as to the threshold of when such a release must be documented. Inspectors may skim through hundreds of hard copy records and/or computerized files in one inspection. The time it would take to document each viewing will add a significant amount of time to the inspection process, increasing the burden and impeding the ability of boards to perform a thorough inspection.

It was noted that the National Association of Boards of Pharmacy has written to the Director of the Office of Civil Rights requesting guidance in this area. NABP expressed concern that such a requirement would adversely affect patient care as pharmacies divert time away form patient care activities in an attempt to comply with this accounting requirement, without a resulting enhancement of the confidentiality of patient records. NABP asked for a supporting position that a standard investigatory review of prescription files (quick viewing of or skimming) would not constitute disclosure for which an accounting is then required.

Also, NABP requested clarification on the prescription monitoring programs, which requires pharmacies to report to a designated state agency, the filling of certain controlled substances. The documentation of such reporting does not enhance patient confidentiality provisions, but could hamper investigatory operations to curb or stop drug diversion. Again, the required accounting documentation would adversely affect patient care as pharmacies would have to divert time aware from patient care activities to comply.

At the last meeting, Staff Counsel Dana Winterrowd stated that he would seek clarification on these issues from the Health and Human Services Agency, California Office of HIPPA Implementation. He reported that he has not received direction on this issue.

Labeling of Compounded Products

Clarification was sought regarding the labeling of compounded products. While the proposed regulations govern the labeling of injectable sterile drug products, it was noted that Business and Professions Code section 4076 govern the labeling of all other compounded products. Guidance was sought as to what "active ingredients" needed to be placed on the label for compliance. The committee agreed that board should provide direction to licensees and inspectors on this issue.

Proposed Strategic Objectives for 2003/04

Executive Officer Patricia Harris reported that during strategic planning last year, the board agreed to revise the format of its plan. With the assistance of facilitator, Lindle Hatton, the board began to revise the goal areas to better identify actual objectives and not activities. Executive staff then worked with Mr. Hatton to refine the objectives. The revised objectives were provided to the committee for its review.

Adjournment

Chairman John Jones adjourned the meeting at 12 noon.

Attachment G

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

Enforcement Team Meeting

December 5, 2003

1:30 p.m. – 4:00 p.m.

Present: Committee Chair and Board Member John Jones
Board Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors
Enforcement Staff

Announcements/Introductions

Committee Chair John Jones called the meeting to order at 1:30 p.m.

Quality Improvement Efforts

Supervising Inspector Robert Ratcliff reported on the status of completed cases since the last team meeting. He displayed the workload for each team and their significant progress. There are 855 pending complaints/investigations. Of these, 411 reports have been submitted and 444 cases are assigned for mediation or investigation. Supervising Inspector Ratcliff reported that cases are starting to age beyond the targeted time frames for closure and reminded inspectors to work on the oldest cases first.

Supervising Inspectors Robert Ratcliff and Judi Nurse noted the many significant inspector accomplishments since the last meeting.

Implementation of Routine Compliance Inspection Program

Supervising Inspector Judi Nurse reported on the implementation of the Routine Compliance Inspection Program. For this fiscal year, 1,253 pharmacies have been inspected. Of these, 79 cases were opened (6%). Since the inception of the program in July 2001, the total number of inspections has reached 5,253. This includes the inspection of over 574 probation and PRP participants.

Discussion of Enforcement Committee Meeting

Request to Amend California Code of Regulations (CCR) title 16, section 1711(c)
Notification of the patient and the prescriber when an error occurs

The Enforcement Team discussed the proposed language modifications. The team expressed concern with the language modification that would require the pharmacist to notify the prescriber only if the patient had taken the wrong medication. It was argued that the prescriber should be notified irrespective of whether the patient has taken the medication or not. In some instances, the wrong medication (whether ingested or not) may delay the patient's appropriate drug therapy and the prescriber should be informed of this. Changing the language from "immediately" to "as soon as possible" appeared reasonable. The team suggested the following modifications:

> (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.

California Code of Regulation (CCR), title 16, section 1707.3 – Duty to Review a Patient's Profile

The enforcement team agreed with the discussion that took place regarding the pharmacist's professional responsibility to review a patient's profile. In those instances, where it is evident that a patient was harmed because a pharmacist failed to exercise his/her professional responsibility, especially as it relates to controlled substances, the pharmacist is in violation of CCR 1761.

Implementation of the Federal Health Insurance Portability and Accountability Act (HIPPA) Requirements

Committee Chair John Jones stated that board would continue to seek guidance from Staff Counsel Dana Winterrowd for implementation of HIPPA.

Labeling of Compounded Products

Committee Chair John Jones directed staff to develop a compliance guide regarding the labeling of compounded products to give direction to licensees based on the discussions during the Enforcement Committee meeting.

Proposed Strategic Objectives for 2003/04

The enforcement team did not make any recommendations to the proposed strategic objectives for 2003/04.

Adjournment

Committee Chair John Jones adjourned the meeting at 4:00 p.m.

Attachment H

Board of Pharmacy Enforcement Statistics
Fiscal Year 2002/2003

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 02/03
Complaints/Investigations					
Initiated	380	292	444	43	1159
Closed	264	331	343	52	990
Pending (at the end of quarter)	749	715	816	807	
Cases Assigned & Pending (by Team) as reported March 5, 2003					
Compliance Team	239	217	245		
Drug Diversion/Fraud	128	146	148		
Mediation Team	187	154	187		
Probation/PRP	71	71	105		
Enforcement	190	208	209		
Site Inspections					
Performed	718	701	571	17	2007
Corrections Ordered	417	391	268	5	
For Patient Consultation	33	24	15	3	
Violations Notices Issued	54	40	19	0	
For Patient Consultation	2	0	0	0	
Application Investigations					
Initiated	127	120	121	1	369
Closed					
Approved	103	75	94	3	275
Denied	9	0	2	0	11
Total*	112	79	130	3	324
Pending (at the end of quarter)	150	187	177	173	173
Citation & Fine					
Issued					
Total	136	193	253	17	599
Abated					
Total	59	123	96	68	346
Fines Collected					
Total Collected	$79,850.00	$77,975.00	$61,075.00	$21,175.00	$240,075.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2002/2003

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 02/03
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	63	22	36	4	125
Pleadings Filed	31	24	10	1	66
Pending					
Pre-accusation	54	42	65	67	59
Post Accusation	96	91	72	65	89
Total	150	138	140	135	148
Closed**	40	23	25	8	47
Revocation					
Pharmacist	3	2	4	0	9
Pharmacy	1	2	2	0	5
Other	5	4	8	1	18
Revocation,stayed; suspension/probation					
Pharmacist	6	4	3	1	14
Pharmacy	0	1	2	0	3
Other	0	0	0	0	0
Revocation,stayed; probation					
Pharmacist	4	4	4	1	13
Pharmacy	1	1	0	1	3
Other	1	0	0	0	1
Suspension, stayed; probation					
Pharmacist	1	0	0	0	1
Pharmacy	1	0	0	0	1
Other	0	0	0	0	0
Surrender/Voluntary Surrender					
Pharmacist	3	1	3	1	8
Pharmacy	0	0	1	1	2
Other	6	4	1	2	13
Public Reproval/Reprimand					
Pharmacist	1	2	1	0	4
Pharmacy	0	1	1	0	2
Other	0	0	0	0	0
Cost Recovery Requested	$85,166.25	$65,605.00	$122,039.95	$18,632.00	$291,443.20
Cost Recovery Collected	$25,786.78	$61,265.41	$59,140.34	$8,793.17	$154,985.70

* This figure includes Citation Appeals

Board of Pharmacy Enforcement Statistics
Fiscal Year 2002/2003

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 02/03

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2002/2003

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 02/03
Probation Statistics					
Licenses on Probation					
Pharmacist	116	133			
Pharmacy	26	26			
Other	25	25			
Probation Office Conferences	14	0			14
Probation Site Inspections	71	4			75
Probationers Referred to AG for non-compliance	1	2	0	0	3

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

Pharmacists Recovery Program

Program Statistics					
In lieu of discipline	0	1	0		1
In addition to probation	1	3	1		5
Closed, successful	3	0	3		6
Closed, non-compliant	2	3	5		10
Closed, other	0	0	1		1
Total Board mandated Participants	50		49		49
Total Self-Referred Participants*	15		15		15
PRP Site Inspections**	29	1	6	0	36
Treatment Contracts Reviewed	31	37	26		26

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

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

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of March 31, 2003.

Attachment I

Quarterly Report
FY 2002--03

April 2003

Enforcement

Goal

Exercise oversight on all pharmacy activities.

Implementation Responsibility

The Enforcement Committee and Staff

Strategic Objectives	Timeline
1. Meet performance expectations of 90 days for complaint mediations and investigations and 6 months for drug diversion investigations that require an audit.	July 2003
10/02 *Reported data at October Board Meeting, 346 cases are pending and of those, 112 are over 90 days and 51 are over 180 days.*	
1/03 *Reported data at January Board Meeting, 353 cases are pending and of those, 94 are over 90 days and 34 are over 180 days.*	
4/03 *Reported data at April Board Meeting, 444 cases are pending and of those, 72 are over 90 days and 68 are over 180 days.*	
2. Continue active recruitment of inspectors so that all authorized inspector positions remain filled.	July 2003
9/02 *Developed examination questions for inspector and supervising inspector exams. Supervising inspector exam scheduled for December 2002, anticipated inspector exam in January 2003.*	
12/02 *Held supervising inspector examination and interviewed 6 applicants.*	
12/02 *Received approval from DPA for inspector reclassification to supervisor.*	
1/03 *Sent contact to supervising inspector applicants for employment interview.*	

Strategic Objectives	Timeline
3/03 *Held inspector civil service examination.*	
4/03 *Hired two new supervising inspectors.*	
4/03 *Two inspector positions are vacant – positions will not be filled pending decision on 10% reduction of personnel services to avoid possible employee lay offs.*	
3. Reduce enforcement prosecution time to one year from the date the board refers the case to the Attorney General's (AG) office by actively managing cases and preparing boilerplate language for draft accusations and stipulations.	July 2003
9/02 *Reported in Sunset Report that it takes an average of 188 days for AG's Office to prepare a pleading (this is 52 days longer than reported in the board's last Sunset Report) and once filed 395 days to resolve the case. This process is now 131 days longer.*	
9/02 *Continued active monitoring and case management – requested status reports.*	
12/02 *Due to anticipated AG deficiency, cases are being reviewed for priority (potential harm to public) for continued prosecution – less serious violations are being withdrawn and referred to the Citation and Fine Committee.*	
4/03 *Continued active monitoring and case management – case data reported at board meeting.*	
4. Seek legislation to mandate that the Board of Pharmacy perform periodic inspections of all board-licensed facilities.	January 2004
9/02 *Made this recommendation in board's report to the Joint Legislative Sunset Review Committee (JLSRC).*	
4/03 *JLSRC did not propose as a recommendation.*	
5. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.	July 2003
7/02 *Submitted a budget change proposal for ongoing augmentation of $300,000.*	
9/02 *Identified as a recommendation in board's report to the Joint Legislative Sunset Review Committee.*	

Strategic Objectives	Timeline
10/02 *Department of Finance disapproved the budget augmentation request.*	
12/02 *Re-evaluated cases pending at AG's Office to withdraw less egregious violations for referral to Cite and Fine Committee.*	
1/03 *Requested board approval for AG deficiency request (consistent with current board position).*	
6. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.	January 2004
7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.	July 2003
9/02 *Withdrew budget change proposal based on Department of Finance directive that it would not approve new or expansion of programs.*	
9/02 *Did not pursue an 800 number for "Notice to Consumer" poster because of fiscal constraints.*	
8. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 Reports).	January 2003
9/02 *Began internal evaluation of CURES data. Met with other CURES agencies. Trained staff person on program. Will pursue request to receive CURES data directly from contractor.*	
10/02 *Began review of 1782 reporting program.*	
2/03 *Developed data base program and will field test with licensees.*	
9. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.	January 2003
10/02 *Presentation on CURES to Los Angeles District Attorney.*	
10/02 *Initiated plan to reinstitute CURES workgroup meetings to identify contract needs, target and coordinate investigation and implement new provision of AB 2655.*	

Strategic Objectives	Timeline
10/02 *Began development of implementation plan and identify participants.*	
11/02 *Held CURES work group meeting.*	
12/02 *Began development of new 1782 reporting program on ACCESS database.*	
1/03 *Met with Special Assistant Attorney General regarding CURES.*	
4/03 *Held workgroup meeting for demonstration of new reporting program.*	
10. 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.	January 2004
11. Perform a comprehensive review of the electronic prescribing laws related to the dispensing of controlled substances and dangerous drugs to determine those areas of law that need modification.	January 2004
9/02 *Issued a compliance guide on Electronic Signatures.*	
3/03 *Compliance guide was published in board's newsletter.*	
12. 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.	January 2004
8/02 *Initiated discussion with California Pharmacists Association (CPhA) and the California Society of Health System Pharmacies (CSHP). Inaugural presentation at CPhA Annual Meeting in February 2003.*	
9/02 *Sought suggested presentation areas: review of board, update on new laws and proposals and identified compliance issues.*	
12/02 *Received request for CE program from CSHP – local chapter in Sonoma County.*	
12/02 *Developed program for CPhA Annual Meeting to be presented March 1, 2003.*	

Strategic Objectives		Timeline
3/03	*Presented CE program at CPhA annual meeting.*	
4/03	*Presented CE program at San Diego local pharmacists association meeting.*	
13. Explore the options for restitution to the consumer for prescription error consumer complaints.		January 2003
7/02	*Board voted not to pursue a restitution program for consumers because the award of restitution is within the purview of the civil court system and the board did not want to interject itself in this matter as it lacks the resources and knowledge to award damages to consumers who are harmed due to a prescription error.*	
9/02	*Reported board action to Joint Legislative Sunset Review Committee.*	
10/02	*Completed.*	

Ongoing Objectives	
14. Mediate consumer complaints.	
9/02	*Reported in Sunset Report that the board has received 5,205 complaints during the last 4 years, a 153 % increase from the previous Sunset Report.*
10/02	*Consumer complaint data for FY 02/03 reported at October Board Meeting.*
1/03	*Consumer complaint data for FY 02/03 reported at January Board Meeting.*
4/03	*Consumer complaint data for FY 02/03 reported at April Board Meeting.*
15. Investigate consumer complaints and other alleged violations of pharmacy law.	
10/02	*Investigation case data for FY 02/03 reported at October Board Meeting.*
1/03	*Investigation case data for FY 02/03 reported at January Board Meeting.*
4/03	*Investigation case data for FY 03/02 reported at April Board Meeting.*

Ongoing Objectives

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

9/02	*Since program inception 7/02, 3,698 inspections have been performed.*
9/02	*Since 7/02 performed 456 inspections, ordered 288 corrections and opened 43 cases.*
12/02	*Since 9/02 performed 680 inspections and opened 54 cases.*
4/03	*Since 12/03 performed 731 inspections and opened 32 cases.*

17. Prosecute administratively and criminally the most serious violations where drug diversion, self-use or potential or actual public harm resulted from the licensee's actions.

10/02	*Presentation to Los Angeles District Attorney cases of egregious drug diversion activity.*
12/02	*Working with BNE and DEA on criminal prosecution for drug diversion activity.*

18. Manage administrative cases and cases under investigation to resolve them expediently and consistently with the board's enforcement priorities.

9/02	*Case management overview at Enforcement Team Meeting.*
12/02	*Case management overview at Enforcement Team Meeting.*
3/03	*Case management overview at Enforcement Team Meeting.*

19. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program).

7/02	*Discussed Citation and Fine Program at July board meeting. Board approved board member and supervising inspector to hear office conference appeals.*
8/02	*Held 2 Citation and Fine meetings.*
9/02	*Held 1 Citation and Fine meeting.*
9/02	*Since program inception, reviewed 143 cases and issued 309 citations.*
9/02	*Discussed Citation and Fine Program and changes to internal operations.*

Ongoing Objectives

9/02	*Reviewed 154 quarterly probation reports, met with 28 new probationers and completed 101 probation inspections.*
10/02	*Advised board of proposed legislative changes to enhance board's enforcement tools to be discussed at December committee meeting.*
10/02	*Held 1 Cite and Fine meeting.*
12/02	*Discussed proposed legislative changes to enhance board's enforcement tools to seek compliance with pharmacy law.*
12/02	*Discussed Citation and Fine Program as requested by the Joint Legislative Sunset Review Committee (JLSRC) to consider delegation to the executive officer. Made recommendation to the board.*
12/02	*Completed 133 probation inspections.*
12/02	*Held 3 Cite and Fine meetings.*
12/02	*Since program inception, reviewed 195 cases and issued 616 citations.*
1/03	*Board adopted JLSRC's recommendation to delegate cite and fine authority to executive officer.*
1/03	*Held 2 Cite and Fine meetings.*
2/03	*Held 1 Cite and Fine meeting.*
3/03	*Held 2 Cite and Fine meetings.*
3/03	*Regulation change to Cite and Fine program was noticed.*
4/03	*Held 1 Cite and Fine meeting.*
4/03	*Citation data reported at April board meeting.*

20. Pursue criminal convictions of the most egregious violations, using specialized investigators in the department's Division of Investigation.

21. Identify and remove impediments to efficient enforcement.

9/02	*Held public Enforcement Committee and Team meetings to discuss quality improvement efforts (case management), the citation and fine process, DCA and BOP complaint disclosure policy, quality assurance program, enforcement guidelines for unprofessional conduct, proposed changes to the wholesaler program, and board-sponsored CE program on pharmacy law.*

Ongoing Objectives

12/02 *Held public Enforcement and Team meetings to discuss quality improvement efforts (case management), citation and fine process, quality assurance program, requirement that board inspectors be pharmacists, proposed changes to wholesaler program, CE for pharmacists who attend board meetings and implementation of HIPPA.*

3/03 *Held public Enforcement and Team meetings to discuss quality improvement efforts (case managemen), changes to pharmacy practice, proposed modifications to quality assurance regulations and HIPAA implementation.*

22. Improve public service of the Consumer Inquiry and Complaint Unit.

8/02 *Suspended consumer satisfaction survey because of program changes – will reinstate in November.*

9/02 *Revised consumer complaint handling process. Updated letters and notification to consumers.*

10/02 *Implemented program changes.*

1/03 *Implemented telephone survey on consumer satisfaction.*

4/03 *Department recommends that board review its survey instrument and not to perform telephone survey.*

23. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.

9/02 *Revised notification form for possible violations.*

12/02 *Added and centralized new form macros for consumer complaint process.*

12/02 *Automated inspection-tracking program to include status 3 inspections.*

3/03 *Automated case-tracking program for administrative cases.*

4/03 *Initiated revisions to inspector activity tracker.*

4/03 *Added on-line consumer complaint form to website.*

24. Cooperate with other federal, state and local law enforcement agencies to pursue effective enforcement of pharmacy law.

9/02 *Attended two FBI diversion meetings.*

11/02 *Assisted the State Food and Drug and FBI.*

Ongoing Objectives	
11/02	*Conducted investigation with DEA.*
12/02	*Participated on BNE task force meetings and investigations.*
3/03	*Participated on BNE task force meeting.*
25. Respond to specialized information requests from other boards and agencies about board programs, licensees (e.g., subpoenas) and Public Records Act requests.	
9/02	*Recommended changes to the board's Complaint Disclosure Policy.*
10/02	*Board adopted new Complaint Disclosure Polity.*