



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: September 9, 2010

To: Enforcement Committee

Subject: Request to Modify Requirements in Board Regulations Agenda Item 1

Earlier this year, the board received two requests for modifications of requirements in board regulations from Omnicare. These are provided on the following pages. This meeting will be the first time the board or one of its committees has the opportunity to discuss these requests.

Scott Huhn, PharmD, will provide a presentation to the board on each of these requests.

1. Request to Modify 16 California Code of Regulations Section 1745 Regarding Partial Filling of Schedule II Prescriptions

Rrequest: Modify regulation section 1745(c)(2) to allow pharmacies, when partially filling a Schedule II controlled substances prescription (C-II prescription), to modify a computer record instead of the prescription document itself. Currently, the board's requirements for partially filling a CII prescription are to annotate the prescription document itself.

This modification would require rulemaking process by the board.

1745. Partial Filling of Schedule II Prescriptions.

- (a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:
 - (1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or
 - (2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.
- (b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.
- (c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:
 - (1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;

- (2) **The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original prescription, also recording the initials of the pharmacist dispensing the prescription;**
 - (3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and
 - (d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.
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2. Permit a waiver of 16 California Code of Regulations Section 1793.7(a) to permit a pharmacy technician to do the final check of a medication if the container is bar coded.

Under current requirements, a pharmacist is required to do a final check of all medication before it is dispensed to the patient.

The request by Omnicare cites three scenarios for the dispensing of medication:

1. The medication container provided to the patient is bar coded by the manufacturer.
2. The medication container provided to the patient is bar coded by the pharmacy, under the supervision of a pharmacist.
3. The medication container is not bar coded.

Omnicare is requesting a waiver for bar-coded medications under items 1 and 2.

1793.7. Requirements for Pharmacies Employing Pharmacy Technicians.

- (a) **Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.**
- (b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
- (c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.
- (d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of

making, records adequate to establish compliance with these sections and written policies and procedures.

- (e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
- (f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Note, however, that there is no waiver process for such a procedure of board regulations, unless an experimental program is conducted with a school of pharmacy pursuant to 16 CCR section 1706.5. Unless this route is pursued, the board would need to consider a rulemaking process to modify 1793.7.

1706.5 Experimental Programs In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board enacts the following:

- (a) The application of particular provisions of the Pharmacy Rules and Regulations contained in Title 16, California Administrative Code, Chapter 17, may be waived as to an accredited school of pharmacy recognized by the Board if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.
- (b) Any plan or program approved by the Board shall have: definite time limitations; progress reports which shall be filed as required by the Board.
- (c) The Board may rescind approval and terminate said plan or program at its discretion, at any time it may deem the public interest is not fully protected; nor shall any such plan or program be approved by the Board if such proposal might jeopardize public health or welfare or conflict with provisions of Chapter 9, Div. 2, Business and Professions Code.

I am enclosing several related articles on this topic from prior issues of *The Script*.

One board inspector has expressed some concern about the elimination of the pharmacist's role in the verification of the final prescription verification. This inspector notes that several corporations now use a scan-verify system for final verification and errors still occur. How? The pharmacist chooses, for expediency, to by-pass the scan step and move on to the next task, skip the scan-verify, and so the error occurs.

Proposal 1

Scott R. Huhn PharmD
Omnicare
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scott.huhn@omnicare.com

Virginia Herold, Executive Director
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

December 18, 2009

Re: Request for amendment to the California Board of Pharmacy Regulation 1745: Partial Filling of Schedule II Prescriptions

Dear Ms. Herold,

This letter respectfully submits a request for consideration of an amendment to the current California Board of Pharmacy Regulation 1745: Partial Filling of Schedule II Prescriptions, to reflect the same requirements currently written in the federal regulation CFR 21 §1306.13 (b).

- CFR 21 §1306.13 (b) currently states, "For each partial filling, the dispensing pharmacist shall record on the back of the prescription **(or on another appropriate record, uniformly maintained, and readily retrievable)** the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist."
- California Board of Pharmacy Regulation 1745, currently states, "(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original prescription, also recording the initials of the pharmacist dispensing the prescription;"

The requested amendment to the current California Board of Pharmacy regulation 1745, would be to add the statement "**(or on another appropriate record, uniformly maintained, and readily retrievable)**" so that pharmacies in California may have the option to provide storage of the partial fill record-keeping requirements in an electronic and readily retrievable format.

Many pharmacy practice settings already provide a means of storing this information electronically to comply with the requirements stated in CFR 21 §1306.13 (b).

For additional information, I may be reached at 707-486-7801 or via email at scott.huhn@omnicare.com. Thank you in advance for your time and consideration.

Sincerely,

Scott R. Huhn PharmD
Regional Compliance Officer
Omnicare



Proposal 2

CREEKSIDE MANAGED CARE PHARMACY – An Omnicare Company

879 Second Street * Santa Rosa, CA * (707) 578-0399 * FAX (707) 578-0596

June 11, 2010

VIA MAIL & FACSIMILE (916-574-8618)

Virginia Herold, Executive Director
California State Board of Pharmacy
1625 North Market Blvd., Suite N219
Sacramento, California 95834

Re: Medication Dispensing Process with Technician Bar-Code Scan

Dear Ms. Herold:

Please find enclosed our request for a waiver authorizing a pharmacy technician utilizing bar-code scan under supervision of a pharmacist to perform the medication to medication label check prior to delivery to the patient. This process requires a waiver of the pharmacist check requirement pursuant to Cal. Code Regs. Title 16, § 1793.7(a). Accordingly, we are submitting the attached Request for Waiver detailing how we propose to perform this medication check with the aid of bar-code scanning technology.

We believe this request will improve pharmaceutical care and reduce the possibility of medication error. We respectfully request the opportunity to present this request for waiver to the Board of Pharmacy at its next meeting on July 28-29, 2010.

If additional information or clarification is needed, please contact me.

Sincerely,

Scott R. Huhn, PharmD
(707) 486-7801

Enclosure

cc: Sue Neuber, RPh
Jennifer Krusa, RPh

**REQUEST FOR WAIVER
MEDICATION DISPENSING PROCESS WITH TECHNICIAN BAR CODE SCAN**

Petitioning Pharmacist

Scott Huhn, PharmD
License Number 37174
(707) 486-7801

Locations

Omnicare Canoga Park
8220 Remmet Ave
Canoga Park, CA 91304
License # PHY45254

Pharmacy Support Services - Hayward
2150 W. Winton Ave.
Hayward, CA 94545
License # PHY46724

Omnicare Chico
3760 Morrow Lane Suite B
Chico, CA 95928
License # PHY47530

Pharmacy Support Services - Los Angeles
13825 A & A2 Cerritos Corporate Dr.
Cerritos, CA 90703
License # PHY46722

Omnicare of Bakersfield
4300 Stine Rd. Suite 700
Bakersfield, CA 93313
License # PHY47560

Creekside Managed Care Pharmacy
879 Second Street
Santa Rosa, CA 95404
License # PHY47561

Omnicare of Lodi
927 Industrial Way
Lodi, CA 95240
License # PHY47257

Broadway LTC Pharmacy
3330 Broadway
Sacramento, CA 95817
PHY #47371

Omnicare of San Diego
5825 Oberline Drive Suite 300
San Diego, CA 92121
License # PHY47251

Omnicare Redding
5200 Churn Creek Rd. Suite A,
Redding, CA 96002
License # PHY47529

Background

Omnicare, Inc. ("Omnicare") owns and/or operates institutional pharmacies throughout the United States. In California, Omnicare's pharmacies provide pharmaceutical services and supplies to residents of long-term care ("LTC") facilities and residential care facilities for the elderly ("RCFE"). Omnicare's California pharmacies, as listed above, only provide services to institutional residents with no "walk-in" customers. Pharmaceuticals are provided to residents of LTC and RCFE facilities in sealed, unit-dose packages with bar-codes.

In connection with its pharmacy operations and consistent with industry efforts, Omnicare has increased its utilization of new technology. In that regard, certain bar-coding technology/software has been developed to assist pharmacies in complying with applicable law and performing the medication to medication label verification prior to delivery to the patient. The bar-coding process utilizes a scanning "gun" to scan the product bar-code and the prescription label bar-code as part of the medication to medication label verification. There are safety checks throughout the bar-coding system. Given the bar-coding technology's accuracy, reduced rate of medication error, and improved patient safety, Omnicare desires to allow technicians to utilize this technology in its California pharmacies.

Under Cal. Code Regs. tit. 16, § 1793.7, a pharmacist is required to verify and document in writing any function performed by a pharmacy technician in connection with the dispensing of a prescription. This verification confirms that the prescription was filled according to the practitioner's order (i.e., the correct amount of the correct drug is dispensed for the proper LTC facility resident). A pharmacist is actively supervising the medication verification process and is identified on the end of day reports in the operating system.

Omnicare seeks to have pharmacy technicians perform the bar-code scan function in its California pharmacies as described below. The Board of Pharmacy has the authority to approve a waiver or variance from the requirements of Cal. Code Regs. tit. 16, § 1793.7.

We note that twelve states have approved this process, including Arizona, Illinois, Indiana, Kansas, Kentucky, Maryland, Michigan, Ohio, Oregon, Rhode Island, Tennessee, and Wisconsin. In addition, California allows pharmacy technicians (rather than pharmacists) to validate the work of other pharmacy technicians pursuant to a "tech-check-tech" program in acute care hospital pharmacies. See Cal. Code Regs. tit. 16, § 1793.8. We also note that in July 2008, the Board heard a presentation on medication errors in the pharmacy setting where it was noted that bar-code scanning can reduce medication errors. See Cal. Bd. of Pharm. Minutes (July 23-24, 2008).

As you know, California law permits pharmacy technicians to perform packaging, manipulative, repetitive, and other nondiscretionary tasks when under the direct supervision of a pharmacist. See Cal. Bus. & Prof. Code § 4115. The Board has defined nondiscretionary tasks to include placing the product into a container and affixing the label or labels to the container. See Cal. Code Regs. tit. 16, § 1793.2. As described further below, a technician's performance of the medication to medication label verification using bar-code scan is a repetitive task that involves no discretion on the part of the technician. It is analogous to affixing labels to a container and other nondiscretionary tasks approved by the Board.

Goals and Objectives

The goals and objectives of the medication dispensing process with technician bar-code scan are to improve pharmaceutical care for patients, reduce medication errors, and allow pharmacists to focus on patient-centric activities such as medication therapy management.

Medication Dispensing Process With Technician Bar-Code Scan – Project Summary

There are two steps to the medication dispensing process with technician bar code scan:

(1) prescription order and entry verification; and (2) prescription filling process. See process flowchart attached as Exhibit A hereto.

1. *Prescription Order and Entry Verification.* When a LTC facility submits an order, either in the form of a new order or a refill order, the technician enters the order into the pharmacy computer system. After the order entry, the pharmacist reviews the order, performs the drug utilization review (“DUR”) and approves the label. After the pharmacist reviews the label, the technician prints and/or produces the patient label.

2. *Prescription Filling Process.* All medications are in one of the following three forms: (1) manufacturer packaging with bar-codes; (2) pharmacy packaging with bar-codes that have been checked by a pharmacist; or (3) medications that are not available with bar-codes.

When the medication comes in manufacturer packaging with bar-codes, a pharmacy technician places the label that was produced in step one described above on the medication. When the medication comes in pharmacy packaging with bar-codes, the pharmacist first checks the packaging to confirm accuracy and signs the records. The pharmacy technician may then select these approved pharmacy packaged medications and place the label on the medication.

The technician then uses a hand-held scanner to read the product bar-code and the prescription label bar-code. This verification process requires the unique NDC/GDC barcode of each drug package to be a perfect match with each patient label. This system will not allow any prescription to leave the pharmacy if there is not a perfect match for drug NDC, dose, quantity, patient, and location.

If there is a scan match, the technician will then scan the final medication label to the delivery tote and place the medication in the tote for delivery. If there is a scan mismatch, the product would be sent to a pharmacist for review. The pharmacist will then manually check the product and enter the verification in the computer system. Once the pharmacist has verified the correct medication, the technician will scan the medication label to the delivery tote.

When the medication is not available with bar-codes, a technician will not perform the medication to medication label verification via bar-coding. Rather, the technician will apply the label produced pursuant to step one described above, and then the pharmacist will manually check the product and enter the verification into the computer system. Once the pharmacist has verified the correct medication, the technician will scan the medication label to the delivery tote.

In all instances, the pharmacist provides direct supervision of the technicians for all prescriptions dispensed, the pharmacist review is captured in the computer system for each Rx and will review an end of day report for all prescriptions dispensed.

Procedures to Ensure Public Health and Safety

Omnicare has established the following procedures to ensure public health and safety:

- All technicians undergo training prior to being able to perform the final product code and label verification;
- Written standard operating procedures are in place and a copy is kept in all pharmacies (See Standard Operating Procedures attached hereto as Exhibit B);
- The written procedures are reviewed and revised at appropriate intervals;
- Any variation from the standard workflow process routes the medication to a pharmacist for approval and the operating system is configured so that only a pharmacist can pass medications through the system if they fail to pass technician bar-code scan;
- Every staff member involved in checking a medication is recorded in the system to provide a greater degree of accountability;
- The label is assigned a unique bar-code identifying patient, date of dispensing, drug strength, dosage form and quantity;
- The scan assures correct medication is properly associated with the correct patient and correct drug;
- The system generates a report at the end of each day with the number of medications dispensed via pharmacist or technician scan and the number of medications dispensed via manual verification.

Timeline

We anticipate utilizing the technician bar-code scan process within thirty days of Board approval.

Waiver Request

Omnicare specifically requests a waiver of Cal. Code Regs. tit. 16, § 1793.7(a), subject to continuing compliance with the conditions approved by the Board.

Additional Comments

Omnicare intends to install this bar-coding technology/software nationwide due to the bar-code technology's proven accuracy and improved patient safety. This initiative echoes the call of legislators and healthcare leaders to increase the use of technology in drug distribution and administration.

Necessity for Pharmacist to Check Automation/Robotic Dispensing

The Board of Pharmacy recently reviewed a request from McKesson Automation, Inc. (McKesson) to approve a proposed protocol for use in hospital and institutional pharmacies that would not require licensed pharmacists to check every medication dispensed by its automated dispensing system, ROBOT-Rx. McKesson proposed a protocol whereby a pharmacist would check 100 percent of the medications packaged by the ROBOT-Rx on a daily basis for at least 30 days after the ROBOT-Rx is deployed. After the 30 days, the pharmacist would then taper off to sampling only 5-10 percent of the doses dispensed.

Pharmacy Law is silent on the question about how a pharmacist must check medication dispensed from automated delivery systems, aside from those provisions relating to placement of such a system in nonprofit or free clinics (Business & Professions Code [B&PC] section 4186). There is no statute or regulation specifically requiring that a pharmacist check every dose dispensed by an automated drug delivery system located in an inpatient setting, nor is there any statute or regulation absolving the dispensing pharmacist of this responsibility. Because of this silence, McKesson concluded that it is within the Board's discretion to approve a protocol that would apply specifically to ROBOT-Rx technology.

In denying McKesson's request, the Board considered the opinions of its counsel, which follow, in relevant part:

The Board has no relevant statutory authority to approve a protocol, and to do so may constitute an impermissible underground regulation. Under current law, it is the responsibility of individual licensees to determine the level of error risk they are willing to assume, and the steps they take to reduce or eliminate that risk.

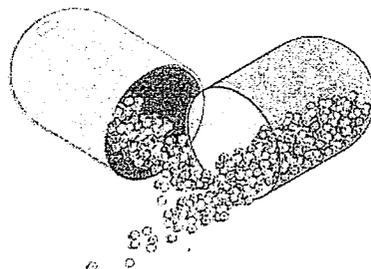
Pharmacy Law is violated where a prescription is dispensed in an insufficiently or inaccurately labeled

container (B&PC sections 4076-4078), where the drug dispensed deviates from requirements of a prescription (Title 16, California Code of Regulations [CCR] section 1716), or where the prescription is dispensed containing significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations (CCR section 1761). These provisions apply to all dispensing, regardless of the setting.

Any licensee that chooses to implement a reduced-error-checking protocol like that suggested by McKesson is assuming the risk of any errors that result. Even if such errors are less likely with the ROBOT-Rx system, the licensee is responsible for any errors that do occur. It may therefore be a risk for licensees to implement a protocol that increases the chance of such an error, however minor, by eliminating 100 percent of the human double-checking that could perhaps catch and correct those few errors made by the machine(s). Any licensee implementing such a protocol will be subject to discipline for any errors that do occur (as would any licensee responsible for errors from any other delivery system). It is possible the severity of the violation may even be greater where the error could have been caught had not such a sampling protocol been in place.

In the absence of any statutes or regulations exempting a dispensing pharmacist or pharmacy working with an automated drug delivery system from the general requirements pertaining to prescription accuracy and propriety of drug delivery, it is the responsibility of

the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of the dispensing. Licensees electing to save costs by reducing their level of error checking do so at their own risk and that of the patient.



Revisiting the Necessity for Pharmacist to Check Automated/ Robotic Dispensing

The January 2005 issue of *The Script* included an article about whether a pharmacist is required to check every medication dispensed by an automated dispensing system (a robotic apparatus into which medications are deposited and that uses bar code technology to automate the storage, dispensing, returning and restocking of medications). Readers were informed that there is neither a law requiring a pharmacist to check each dose dispensed by the system to assure the right medication is dispensed to the right patient, nor a law absolving the pharmacist from checking. However, the following questions on this subject have been asked:

Q. If an inpatient pharmacy elects to do random quality checking of robot-dispensed doses, are they in compliance with current Board of Pharmacy regulations?

A. As stated, there is no statute or regulation requiring a pharmacist to check doses dispensed by an automated drug delivery system.

Q. Will Board of Pharmacy inspectors require pharmacists to check 100 percent of the medications dispensed by an automated dispensing system?

A. The law does not require the pharmacist to check any of the medications dispensed by an automated dispensing system; however, **the pharmacist is responsible for any errors that occur—the same way the pharmacist is responsible for any erroneous prescription dispensed from any type delivery system, personal or automated.** The law is violated only when a prescription is dispensed erroneously.

The bottom line here is that it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of the dispensing. Licensees electing to save costs or time by reducing their level of error checking do so at their own risk.

If the Board chooses to enforce a particular process for checking or not checking automated dispensing, new statutes or regulations would be required.



California State Board of Pharmacy

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

Date: September 9, 2010

To: Enforcement Committee

Subject: Questions and Answers on Compounding Agenda Item 2

At the last Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July. The answers to these and other submitted questions have been compiled into a document and follow this page. The board is responding to these questions to aid pharmacies in complying with the new requirements.

The board will also place these Qs and As on our Web site.

During this portion of the meeting, Supervising Inspector Ratcliff will accept and answer additional questions if they are posed.

Question: Does every product and/or formulation compounded by a pharmacy have to undergo qualitative and quantitative analysis? If not, can the board provide guidance for selecting products to be analyzed?

Answer: The pharmacy, and the pharmacist, are responsible for insuring the compounded product complies quantitatively and qualitatively with the prescriber's prescription.

A compounded product that is compounded on a one-time basis for immediate dispensing it would not be likely there would be a quantitative or qualitative analysis conducted.

For products compounded for on-going therapy it would be expect there would be analysis done initially and on a periodic basis to validate the product and compounding process.

The same holds true for sterile injectable drug products too.

However, for batch (two or more) produced sterile injectable drug products that are compounded from one or more non-sterile ingredients the batch shall be quarantined until end-product testing confirms sterility and acceptable levels of pyrogens.

Reference: CCR 1735.8(c); 1751.5(c)

Question: Do cytotoxic agents and other hazardous substances have the same requirements for qualitative and quantitative analysis?

Answer: Yes

Question: If using a barrier isolator/glove box is, a gown required to prepare a cytotoxic parenteral product?

Answer: No.

CCR 1751.5 subdivision (a) requires the wearing of gowns and gloves when preparing a cytotoxic agent and subdivision (b) goes on to define "garb" requirements.

However, subdivision (c) of the same section goes on to state that if a barrier isolator is used the requirements do not apply.

Reference: CCR 1751.5(a)

Question: Is a non-resident pharmacy (NRP) that provides compounded product into CA required to meet the same staffing requirements as CA pharmacies?

Answer: No.

A Non-resident pharmacies (NRP) is a pharmacy located in another that furnishes dangerous drugs to patients in CA., and are required to be licensed with the board. Part of the licensure requirement is the NRP be in compliance with pharmacy laws in the state where it is located.

The board has no authority to dictate staffing requirements for pharmacies located in states other than CA. The board expects the NRP to be staffed in accordance with requirements where it is located.

Reference: Business and Professions Code § 4112(a); 4112(d)

Question: What constitutes sterile compounding?

Answer: First, let's define "compounding" in general:

"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a drug product from chemicals or bulk drug substances

With the above in mind, sterile compounding is a specific sub-type of general compounding whereby there is a requirement for the compounded drug product to be sterile. Sterile compounding almost exclusively involves sterile parenteral compounding for which there are additional requirements.

Reference: CCR 1735(a) 1735(d); 1751 et seq.

Question: Is the adding of 20 mEq of potassium chloride to 1000cc of normal saline for intravenous administration considered sterile compounding.

Answer: Yes, and this is also considered sterile parenteral compounding

Question: Can a pharmacy mix three liquids (Maalox, Benadryl, and Xylocaine) in equal parts or two creams in equal parts, and would this be considered compounding.

Answer: Yes in the examples given, a pharmacy may mix those products in equal parts. And yes, it is considered compounding.

Reference: CCR 1735(a)

Question: What happens in a situation where an IV is made to be used on a one time basis for administration within 24 hours for a registered inpatient of a health care facility and product is not used and returned to the pharmacy? Can it be reused?

Answer: No.

The compounding regulations require specific records for compounded drug products. For each compounded drug product, the pharmacy records shall include:

- (1) The master formula record.
- (2) The date the drug product was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug product.
- (4) The identity of the pharmacist reviewing the final drug product.
- (5) The quantity of each component used in compounding the drug product.
- (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements of this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient in a health care facility.
- (7) The equipment used in compounding the drug product.
- (8) A pharmacy assigned reference or lot number for the compounded drug product.
- (9) The expiration date of the final compounded drug product.
- (10) The quantity or amount of drug product compounded.

If all the information is not recorded [as provided by the exemption in (6)] then there is a lack of complete traceability and accountability for the compounded drug product and there it cannot be reused.

Reference: CCR 1735.3

Question: Our medical center's policies and procedures have the initial dose of an IV admixture compounded in the pharmacy satellite to assure timely initiation of therapy, with all subsequent doses mixed in the central pharmacy.

Is the initial IV admixture compounded in the satellite pharmacy subject to the recording requirements.

Answer: Yes, with the possible exception of documenting the manufacturer and lot number of each component of the admixture.

Reference: CCR 1735.3(a)(6)

Question: Is a master formula record equivalent to a "recipe card?"

Answer: Basically, yes.

Like a recipe card the master formula record includes the active and inactive ingredients to be used, the process and/or procedure used to prepare the drug, quality reviews required at each step in the preparation of the drug, post-compounding process or procedures required, and the expiration dating requirements.

The master formula record must be created prior to compounding the drug product.

The prescription document itself may be as the master formula record if a pharmacy does not routinely compound a particular drug product.

Reference: CCR 1735.2(d)

Question: When compounding a product, is it required to have master formula record available and used when the product is compounded?

Answer: Yes, the master formula record must be created prior to compounding the drug product and its use will provide guidance for compounding personnel and consistency in the product produced.

Reference: CCR 1735.2(d)

Question: Is it required to inspect the master formula record as part of pre-check process?

Answer: The law is silent on a "pre-check process." However, the master formula record will provide guidance to compounding personnel in what to use and how to compound the particular drug product to be compounded. So its use could be used in a "pre-check" process to insure consistency in the compounding process.

Reference: CCR 1735.3

Question: What are the requirements for compounding documentation?

Answer: The compounding regulations require specific records for compounded drug products. For each compounded drug product, the pharmacy records shall include:

- (1) The master formula record.
- (2) The date the drug product was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug product.
- (4) The identity of the pharmacist reviewing the final drug product.
- (5) The quantity of each component used in compounding the drug product.
- (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements of this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient in a health care facility.
- (7) The equipment used in compounding the drug product.
- (8) A pharmacy assigned reference or lot number for the compounded drug product.
- (9) The expiration date of the final compounded drug product.
- (10) The quantity or amount of drug product compounded.

Reference: CCR 1735.3

Question: When using exemption to compound a one time Vancomycin IV with a seven day expiration date and to be used within 24 hours, is the manufacturer and lot number required?

Answer: No.

The regulations provide for an exemption for sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient of a health care facility.

Reference: CCR 1735.3(a)(6)

Question: When must the manufacturer and lot number be recorded?

Answer: This information must be documented if the product is not for a one time use for a specific patient to be used within 24 hours.

Reference: CCR 1735.3(a)(6)

Question: How will the board insure compliance by non-resident pharmacies (NRP's) that provide compounded drug products into CA?

Answer: The board does not have the ability to inspect NRP's.

However, NRP's are required to be licensed with the board and to maintain compliance with pharmacy regulations of their home state. Also, a NRP performing sterile parenteral compounding as a condition of renewal will be required to submit a completed Compounding Self Assessment Form.

Reference: B&P §§ 4112, 4127.2

Question: Is the dilution per the manufacturer's instructions and adding to the IV solution considered compounding?

Answer: Yes if done in a pharmacy. However, statute provides for exemption from sterile compounding licensure if the sterile powder was obtained from a manufacturer and the drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection.

Reference: CCR 1735(a)(1); B&P 4127.1(e)

Question: Are proprietary drug delivery systems such as ADD-Vantage, Mini-Bag Plus, and At-Eas considered compounded products after the vials have been attached to the IV bags?

Answer: These types of delivery systems are exempt from the compounding requirements if the sterile powder was obtained from a manufacturer and the drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection.

Reference: CCR 1735(a)(1); B&P 4127.1(e)

Question: What specifically will be required or what process is acceptable to achieve such quality assurance?

Answer: Quality assurance, as the term implies, is designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded products.

A quality assurance plan will touch all parts of the compounding process – drug product and equipment acquisition/storage; compounding processes; documentation of compounding and related analysis; employee training and monitoring; recall procedure; etc

Reference: CCR 1735.8; 1735.3; 1735.5; 1735.6; 1735.7; 1751 et seq.

Question: When recycling an IV that was previously compounded by the pharmacy, can the previous lot number of the recycled IV be used as long as the lot number can be traced to all the requirements listed in section 1735.3?

Answer: Yes.

Reference: CCR 1735.3

Question: What is a “reliable supplier?”

Answer: FDA licensed manufacturers, CA licensed wholesalers, and CA licensed pharmacies are examples of reliable suppliers. These types of entities must be licensed and meet/maintain their premises to stay licensed.

Reference: B&P §§ 4160, 4163, 4126.5, 4169; CCR §§ 1780, 1783

Question: Does CCR section 1735.5 require a pharmacy to test each and every compounded product for integrity, potency, quality, and labeled strength of the compounded product?

Answer: No. However, if the compounded product involves a complex process it would see prudent to have documentation of the final product. This is even more important when the product is compounded on a more routine basis.

Compounding involves not just the QA process, but staff training, equipment maintenance, proper documentation and appropriate analysis of products compounded.

Reference: CCR 1735.8; 1735.3; 1735.5; 1735.6; 1735.7; 1751 et seq.

Question: For the purposes of CCR section 1735.3(a)(6) and 1751.2(a), would patients receiving chemotherapy administered in an infusion center that is part of a health care facility be considered “inpatients” and exempt from the labeling requirements?

Answer: If the infusion center is part of the licensed health care facility and the patients receiving care there are registered as hospital inpatients, then yes the exemption provided by CCR 1735(a)(6) would apply. However, the labeling requirements as defined in CCR 1751.2 would apply and compliance would be expected.

Reference: B&P §§ 4027, 4019, 4029; CCR 1735.3(a)(6), 1751.2

Question: CCR section 1735.3 defines what must be recorded for each compounded drug product. CCR 1735.3(a)(7) states, “The equipment used in compounding the drug product.” Does this include tubing sets, spikes, needles, syringes, etc.?

Answer: Yes, if all equipment used compounding the drug product must be recorded.

Reference: 1735.3(a)

Question: Where would the lot number, manufacturer, and expiration date be recorded?

Answer: The law does not specify where or how the information is to be recorded. A pharmacy may develop it own form(s) for the proper documentation.

The pharmacy shall maintain the record for three years from the date it was created.

Reference: 1735.3

Question: Some equipment used in compounding (needles, syringes, spikes, etc.) have lot numbers but not an expiration date. What information should be recorded?

Answer: As much information as required if available would be required to be recorded.

Reference: 1735.3

Question: CCR section 1751.2(d) states, "All cytotoxic agents shall bear a special label which states 'Chemotherapy – Dispose of Properly.'" This appears to give no wiggle room for the text of the message.

Answer: There are no exceptions. If a drug is classified as a cytotoxic agent then the special label must be used.

Reference: CCR 1751.2(d)

Question: Gancyclovir is a cytotoxic agent but is not a chemotherapeutic agent. Does the special label need to be applied?

Answer: Yes, the regulation does not provide for exceptions. However, nothing prevents the pharmacist from consulting the patient on the drugs classification and use.

Reference: CCR 1751.2(d)

Question: CCR section 1751.5(b)(1) states, in pertinent part,, "Cleanroom garb consisting of low-shedding coverall, head cover...must be worn inside the designated area at all times." USP 797 does not require the use of a coverall, only a gown.

Answer: The board does not enforce USP 797, but expects compliance with board regulations.

A coverall is much more encompassing than a gown and would provide better protection during the compounding process.

Reference: CCR 1751.5(b)(1)

Question: For a compounded drug product can a pharmacy use an expiration date, or beyond use date, of greater than 180 days?

Answer: Yes, if the longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging.

Reference: CCR 1735.2(h)

Question: Master formulas and compounding records are filed in separate locations, can easily be linked together, and are readily retrievable. Is it an absolute requirement to file these documents together?

Answer: No, there is no such requirement for the above records to be maintained together as long as they are readily retrievable and available for inspection. These records may be maintained in a paper or electronic manner.

All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated (kept together) with the compounding record and master formula.

Reference: CCR 1735.8(c)

Question: Is record keeping for compounding just referring to products that are administered intravenously or intraocular (e.g. where sterile preparation is imperative) or does it extend to oral and topical compounding?

Answer: The regulations apply to all forms of compounding – oral, inhalation, topical, sterile parenteral, etc.

Reference CCR §§ 1735 et seq & 1751 et seq.

Question: What is meant by proper acquisition?

Answer: Records of proper acquisition of dangerous drugs and dangerous devices would include purchase records that correctly give the date, the names and address of the supplier and the buyer, the drug or device, and its quantity.

Reference: B&P § 4059(b)



California State Board of Pharmacy

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

Date: September 9, 2010

To: Enforcement Committee

Subject: Update on Drug Take Back Programs – Agenda Item 3

At the July Board Meeting, the board reviewed a proposed draft of a CalRecycle report to the Legislature on the implementation of drug take back programs from patients seeking to destroy their unwanted medications.

This report to the Legislature is required by SB 966 (Simitian, Chapter 562, Statutes of 2007), and is due December 1, 2010. The legislative report must:

. . . include an evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness. The report shall include the consideration of the incidence of diversion of drugs for unlawful sale and use, if any. The report also shall provide recommendations for the potential implementation of a statewide program and statutory changes.

During the board meeting, staff was directed to provide comments on this draft. These comments were submitted to CalRecycle in mid-August. A copy of the comments follows this page.

Additionally, on September 25, the federal Drug Enforcement Administration will host a nationwide drug take back event so the public can dispose of its unwanted/unneeded medications. This event will be discussed under the next agenda item.



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

August 13, 2010

Mr. Burke Lucy
CalRecycle
801 K Street
Sacramento, CA 95814

Sent via email to: Burke.Lucy@calrecycle.ca.gov

RE: Comments on Evaluation of Home-Generated Pharmaceutical Programs in California

Dear Burke,

Thank you for this opportunity to provide comments on the above draft report to the Legislature that was issued in July by CalRecycle.

Your 2010 draft report focuses on three categories of assessment for drug take-back programs:

- An evaluation of the model programs for efficacy, safety, statewide accessibility and cost effectiveness,
- Consideration of the incidence of diversion of drugs for unlawful sale and use, and
- Recommendations for the potential implementation of a statewide program and statutory changes.

Our comments will address these categories.

The board strongly supports the development of appropriate drug-take back programs to meet an ever growing demand by the public to dispose of their unwanted pharmaceuticals in ways other than flushing them down the drain or placing them in trash receptacles. Over the last two years, the board has worked closely with CalRecycle (then the Integrated Waste Management Board) and the Department of Public Health in developing Model Guidelines for pharmacies and others that operate occasional or ongoing drug take-back programs.

These guidelines, adopted by the California Integrated Waste Management Board in February 2009, were promoted to California pharmacies in the February 2010 board newsletter to its licensees. However, due to budget and staffing issues in mid-2009, what would have been the August 2009 newsletter became the February 2010 newsletter, which was the next published newsletter of the board. As such, it is important to note that

pharmacies were not officially advised of the board's recommendations for use of the model guidelines until March 2010.

Thus, data collected from pharmacies operating take-back programs in 2010 or earlier are not likely to include data from model programs operating in pharmacies. Many pharmacies declined to establish take back programs at all until they knew the board's policy on such programs. Instead, only a limited number of pharmacies operated take back programs, none of which the board is aware of complied with the model guidelines.

At the current time, the board has just begun to add compliance checks of drug take-back programs in pharmacies during board inspections. The prevalence of such programs and the degree of adherence to the model take-back program requirements has not been assessed. However, board inspectors are advising any collection program operated in a pharmacy to comply with the guidelines.

Consequently and unfortunately, data reported from drug take back programs in California does not represent the impact of the model guidelines on collection possible through drug take-back programs in pharmacies.

From the Board of Pharmacy's perspective, the danger of drug take-back programs is one of creating drug diversion opportunities. Prescription drugs have value when they are no longer wanted by the consumer. This is a problem when they are left in the home and not disposed of, as well as when disposed of in a take-back program. Thus any take-back program needs to ensure it has appropriate safeguards against drug diversion by pharmacy staff, collection staff, and by the public.

In the last two years, the board has identified the diversion issues from non-model guideline take-back programs. Here are some examples:

1. Several months ago, a Northern California coroner's office advised the board of the death of a young woman who died from a drug overdose. An inspection of the woman's home identified a number of pills in baggies, and multiple prescription containers with diverse patient and pharmacy names on them. The woman worked as an esthetician outside a pharmacy, and near where an unattended large take-back drug collection bin was located. On the collection bin were directions to empty drugs from a prescription vial into a baggie before placing the drugs in the bin. The coroner believed that this was the likely source of this woman's drugs and reported this situation to the board. The board has contacted one individual whose name was on one prescription vial found in the home, and the patient stated she had given her drugs to someone in the pharmacy to place in the take-back bin. This take-back bin did not conform to California's model guidelines. The board also notes that once it began its investigation, the pharmacy discontinued the collection program.
2. In November 2008, a pharmacist in Washington pleaded guilty to collecting expired and unexpired medication from medical providers, hospices and clinics

- purportedly to redistribute for humanitarian relief. However, he was instead filling the pharmacy's stock bottles with these drugs for re-dispensing the drugs to unknowing patients of the pharmacy (Attachment 1).
3. The board disciplined two unrelated pharmacies in 2009 for different schemes involving kick backs from reverse distributors for falsely claiming to return drugs to the manufacturer to obtain a rebate for returned drugs that the pharmacies had not really purchased but instead obtained from a reverse distributor (Attachment 2).
 4. A photograph of an inappropriate collection activity where a large fishbowl is placed on a pharmacy's cashier counter that creates diversion opportunities by making returned drugs accessible to the public (Attachment 3).
 5. A photograph displaying the need for security of the collected bins given the diversity and volume of items collected (Attachment 4).
 6. A 2009 newspaper article about a police officer accused of stealing prescription pain medicine from the family of a man who had recently died. According to the report, the officer had advised the family that the police department offered a disposal service for prescription medicine (Attachment 5).

The board notes that is extraordinarily difficult to catch pharmacies that collect or purchase drugs from any unapproved source (such as drug take back, drug samples, physicians) and place them in pharmacy stock containers. The examples above are rarities in that they were detected.

Simply put, drug take-back programs operating where the pharmacy or patients can access the surrendered drugs, creates serious problems.

California has enacted the nation's toughest control measures to preserve the integrity of the state's prescription drug supply. This was in response to drug diversion and counterfeit drugs identified the nation's and California's drug supply. Over a staggered implementation schedule from 2015-2017, prescription drugs dispensed in California must be accompanied by an electronic pedigree that originates with the manufacturer identifying any entity that has owned the drugs as they are transferred through the pharmaceutical supply chain from manufacturer to wholesaler(s) to pharmacy. This e-pedigree system will ensure that drugs located in a pharmacy can be traced to their origins via electronic coding on the prescription stock bottle. However, despite the complexity of the e-pedigree system with respect to the statutory requirements and the accompanying technology to comply (which necessitated the far-off future implementation schedule), the value of the e-pedigree system could be lessened if pharmacy staff can access drugs from non-model take-back programs and re-add these drugs to stock containers. This would be a significant loss to the prescription drug supply and to patients in California.

Returning to the report, the board specifically agrees with the statement (page 24):

Certain requirements in the Guidelines presented unique challenges to some programs. As discussed above safety (security) issues are usually the primary reason why existing programs did not qualify as model programs. Meeting these safety issues often involve increased costs.

However, it is these security features that provide the appropriate safety necessary to guard against drug diversion. Drug diversion by patients and licensed entities is a significant problem and the state needs to ensure that its drug take-back programs do not create more venues for diversion. Thus the costs of such security measures are necessary for those entities desiring to operate drug take-back programs.

The board strongly believes that the CIWMB/CalRecycle model guidelines need to be enacted so that they can be more effectively enforced. Enactment will increase compliance with appropriate disposal and end the current confusion about how to operate a take-back program statewide.

The board also notes that mail return by patients of unwanted drugs may offer additional advantages that are not greatly emphasized in the guidelines. This option warrants further review and discussion.

And as stated earlier, California pharmacies' adherence to these model programs has really not yet occurred as few pharmacies have modeled their programs on the guidelines in the few months since the board's policy position was published. Enactment of the standards, where participation by the pharmacy is voluntary, would likely increase participation.

The board anticipates working with interested stakeholders to enact the model guidelines and ensure the safety of the state's prescription drug supply and yet allow patients to appropriately dispose of their unwanted drugs.

Please do not hesitate to contact either me or the board's executive officer, Virginia Herold, with questions.

Sincerely,


STAN WEISSER
President

Attachments

Attachment 1

News Release

FOR IMMEDIATE RELEASE

November 04, 2008

Contact: Jodie Underwood

Number: (206) 553-1162

Edmonds Pharmacy "Manager of the Year" Pleads Guilty*Thousands of Pills Involved, Including Oxycodone and Hydrocodone*

NOV 04 -- (Seattle) – DEA Special Agent in Charge (SAC) Arnold R. Moorin and the United States Attorney for the Western District of Washington, Jeffrey Sullivan, announced that on October 31, 2008, Milton W. Cheung, a Washington State licensed pharmacist, entered guilty pleas to two felony offenses: Acquiring Controlled Substances by Deception and Misbranding Drugs. These offenses are punishable by up to four years in prison, a \$250,000 fine, and up to one year of supervised release. Cheung is set for sentencing on February 13, 2009.

Cheung, 55, of Lynnwood, Washington, has been employed for the last several years as a Pharmacy Manager at the Top Food Drug Store, in Edmonds, Washington. As pharmacy manager, Cheung was the principal pharmacist responsible for the daily activities and operations at the Edmonds Top Food Drug Store. From 2003 continuing through September 2008 (when he resigned), Cheung was named Pharmacy Manager of the Year, by Haggen Incorporated, the owner of Top Food Drug Store.

During 2007, and continuing through September 2008, Cheung solicited a number of Washington State medical providers, including doctors, hospices, and clinics, as well as Top Food Drug Store customers, to provide expired and unexpired drugs to him at the Edmonds Top Food Drug Store, on the alleged basis that he would provide these drugs to less developed countries as part of a philanthropic mission. While Cheung collected these drugs, he purposefully diverted much of the drugs collected by placing the drugs into the regular supply bottles at the Top Food Drug Store. This gave him a much larger inventory of drugs to distribute to pharmacy customers and made the pharmacy which he managed appear more profitable. Cheung then proceeded to distribute these returned drugs to customers at the Edmonds Top Food Drug Store when filling new customer prescriptions, even though a large portion of these drugs were expired, and despite the fact that all of the drugs had been adulterated in that they had already been distributed to and possessed by others, and were returned merchandise which Cheung was doling out as new inventory. Among the drugs deceptively collected by Cheung and later distributed by him, were such Schedule II through IV controlled substances as fentanyl, methadone, morphine, oxycodone, hydrocodone, and lorazepam, in addition to other drugs.

All prescription drugs carry an expiration date after which the drugs are no longer regarded as medically effective or safe to consumers. The entire drug re-distribution scheme conducted by Cheung, under the guise of providing drugs to developing nations, was unlawful; no such program had been sanctioned by the DEA or any other valid regulatory authority. In addition, all prescription medications in pharmacies are required by federal regulation to be maintained in stock containers which show their true lot number and expiration date. This is done to ensure the safety of what is being sold and distributed to the public. Cheung's prescription misbranding effectively countermanded and negated these safeguards.

In September 2008, in response to the criminal conduct by Cheung, Haggen Incorporated issued a drug recall, printed in the Seattle Times, advising customers of the Edmonds Top Food Drug Store to return all potentially expired drugs.

This case was investigated by the Drug Enforcement Administration, Internal Revenue Service and the Edmonds Police Department.

Attachment 2

1 EDMUND G. BROWN JR. Attorney General
of the State of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 NANCY A. KAISER, State Bar No. 192083
Deputy Attorney General
4 California Department of Justice
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 897-5794
6 Facsimile: (213) 897-2804

7 Attorneys for Complainant

8 **BEFORE THE**
9 **BOARD OF PHARMACY**
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 3082

12 **DAVID JUE FONG**
13 502 S. Almansor St.
Alhambra, CA 91801

ACCUSATION

14 **Pharmacist License No. RPH 37204**

15 Respondent.

16
17 Complainant alleges:

18 **PARTIES**

- 19 1. Virginia Herold (Complainant) brings this Accusation solely in her official
20 capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 21 2. On or about August 26, 1982, the Board of Pharmacy issued Pharmacist
22 License Number RPH 37204 to David Jue Fong (Respondent). The Pharmacist License was in
23 full force and effect at all times relevant to the charges brought herein and will expire on
24 September 30, 2009, unless renewed. Respondent is the Pharmacist-in-Charge of Cathay
25 Medical Pharmacy, Inc. dba Cathay Medical Pharmacy, Pharmacy Permit No. PHY 36574,
26 located at 626 W. College Street, Los Angeles, California.

27 ///

28

JURISDICTION

1
2 3. This Accusation is brought before the Board of Pharmacy (Board),
3 Department of Consumer Affairs, under the authority of the following laws. All section
4 references are to the Business and Professions Code (Code) unless otherwise indicated.

5 4. Section 118, subdivision (b), of the Code provides that the suspension,
6 expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to
7 proceed with a disciplinary action during the period within which the license may be renewed,
8 restored, reissued or reinstated.

9 5. Section 4300, subdivision (a) of the Code states: "Every license issued
10 may be suspended or revoked."

11 6. Code section 477, subdivision (b), states that "'License' includes
12 certificate, registration or other means to engage in a business or profession regulated by this
13 code."

14 7. Section 480, subdivision (a)(2), provides that a board may deny a license if
15 the applicant has committed dishonest, fraudulent, or deceitful acts with the intent to
16 substantially benefit himself.

17 8. Section 810 of the Code states:

18 (a) It shall constitute unprofessional conduct and grounds for
19 disciplinary action, including suspension or revocation of a license or certificate,
20 for a health care professional to do any of the following in connection with his or
21 her professional activities:

22 (2) Knowingly prepare, make, or subscribe any writing, with intent to
23 present or use the same, or to allow it to be presented or used in support of any
24 false or fraudulent claim.

25 9. Section 4301 of the Code states:

26 The board shall take action against any holder of a license who is guilty of
27 unprofessional conduct. . . . Unprofessional conduct shall include, but is not
28 limited to, any of the following:

///

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

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

5 (p) Actions or conduct that would have warranted denial of a license.
6

7 COST RECOVERY

8 10. Section 125.3 of the Code provides that the Board may request the
9 administrative law judge to direct a licensee found to have committed a violation or violations
10 of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
11 enforcement of the case.

12 BACKGROUND

13 11. Cathay Medical Industries, Inc., owns Cathay Medical Pharmacy,
14 Pharmacy Permit No. PHY 22806, and College Pharmacy, Pharmacy Permit No. PHY 36574.
15 Cathay Medical Industries, Inc., is owned by Henry Fong (75%) and *Gerald Wu* (25%). Henry
16 Fong is the Pharmacist-In-Charge of College Pharmacy, and Henry Fong's son, David Fong, is
17 the Pharmacist-In-Charge of Cathay Medical Pharmacy.

18 12. Easy Returns Worldwide, Inc. (ERW) was a reverse distributor of
19 pharmaceuticals. ERW returned expired drugs to the appropriate manufacturers for credit to its
20 client pharmacies who purchased the drugs. ERW usually charged the pharmacies a 5-10% fee
21 for said returns, which was based on the expected credits that the manufacturer would give to the
22 pharmacies. Most manufacturers required the return of the actual products from ERW's retail
23 pharmacies in order to give them credit.

24 13. In a criminal proceeding entitled *United States of America v. Richard J.*
25 *Drury*, United States District Court, Eastern District of Missouri, Case No. S1-4:05 CR 33 ERW,
26 Richard Drury, a corporate officer of ERW (Drury), was indicted, found guilty, and convicted of
27 four counts of mail fraud for defrauding drug manufacturers by making false claims with
28 pharmacies in connection with returned drugs. Pursuant to Drury's Indictment, between August

1 2000 and January 2002, Drury devised and participated in a scheme to create fraudulent returns
2 of expired drugs to pharmaceutical manufacturers on behalf of pharmacies that had not purchased
3 them with the false assertion that the pharmacies had purchased the drugs. This scheme caused
4 the manufacturers to credit various pharmacies for returns that did not belong to them. The
5 pharmacies paid approximately a 33% fee to Drury and ERW for the false returns credited to
6 them.

7 14. David Fong agreed with ERW to participate in its fraudulent scheme in
8 order to obtain easy profits for his family business. ERW returned dangerous drugs in November
9 and December of 2000 under both Cathay Medical Pharmacy's and College Pharmacy's
10 pharmacy permits and federal Drug Enforcement Administration (DEA) numbers, even though
11 the returned drugs did not belong to either pharmacy. Based on the amount of the false returns
12 on behalf of the two pharmacies, the Board investigator estimated that Respondent gained
13 approximately \$14,000 for College Pharmacy and approximately \$19,000 for Cathay Medical
14 Pharmacy by participating in ERW's fraudulent scheme.

15 **FIRST CAUSE FOR DISCIPLINE**

16 **(Unprofessional Conduct / Commission of Fraudulent, Deceitful Acts)**

17 15. Respondent is subject to disciplinary action under Code section 4301,
18 subdivision (f), for committing fraudulent and deceitful acts constituting unprofessional conduct.
19 In or about the year 2000, through ERW, a reverse distributor, Respondent presented false claims
20 to drug manufacturers regarding returned drugs in order to obtain unearned financial benefit.
21 Respondent's involvement in the fraudulent scheme is more fully described in paragraphs 11
22 through 14, above.

23 **SECOND CAUSE FOR DISCIPLINE**

24 **(Knowingly Creating a Document Containing Factual Misrepresentations)**

25 16. Respondent is subject to disciplinary action under Code section 4301,
26 subdivision (g), for knowingly creating documents containing factual misrepresentations, thus
27 constituting unprofessional conduct. In or about the year 2000, Respondent presented claims
28 through ERW to drug manufacturers that contained factual misrepresentations regarding

1 allegedly returned drugs in order to obtain unearned financial benefit. Respondent's involvement
2 in the fraudulent scheme is more fully described in paragraphs 11 through 15, above.

3 **THIRD CAUSE FOR DISCIPLINE**

4 **(Unprofessional Conduct / Commission of Acts That**
5 **Would Have Warranted the Denial of a License)**

6 17. Respondent is subject to disciplinary action under Code sections 480 and
7 4301, subdivision (p), for engaging in unprofessional conduct, specifically, for committing acts
8 that would have warranted the denial of a license. Section 480, subdivision (a)(2) provides that a
9 board may deny a license if the applicant has committed dishonest acts in order to benefit himself
10 financially. In or about the year 2000, Respondent presented false claims through ERW
11 regarding allegedly returned drugs in order to obtain unearned financial benefit, thus constituting
12 a valid ground for license denial under section 480 and constituting unprofessional conduct and a
13 cause for discipline under section 4301, subdivision (p). Respondent's involvement in the
14 fraudulent scheme is more fully described in paragraphs 11 through 16, above.

15 **FOURTH CAUSE FOR DISCIPLINE**

16 **(Unprofessional Acts and Omissions Involving the Exercise of**
17 **Pharmaceutical Education, Training, and Experience)**

18 18. Respondent is subject to disciplinary action under Code section 4306.5 for
19 committing unprofessional acts involving the exercise of professional pharmaceutical education,
20 training, and experience. In or about the year 2000, Respondent fraudulently committed
21 unprofessional acts when he presented false claims through ERW regarding allegedly returned
22 drugs in order to obtain unearned financial benefit. The process of preparing false claims
23 through ERW, and the utilization of a pharmaceutical specialty company, namely ERW, to
24 process these claims, utilized specialized knowledge, which Respondent had gained through his
25 pharmaceutical education, training, and experience, constituting unprofessional conduct and a
26 cause for discipline under section 4306.5. Respondent's involvement in the fraudulent scheme is
27 more fully described in paragraphs 11 through 17, above.

28 ///

1 FIFTH CAUSE FOR DISCIPLINE

2 (Preparing and Presenting False Claims for Payment)

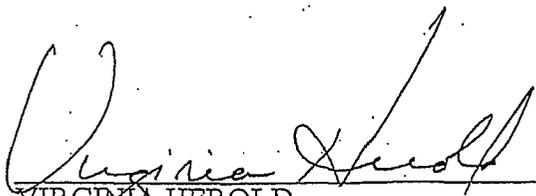
3 19. Respondent is subject to disciplinary action under section 810, subdivision
4 (a)(2) for preparing and presenting false claims for payment, which constitutes a specifically
5 identified form of unprofessional conduct. In or about the year 2000, Respondent fraudulently
6 presented false claims through ERW regarding allegedly returned drugs in order to obtain
7 unearned financial benefit. Respondent's involvement in the fraudulent scheme is more fully
8 described in paragraphs 11 through 19, above.

9 PRAYER

10 WHEREFORE, Complainant requests that a hearing be held on the matters herein
11 alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- 12 1. Revoking or suspending Pharmacist License Number RPH 37204, issued
13 to Respondent;
- 14 2. Ordering Respondent to pay the Board of Pharmacy the reasonable costs of
15 the investigation and enforcement of this case, pursuant to Business and Professions Code
16 section 125.3; and
- 17 3. Taking such other and further action as deemed necessary and proper.

18
19 DATED: 7/22/08

20
21 
22 VIRGINIA HEROLD
23 Executive Officer
24 Board of Pharmacy
25 Department of Consumer Affairs
26 State of California
27 Complainant
28

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9
10 **BEFORE THE**
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
11

12 In the Matter of the Accusation Against:
13 **MICHELLE H. MAI**
15837 E. Palomino Blvd.
14 Fountain Hills, Arizona 85268
15 Pharmacy License No. RPH 58012
16 Respondent.

Case No. 3234
AMENDED ACCUSATION

17
18 Complainant alleges:

19 PARTIES

20 1. Virginia K. Herold (Complainant) brings this Accusation solely in her
21 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer
22 Affairs.

23 2. On or about December 29, 2005, the Board of Pharmacy issued Pharmacist
24 License No. RPH 58012 to Michelle H. Mai (Respondent). The Pharmacist License was in full
25 force and effect at all times relevant to the charges brought herein and will expire on December
26 31, 2009, unless renewed. Respondent also holds Pharmacist License No. 12319 issued by the
27 Arizona State Board of Pharmacy, restricted as alleged herein.

28 ///

1 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the
2 following:

3

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

7 ...

8 (l) The conviction of a crime substantially related to the qualifications, functions,
9 or duties of a licensee under this chapter.

10 ...

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

14 ...

15 7. Section 4301.5(a) of the Code states, in pertinent part:

16 “If a pharmacist possesses a license or is otherwise authorized to practice
17 pharmacy in any other state or by an agency of the federal government, and that license or
18 authority is suspended or revoked, the pharmacist’s license shall be suspended automatically for
19 the duration or revocation, unless terminated or rescinded as provided in subdivision (c).”

20 8. Section 125.3 of the Code states, in pertinent part, that the Board may
21 request the administrative law judge to direct a licentiate found to have committed a violation or
22 violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation
23 and enforcement of the case.

24 FIRST CAUSE FOR DISCIPLINE

25 (Conviction of a Crime)

26 9. Respondent is subject to disciplinary action for unprofessional conduct
27 under sections 490 and 4301(1) of the Code in that Respondent is convicted of a crime
28 substantially related to the qualifications, functions, or duties of the pharmacist license issued to

1 Respondent. On or about November 17, 2008, in *United States of America v. Michelle Hoa-*
2 *Chuong Mai*, United States District Court, District of Arizona, Case No. CR-08-00592-001PHX-
3 FJM, Respondent entered her plea of guilty to violation of Title 18, United States Code section
4 1341 (mail fraud), a felony, whereby Respondent and Robert Hahn knowingly and willfully
5 devised and intend to devise a scheme and artifice to defraud and to obtain money by means of
6 materially false and fraudulent pretenses and representations. As part of her sentence,
7 Respondent is prohibited from the practice of pharmacy until June 16, 2013. The circumstances
8 of Respondent's felony conviction are given below.

9 (a) Respondent and Robert Hahn, both licensed pharmacists employed at Basha's
10 Pharmacy #19, 3115 S. McClintock Road, Tempe, Arizona., submitted false and fraudulent
11 prescription labels with rebate coupons to various pharmaceutical companies and requested
12 rebate checks by mail to Respondent and her co-conspirator.

13 (b) Between September 2004 and August 2005, more than 2,500 false and
14 fraudulent prescriptions were issued by Respondent and Robert Hahn, resulting in unearned
15 rebate checks totaling about \$29,749.60.

16 SECOND CAUSE FOR DISCIPLINE

17 (Moral Turpitude, Dishonesty, Fraud, Deceit or Corruption)

18 10. Respondent is subject to disciplinary action for unprofessional conduct
19 under section 4301(f) of the Code in that Respondent committed acts of moral turpitude,
20 dishonesty, fraud, deceit and corruption during the course of her employment as a pharmacist at
21 Basha's Pharmacy #19, 3115 S. McClintock Road, Tempe, Arizona. The circumstances are as
22 set forth in Paragraph 9 hereof, incorporated herein, and concern fraudulent and false prescription
23 orders processed by Respondent for controlled substances and other medications that included,
24 but were not limited to, Triazolam .25 mg tablets, Tussionex Suspension, and Phentermine 15
25 mg capsules. Respondent also offered, delivered, received, or accepted unearned consideration
26 while engaged in such conduct, and failed to maintain prescription records as required by law.

27 ///

28 ///

Attachment 3

consultation



Attachment 4

THE PHARMACEUTICAL DISPOSAL PROGRAM IS FOR
RESIDENTIAL DISPOSAL ONLY.
COMMERCIAL DISPOSAL FROM MEDICAL FACILITIES, DOCTOR DENTAL OFFICES, BOARD AND CARE FACILITIES, BUSINESSES, ETC., IS PROHIBITED BY STATE LAW. VIOLATORS WILL BE REFERRED TO THE SAN MATEO COUNTY ENVIRONMENTAL HEALTH DEPARTMENT.

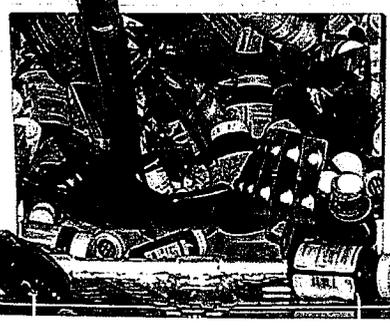
SAN MATEO COUNTY
ENVIRONMENTAL HEALTH DEPARTMENT



PHARMACEUTICAL DISPOSAL
ONLY



DESCHOS FARMACEUTICOS
SOLAMENTE



Attachment 5

SFGate.com

Alameda officer accused of painkiller scam

Henry K. Lee, Chronicle Staff Writer

Friday, February 27, 2009

(02-26) 16:57 PST ALAMEDA -- A veteran Alameda police sergeant was arrested Thursday on suspicion of stealing prescription painkillers from the family of a man who recently died, authorities said.

Ronald R. Jones, a 26-year department veteran, was arrested on suspicion of two counts of fraud and misrepresentation to obtain a controlled substance, said Alameda police Lt. Bill Scott.

Jones, 48, was booked at a downtown Oakland jail and then released. He has been placed on paid administrative leave.

Jones allegedly told the family of a man who died of natural causes that police offered a disposal service for prescription medications, Scott said. The department does not provide such a service. Authorities suspect that Jones contacted the families of several other people who died recently and offered to take away prescription medicines. Authorities said their investigation is continuing.

Investigators did not disclose what, if anything, Jones did with the medications.

Jones' attorney, Alison Berry Wilkinson, called the case "a complete and utter misunderstanding. He wasn't doing anything improper. He was operating within his responsibilities."

E-mail Henry K. Lee at hlee@sfchronicle.com.

<http://sfgate.com/cgi-bin/article.cgi?f=/c/a/2009/02/27/BAOH165OKH.DTL>

This article appeared on page **B - 3** of the San Francisco Chronicle



California State Board of Pharmacy

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Fax (916) 574-8618
www.pharmacy.ca.gov

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

Date: September 9, 2010

To: Enforcement Committee

Subject: Presentation by the Drug Enforcement Administration – Agenda Item 4

As has been discussed at prior Enforcement Committee and Board Meetings, drug diversion issues and prescription drug abuse are serious enforcement matters for the board and other regulators.

At this meeting Mike Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles, will provide information on three DEA activities or objectives aimed at preventing drug diversion and prescription drug abuse:

1. DEA Regulations to permit e-prescribing of controlled substances were released this spring. However, the requirements are very technical and run about 330 pages. At this meeting, the DEA will provide an overview of its requirements for e-prescribing. At some point, the board/committee may will to issue informational guidelines or promulgate regulations for e-prescribing of controlled drugs.
2. National Drug Take Back Day: September 25, 2010. The DEA is hosting this event, for which they will pick up the costs of the drug destruction. Flyers describing this event follow this page. One problem inhibiting drug take back programs are requirements that prevent the return of controlled substances unless provided to a law enforcement agency. This DEA event seemingly solves this problem for the day.
3. Drug Diversion of Controlled Substances in California. The DEA will provide information about drug diversion, which seems to be increasing in frequency and volume.

Materials for this discussion are provided following this page.



NEWS RELEASE

Date: August 19, 2010
Contact: DEA Public Affairs
Number: 202-307-7977

DEA HEADS FIRST-EVER NATIONWIDE PRESCRIPTION DRUG TAKE-BACK DAY

WASHINGTON, D.C. – The Drug Enforcement Administration and government, community, public health and law enforcement partners today announced a nationwide prescription drug “Take-Back” initiative that seeks to prevent increased pill abuse and theft. DEA will be collecting potentially dangerous expired, unused, and unwanted prescription drugs for destruction at sites nationwide on Saturday, September 25th from 10 a.m. to 2 p.m. local time. The service is free and anonymous, no questions asked.

This initiative addresses a vital public safety and public health issue. Many Americans are not aware that medicines that languish in home cabinets are highly susceptible to diversion, misuse, and abuse. Rates of prescription drug abuse in the U.S. are increasing at alarming rates, as are the number of accidental poisonings and overdoses due to these drugs. Studies show that a majority of abused prescription drugs are obtained from family and friends, including from the home medicine cabinet. In addition, many Americans do not know how to properly dispose of their unused medicine, often flushing them down the toilet or throwing them away – both potential safety and health hazards.

“Today we are launching a first-ever National Prescription Drug Take-Back campaign that will provide a safe way for Americans to dispose of their unwanted prescription drugs,” said Michele M. Leonhart, Acting Administrator of the Drug Enforcement Administration. “This effort symbolizes DEA’s commitment to halting the disturbing rise in addiction caused by their misuse and abuse. Working together with our state and local partners, the medical community, anti-drug coalitions, and a concerned public, we will eliminate a major source of abused prescription drugs, and reduce the hazard they pose to our families and communities in a safe, legal, and environmentally sound way.”

“With this National Prescription Drug Take-Back campaign, we are aggressively reaching out to individuals to encourage them to rid their households of unused prescription drugs that pose a safety hazard and can contribute to prescription drug abuse,” said Acting Deputy Attorney General Gary G.

Grindler. "The Department of Justice is committed to doing everything we can to make our communities safer, and this initiative represents a new front in our efforts."

"Prescription drug abuse is the Nation's fastest-growing drug problem, and take-back events like this one are an indispensable tool for reducing the threat that the diversion and abuse of these drugs pose to public health," said Director of National Drug Control Policy Gil Kerlikowske. "The Federal/state/and local collaboration represented in this initiative is key in our national efforts to reduce pharmaceutical drug diversion and abuse."

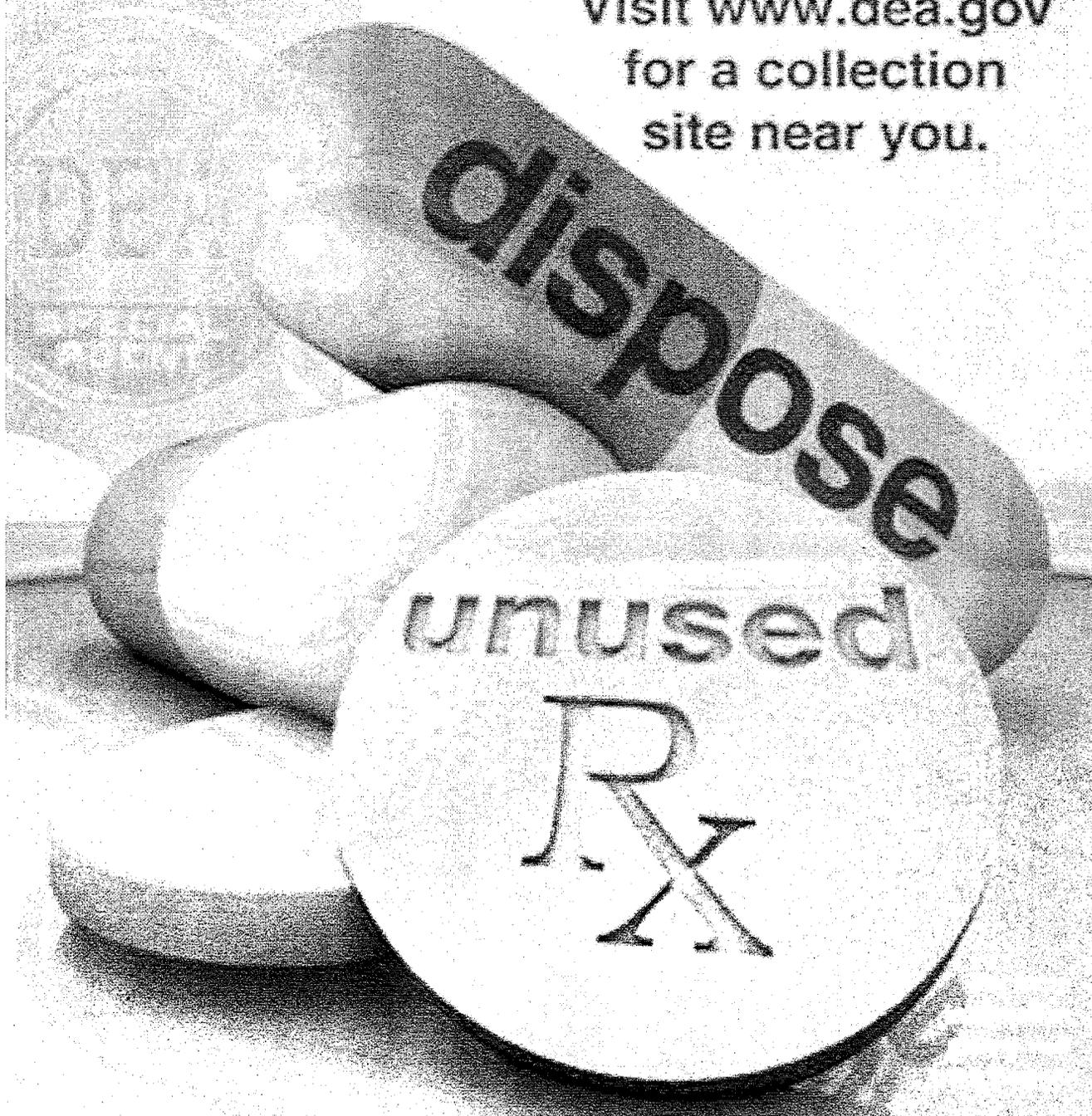
Collection sites in every local community can be found by going to www.dea.gov. This site will be continuously updated with new take-back locations. Other participants in this initiative include the White House Office of National Drug Control Policy; the Partnership for a Drug-Free America; the International Association of Chiefs of Police; the National Association of Attorneys General; the National Association of Boards of Pharmacy; the Federation of State Medical Boards; and the National District Attorneys Association.

###

Got Drugs?

Turn in your unused or expired
medication for safe disposal
Saturday, Sept. 25th

Visit www.dea.gov
for a collection
site near you.



The New Drug Crisis: Addiction By Prescription

Well-intentioned pain policies plus powerful opiate meds is leading to a national epidemic of pill popping—and accidental overdosing

BY JEFFREY KLUGER

IT'S NOT EASY TO FIND A MOTHER who would look back fondly on the time her son had cancer. But Penny (not her real name) does. Penny lives in Boston, and her son got sick when he was just 13. He struggled with the disease for several years—through the battery of tests and the horror of the diagnosis and, worst of all, through the pain that came from the treatment. For that last one, at least, there was help—Oxycontin, a time-released opioid that works for up to 12 hours. It did the job, and more.

The brain loves Oxycontin—the way the drug lights up the limbic system, with cascading effects through the ventral striatum, midbrain, amygdala, orbitofrontal cortex and prefrontal cortex, leaving pure pleasure in its wake. What the brain loves, it learns to crave. That's especially so when the alternative is the cruel pain of cancer therapy. By the time Penny's son was 17, his cancer was licked—but his taste for Oxy

wasn't. When his doctor quit prescribing him the stuff, the boy found the next best—or next available—thing: heroin. Penny soon began spending her Monday nights at meetings of the support group Learn to Cope, a Boston-based organization that counsels families of addicts, particularly those hooked on opioids or heroin.

"Penny told the group that she actually misses her son's cancer," says Joanne Peterson, the founder of Learn to Cope. "When he had that, everyone was around. When he had that, he had support."

Penny and her son are not unique. Humans have never lacked for ways to get wasted. The natural world is full of intoxicating leaves and fruits and fungi, and for centuries, science has added to the pharmacopoeia. In the past two decades, that's been especially true. As the medical community has become more attentive to acute and chronic pain, a bounty of new drugs has rolled off Big Pharma's production line.

There was fentanyl, a synthetic opioid around since the 1960s that went into wide use as a treatment for cancer pain in the 1990s. That was followed by Oxycodone, a short-acting drug for more routine pain, and after that came Oxycontin, a 12-hour formulation of the same powerful pill. Finally came hydrocodone, sold under numerous brand names, including Vicodin. Essentially the same opioid mixed with acetaminophen, hydrocodone seemed like health food compared with its chemical cousins, and it has been regulated accordingly. The government considers hydrocodone a Schedule III drug—one with a "moderate or low" risk of dependency, as opposed to Schedule II's, which carry a "severe" risk. Physicians must submit a written prescription for Schedule II drugs; for Schedule III's, they just phone the pharmacy. (Schedule I substances are drugs like heroin that are never prescribed.) For patients, that wealth of choices spelled danger.

But the real test of leadership—amongst all the tests of policy, judgment, politics and ability—is whether, in the final analysis, you put the country first; that ultimately you are prepared to put what you perceive to be the common good of the nation before your own political self. It is the supreme test. Very few leaders pass it. Each of these Presidents does and for a reason not connected simply to them.

Americans can be all that the rest of the world sometimes accuses them of: brash, loud, insular, obsessive and heavy-handed. But America is great for a reason. It is looked up to, despite all the criticism, for a reason. There is a nobility in the American character that has been developed over the centuries, derived in part, no doubt, from the frontier spirit, from the waves of migration that form the stock, from the circumstances of independence, from the Civil War, from a myriad of historical facts and coincidences. But it is there.

That nobility isn't about being nicer, better or more successful than anyone else. It is a feeling about the country. It is a devotion to the American ideal that at a certain point transcends class, race, religion or upbringing. That ideal is about values: freedom, the rule of law, democracy. It is also about the way you achieve: on merit, by your own efforts and hard work. But it is most of all that in striving for and protecting that ideal, you as an individual take second place to the interests of the nation as a whole. It is what makes the country determined to overcome its challenges. It is what makes its soldiers give their lives in sacrifice. It is what brings every variety of American, from the lowest to the highest, to their feet when "The Star-Spangled Banner" is played. Of course the ideal is not always met—that is obvious. But it is always striven for.

The Need for American Confidence

THE NEXT YEARS WILL TEST THE AMERICAN CHARACTER. America won't be loved in this presidency any more than in previous ones. But America should have confidence. That ideal, which produces the optimism that generates the achievement, is worth all the striving. It is the most precious gift a nation can have. The world is changing. New powers are emerging. But this does not diminish the need for that American ideal. It reaffirms it, renews it, gives it added relevance. There is always one, more prosaic, test of a nation's position: Are people trying to get into it, or to get out of it? I think we know the answer to that in America's case, and that ideal is the reason.

A friend of mine whose parents were immigrants, Jews from Europe who came to America in search of safety, told me this story. His parents lived and worked in New York. They were not well off. His father died when he was young. His mother lived on, and in time my friend succeeded and became wealthy. He often used to offer his mother the chance to travel outside America. She never did. When eventually she died, they went back to recover the safety box where she kept her jewelry. They found there was another box. There was no key. So they had to drill it open. They wondered what precious jewel must be in it. They lifted the lid. There was wrapping and more wrapping and finally an envelope. Intrigued, they opened it. In the envelope were her U.S. citizenship papers. Nothing more. That was the jewel, more precious to her than any other possession. That was what she treasured most. So should America today. ■

Q&A WITH TONY BLAIR

'The only just way is two states for two peoples'

TONY BLAIR TALKED RECENTLY TO *TIME*'S MICHAEL ELLIOTT about being prepared for office, a turning point in the Iraq war and the hopes for Middle East peace.

What most surprised you about taking a leadership position rather than just thinking about it?

The huge difference between exploring a problem, talking about it, even putting forth a solution to it, and doing it. What you are unprepared for is the sheer complexity and difficulty of the business of governing. I always come back to that Mario Cuomo phrase, "You campaign in poetry and govern in prose." It's absolutely correct. [But] you do learn. It's like anything else—you do learn.

Do you think it is now more difficult for the Western democracies to advance the ideas in your 1999 Chicago speech on the responsibilities of the international community?

More difficult, yes, because it is clear that if you are engaged in intervention in which [this new strain of extremism based on a perversion of Islam] is a factor, then that intervention may be protracted and hugely challenging. [The ideas are] not any less necessary, however.

It seemed that your objective in the pages on Iraq was simply to ask people to think again about their ideas of what the war was about and how it was fought.

Yes, exactly so. My function in the book is not to persuade you but to ask you to understand there is a different point of view. I simply ask people to open their minds.

I was struck by your suggestion that a defining moment in Iraq was the attack on the U.N. in August 2003.

This was an act absolutely aimed at the international community, not at the Americans or the British or the coalition of countries that had supported [the war]. What really should have happened is that the international community came together and said, Look, this is an assault on us, and we should defend ourselves, and we should ensure that we come together. But that's not what happened.

Tell me a little about the donation of your proceeds from the book to the British Legion, which works with members of the armed forces and their families.

I have a huge respect for them, and it is right that we honor them and help them in any way that [we] can.

The Middle East peace talks are about to get under way again. Are there reasons to be optimistic?

Yes, there are. First of all, there is no alternative but to find a just way of people living together in peace, and the only just way is two states for two peoples, as it were. So let's get on and do it. The single most important thing is the Obama decision to do this from the beginning. That gives us the space and the time to get this thing done. ■

PILL BOTTLE: DANNY KIM FOR TIME; HEAD SHOTS: CLOCKWISE FROM TOP LEFT: GENE KORNMAN—JOHN KOBAL/GETTY IMAGES; GAB ARCHIVE/REDFERNS/GETTY IMAGES; AP; MIKE FLORES—GETTY IMAGES; ERIC NEITZEL—WIREIMAGE; TOM CASINO—WIREIMAGE

2000, which was not only about the time the new opioids were hitting the market but also shortly after the Federal Trade Commission began allowing direct-to-consumer drug advertising. When market, mission and product converge this way, there's little question what will happen. And before long, patients were not only being offered easy access to drugs but were actually having the medications pushed on them. No tooth extraction was complete without a 30-day prescription for Vicodin. No ambulatory surgery ended without a trip to the hospital pharmacy to pick up some Oxy. Worse, people with chronic pain were getting prescriptions that could be renewed again and again.

"For me, it started with lower-back pain," says Jason (not his real name), a carpenter in his late 50s. Jason is a 90-day inpatient at the Hanley Center, a residential addiction facility in West Palm Beach, Fla. "I went to my doctor, and he prescribed Oxycontin. After a little while, I was finishing a one-month prescription in three weeks, then in two. I started complaining of more pain than I had so I could get more Oxy, and finally I started buying it on the street. In a pharmacy, I paid \$8 for 160 pills. On the street, I was paying \$25 each."

Jason's demographic profile is typical of Hanley's—older, whiter and generally wealthier than addicts of previous generations. And while some people do wind up buying on the street, many never need to, thanks to the gray market that has sprouted up around opioid sales. As long as the drugs are legal and real M.D.s are prescribing them, it's a simple matter to hang out a shingle and call yourself a pain clinic. Pay-to-play patients are given prescriptions based on little more than their word that they're in pain—sometimes backed up by self-evidently altered MRIs.

Says Evelyn (another pseudonym, and another baby boomer at Hanley), "When my physician refused to prescribe me more pills, he sent me to a clinic. The doctor there didn't even ask me my name at first. He wrote me a prescription while he was on the phone dealing with some court case he was involved in. When you're well dressed and you have insurance, they don't think of you as an addict."

Florida is lousy with such pain-clinic pill mills, in part because of extremely loose oversight of the people operating them. Until June, when Governor Charlie Crist signed a new law cracking down on the operations, there was nothing to prevent felons from opening a clinic and hiring doctors to write the prescriptions. Indeed, on the national ranking of practi-

tioners dispensing Oxycodone, every doc in the top 50 has a Sunshine State address.

"I've taken to calling the problem 'pharmageddon,'" says Dr. Barbara Krantz, Hanley's CEO and medical director. "There are seven deaths per day in Florida from prescription-drug overdoses." The state has also become a hub for opioid traffickers in the Southeast.

What worries Krantz and other substance-abuse professionals is that an addiction scourge that is, for now, hitting the boomer demographic hardest won't stay there and instead will gather greater strength in the under-25 cohort. It's not just young cancer patients given a legal taste of Oxy who are in danger in this group; it's everyone. "A parent comes home from the dentist with 30 doses of Oxycontin and only takes a few," says Barber. "Then the pills are stored in the medicine chest, where anyone can get them."

This is leading to a rise in the incidence of what's known as skittling, a social phenomenon with deadly consequences. "Kids steal from their parents' medicine chests, go to a party and dump everything into a bowl at the door," says Juan Harris, a Hanley drug counselor. "Anyone who comes in just grabs a handful."

Killing the Buzz

FOR KIDS, EDUCATION PROGRAMS IN schools help a little, at least in terms of informing them of the risks associated with drugs. But such a rearguard action goes just so far, and a longer-term solution will come only when the government increases its control over the legal dispensation of the most popular pills. The first step would be better surveillance and tracking. An alphabet soup of agencies—from the FDA to the CDC to SAMHSA to the National Institute of Drug Abuse—all have a hand in monitoring prescription meds, but no single one is in charge.

Overdoses were claiming celebs even before the recent opioid boom



Marilyn Monroe

Elvis Presley

Dorothy Dandridge



Michael Jackson

Anna Nicole Smith

Heath Ledger

"You need Congress choosing an agency and saying, 'This is your baby,'" says Barber. Most epidemiologists cite 2007 numbers when discussing addiction, simply because more recent data aren't available. "We're trying to hit a moving target last seen three years ago" is how Dr. Len Paulozzi, a CDC epidemiologist, puts it.

In early 2009, the FDA announced that it was initiating a "risk-evaluation and mitigation strategy," contacting the opioid manufacturers and requiring them to participate in a study of how their meds can continue to be made available while at the same time being better controlled. The regulations the FDA is empowered to issue include requiring manufacturers to provide better information to patients and doctors, requiring doctors to meet certain educational criteria before writing opioid prescriptions and limiting the number of docs and pharmacies allowed to prescribe or dispense the drugs.

"And with all that," warns Dr. John Jenkins, director of the FDA's Office of New Drugs, "we do still have to make sure patients have access to drugs they need." Any regulations the FDA does impose won't be announced until 2011 at the earliest and could take a year or more to roll out.

Other solutions don't face the same regulatory maze. An electronic database of all pharmacies across the country could help catch patients and doctors who are gaming the system, particularly those who hopscotch across state lines. Doctors need to be less cavalier about prescribing drugs and stingier with the amount they do allow. They could also do a better job of assessing patients for addictive histories and requiring urine tests if they suspect a problem. If the patients don't want to comply, they don't have to—but they won't get their drugs either.

Insurers—the bad guys in so many policy debates—can do a lot of good, keeping better track of the number and types of controlled substances policyholders are receiving. Big Pharma must help as well, and that means climbing down off the opioid gravy train and working harder to develop more nonaddictive painkillers—even if it means fewer sales and lower profits.

Until then, it's up to responsible doctors and cautious patients to keep the epidemic in check. That, certainly, is not easy. "When drug addicts or alcoholics ask us if they can ever use substances in moderation, we tell them no," says Krantz. "Once your brain becomes a pickle, it can't go back to being a cucumber." Too many Americans are pickled already. The time to help them—and protect the rest—is now. ■

Virginia K. Herold

From: Karen Abbe

Sent: Wednesday, September 01, 2010 5:14 PM

To: Virginia K. Herold

Subject: San Diego Union-Tribune: Medical examiner releases stats on causes of deaths in 2009

Medical examiner releases stats on causes of deaths in 2009

Drug- and alcohol-related deaths continue as No. 1 cause of non-natural deaths in county

By Debbi Baker and Karen Kucher
San Diego Union-Tribune

Originally published August 25, 2010 at 3:41 p.m., updated August 25, 2010 at 6:51 p.m.

Deaths from drug and alcohol use remained the No. 1 cause of non-natural deaths in the county in 2009, a trend that started in 2003, according to statistics the Medical Examiner's Office released Wednesday.

Of the 2,707 deaths that the office had jurisdiction over last year, 443 were from illegal drugs, prescription medications and alcohol, said Dr. Jonathan Lucas, a deputy medical examiner.

"Not only are we seeing more prescription medications and alcohol-related deaths, but we are seeing more mixing of alcohol, prescription meds and illicit drugs," Lucas said. "These are concerning trends."

2009 causes of death

Cardiovascular: 592

Drug- and alcohol-related: 443

Suicide: 377

Fall: 374

Motor vehicle: 284

SOURCE: County Medical Examiner's Office

The most abused prescription drugs are analgesic pain relievers, including oxycodone, hydrocodone, Valium, fentanyl and methadone, Lucas said. The U.S. Drug Enforcement Administration and other law enforcement agencies have seen increases in illegal activity involving those drugs, especially among young people under 30, Lucas said.

Where to get help

For referrals to alcohol and drug treatment programs or mental health counseling, call the county's

Access and Crisis Line at (800) 479-3339.

Among young people, there also has been an uptick in fatal overdoses from heroin, Lucas said. So far this year, five people under 20 have died from heroin use, compared to seven over the past six years. Lucas said the numbers may be small, but they could represent a warning sign of increased heroin use on the streets.

"It also could represent the phenomenon of oxycodone being a gateway to heroin use," he said. "When people get addicted to oxycodone and they can no longer afford the drug, they move on to heroin that is cheaper and perhaps even easier to find."

Susan Bowers, deputy director of the county's alcohol and drug services, said drug-treatment providers are seeing fairly low admissions for prescription drug addictions but a continual increase in admissions due to heroin abuse. She said prescription drugs like oxycodone, a synthetic opiate, can be very hard to kick because they are "incredibly addicting."

The county has several drug treatment programs that serve some 13,000 people every year, said county spokesman José Alvarez.

Lucas cited multiple factors for the rising number of deaths overall from prescription medications. Young people often get pills from their parents' medicine cabinets, he said. Adults also go "doctor shopping" — seeing multiple physicians for prescriptions — and some doctors overprescribe, Lucas said.

To combat the problem, county officials last fall formed the OxyContin Task Force, made up of 29 federal, county and city law enforcement agencies. County Supervisor Pam Slater-Price, in conjunction with the Sheriff's Department, also started Prescription Take-Back Day, which allows people to drop off unused pills at secure locations across the county.

At drop-off events in October and April, more than 2,800 pounds of unwanted or expired medications were turned in. The DEA is planning a similar event for Sept. 25, a campaign dubbed "national clean out your medicine cabinet day."

Temporary drop-off boxes also have been set up at sheriff's offices in Vista, Imperial Beach, Santee and Kearny Mesa.

"They have been filling the boxes every day or two," said sheriff's Lt. Todd Richardson. By next month, 23 permanent boxes should be placed at sheriff's substations, detention facilities and courthouses around the region for people interested in emptying out their medicine cabinets, he said.

"We are really looking forward to getting these other ones out there," Richardson said.

While drug deaths are increasing, the statistics from the Medical Examiner's Office show that heart disease continues to be the No. 1 killer in the county in cases the office reviews, accounting for 592 deaths in 2009.

Suicides were also on the rise, increasing 20 percent since 2006, while motor vehicle fatalities were at a 10-year low, with 284 cases last year.

Lucas said the drop in automobile accident deaths started in 2008 and could correspond to higher gas prices and fewer drivers on the road. "There is no way to know for sure," he said.

There also were fewer homicides last year, a reflection of the overall drop in violent crime, Lucas said. In all, 109 people died in 2009 at the hands of another.

About 11,000 deaths are reported to the medical examiner each year, and of those about 3,000 are investigated. The medical examiner's office investigates cases where a person dies in unusual circumstances or at a home where they are not attended by a physician and the cause of death needs to be determined.

Lucas said the information stemming from those cases are an essential tool for elected officials and law enforcement authorities to track trends and set public policies.

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karen.kucher@uniontrib.com (619) 293-1350

Find this article at: <http://www.signonsandiego.com/news/2010/aug/25/medical-examiner-releases-stats-causes-deaths-2009>

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

Date: September 9, 2010

To: Enforcement Committee

Subject: Presentation on Drug Thefts from Pharmacies – Agenda Item 5

In June, Supervising Inspector Judi Nurse provided information about pharmacy thefts and robberies from pharmacies, and from various entities in the pharmaceutical supply chain (e.g., common carriers) to a group of San Diego pharmacists brought together by the DEA at a forum to discuss and prevent drug diversion.

At this meeting Supervising Inspector Nurse, who oversees the board's drug diversion team of inspectors, will provide an abbreviated form of this presentation.

Coincidentally and unfortunately, last week an independent pharmacy in Sacramento was the victim of an armed robbery at 12:30 p.m. in strip mall. A pharmacy clerk was killed and another injured (as was one of the robbers) in the gun melee that occurred during this robbery. I will attach newspaper clippings reporting this and another unrelated attempted pharmacy robbery that has occurred this week.

Virginia K. Herold

From: Karen Abbe
Sent: Thursday, September 02, 2010 3:57 PM
To: Virginia K. Herold
Cc: Anne Sodergren; Carolyn Klein
Subject: Sacramento Bee - Sacto 911: Sacramento pharmacy employee, robbers exchange gunfire; 2 wounded



The Sacramento Bee's Crime blog is a comprehensive report of crime news, trends and information for your community and beyond.

Sacramento pharmacy employee, robbers exchange gunfire; 2 wounded

By Matt Kawahara
mkawahara@sacbee.com
September 2, 2010-09-02

A gun battle this afternoon between an employee of a North Highland pharmacy and two robbers left two pharmacy employees wounded and maybe one of the robbers, a Sacramento County Sheriff's Department spokesman said.

Gunshots were exchanged in the Rexall Pharmacy in the 5600 block of Watt Avenue and in the parking lot, said Sgt. Tim Curran.

"Bullets were flying everywhere" he said.

One of the wounded employees, a 27-year-old woman, is in critical condition with a gunshot wound in the chest, said Sgt. Tim Curran. The other employee, a pregnant 37-year-old woman, was struck in the foot.

The robbers were still at large as of 3 p.m. One of them may have been hit by gunfire, Curran said.

Just before 12:30 p.m., the robber entered the pharmacy and demanded drugs, Curran said. One of the robbers was armed.

A male employee also was armed. Curran said he doesn't know who fired first. After an exchange of gunfire, the robbers fled.

The male employee followed them out of the store and more shots were exchanged, Curran said.

The male employee was not wounded.

The robbers are described as two black male adults. One is in his 40s, between 5 feet 10 inches and 6 feet 2 inches tall and weighing 160 to 180 pounds. The other is in his mid to late 20s, about 5 feet 8 inches tall and thin.

Posted by Bill Enfield
3:32 PM

Virginia K. Herold

From: Karen Abbe
Sent: Thursday, September 09, 2010 8:33 AM
To: Virginia K. Herold
Cc: Anne Sodergren; Carolyn Klein
Subject: KCRA.com: Guard Stops Sac Pharmacy Robbery



Guard Stops Sac Pharmacy Robbery

Suspect Demanded OxyContin, Police Say

POSTED: 2:49 pm PDT September 8, 2010
UPDATED: 4:11 pm PDT September 8, 2010

SACRAMENTO, Calif. -- A security guard foiled a man's attempt to steal OxyContin from a Sacramento pharmacy, authorities said.

Dennis Pacheco, 63, was booked into jail on Tuesday on suspicion of trying to rob the Rite Aid store at 1125 Alhambra Blvd., according to a police report. Police said Pacheco entered the store at about 10 a.m., simulated holding a gun and demanded the prescription drug.

A report said a security guard grabbed Pacheco's hand and found that Pacheco was holding a stick instead of a firearm.

Police said the guard wrestled Pacheco to the ground and held him until police arrived. Pacheco, who was also sought on a federal warrant, remained in jail Wednesday. He was being held without bail. Pacheco is set to appear in court on Thursday.

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

Date: September 9, 2010

To: Enforcement Committee

**Subject: Update on the Board's Efforts to Implement Components of the
Department of Consumer Affairs Consumer Protections Enforcement
Initiative**

Agenda Item 6

Background

Beginning in July 2009, the Department of Consumer Affairs has been work with health care board to improve capabilities to investigate and discipline errant licensees to protect the public from harm. These results yielded the Consumer Protections Enforcement Initiative (CPEI). The CPEI was comprised of a three pronged solution designed to ensure that investigation were completed and final action taken against a licensee within 12 – 18 months. The solution included legislative changes designed to remove barriers to investigations, a new computer system that would meet the boards needs to collect information and monitor performance, and additional staff resources.

Many of the legislative changes identified by the department were incorporated in SB 1111 (Negrete McLeod). Unfortunately this bill failed passage early in the year during its first policy committee. Subsequent to that, the department identified provisions in the bill that could be implemented through regulation and encouraged boards to develop language and initiate the rulemaking process.

In addition to working with the department on a department wide solution, the board also identified statutory changes that would specifically address pharmacy related issues. Language for these provisions was discussed during the January 2010 Board Meeting, and the board voted to pursue the changes. Because of the timing with the legislative cycle, these provisions were not pursued this year.

More recently, during the June 2010 Board Meeting, the board discussed proposed regulatory language developed by counsel, designed to implement the provisions requested by the department. The board expressed concern on many of the provisions and with one exception, did not take action on the items.

Recent Update

In August, 2010, at the department's request, board staff target timelines to meet the DCA's Enforcement Performance Measurements. Many of these elements are currently

reported to the board in quarterly strategic plan updates. However, the department is working towards standardizing performance measures.

During this Meeting

The department continues to encourage boards to pursue regulations changes. The committee may wish to discuss the policy behind each proposed change and provide staff with guidance on which policies it wishes to pursue as a future rulemaking. Board staff can provide a brief problem statement on the proposals to facilitate discussion should the committee so choose.

The committee may also wish to discuss the measures submitted to the department to confirm agreement with or recommend changes.

Further, the board's disciplinary guidelines have not been updated since 2008. The committee may wish to direct staff to initiate review of the disciplinary guidelines and report back recommended changes for future committee and board discussion and action.

Following this memo is a copy of the language that was discussed during the June 2010 meeting. A copy of the measures provided to the department is also provided.

Proposed amendments to section 1760 of Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled “Disciplinary Guidelines” (Rev. ~~10/2007~~ 6/2010), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

(a) Notwithstanding the disciplinary guidelines, any proposed decision issued by an Administrative Law Judge in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code that contains any findings of fact that:
(1) the licensee engaged in any act of sexual contact with a patient, client or customer; or,
(2) the licensee has been convicted of or committed a sex offense, shall contain an order revoking the license. The proposed decision shall not contain an order staying the revocation of the license or placing the licensee on probation.

(b) Subdivision (a) shall not apply to sexual contact between a pharmacist and his or her spouse or person in an equivalent domestic relationship when that pharmacist provides services as a licensed pharmacist to his or her spouse or person in an equivalent domestic relationship.

(c) For the purposes of this section, “sexual contact” has the same meaning as defined in subdivision (c) of Section 729 of the Business and Professions Code and “sex offense” has the same meaning as defined in Section 44010 of the Education Code.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

Proposed addition of Section 1762. to Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1762. Unprofessional Conduct Defined

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later, unless the licensee is unable to provide the documents within this time period for good cause. For the purposes of this section, "good cause" includes physical inability to access the records in the time allowed due to illness or travel.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Failure to report to the board, within 30 days, any of the following:

(1) The bringing of an indictment or information charging a felony against the licensee.

(2) The arrest of the licensee.

(3) The conviction of the licensee, including any verdict of guilty, or pleas of guilty or no contest, of any felony or misdemeanor.

(4) Any disciplinary action taken by another licensing entity or authority of this state or of another state or an agency of the federal government or the United States military.

(e) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority cited: 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301 Business and Professions Code.

Proposed amendments to Section 1769. of Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1769. Application Review and Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The report of the examiners shall be made available to the applicant. The board shall pay the full cost of such examination. If after receiving the report of evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 480, 482, 820, 4030, 4200 and 4400, Business and Professions Code.

Proposed amendments to Section 1770. of Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1770. Substantial Relationship Criteria.

(a) For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

(b) An applicant's, licensee's or registrant's crime or act shall be considered to be substantially related to the qualifications, functions or duties of the license or registration if such crime or act resulted in the licensee or registrant being required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law.

Authority cited: Sections 481, 4005, Business and Professions Code. Reference: Sections 475, 480, 481, 4200, 4300, 4309 and 4301, Business and Professions Code.

Board / Bureau / Program Name:		Pharmacy	
Measure Type / Name	Collection Method	Example	Your Program's Target
PM 1: Volume Number of complaints received	Extracted from CAS and submitted quarterly through the Performance Measure Workbook	<i>N/A</i>	<i>No target required</i>
PM 2: Cycle Time Average number of days to complete complaint intake	Extracted from CAS and submitted quarterly through the Performance Measure Workbook	<i>7 days</i>	20 days
PM 3: Cycle Time Average number of days to complete closed cases not resulting in formal discipline	Extracted from CAS and submitted quarterly through the Performance Measure Workbook	<i>80 days</i>	210 Days
PM 4: Cycle Time Average Number of Days to Complete Cases Resulting in Formal Discipline	Extracted from CAS and submitted quarterly through the Performance Measure Workbook	<i>360 days</i>	18 Months
PM 5: Efficiency (Cost) Average cost of intake and investigation for complaints not resulting in formal discipline	TBD	<i>N/A</i>	<i>Targets will not be required until first quarter baseline has been established</i>
PM 6: Customer Satisfaction Consumer satisfaction with the service received during the enforcement process.	Results extracted from survey by SOLID staff and reported to programs	<i>85% Satisfaction</i>	75 percent
PM 7: Cycle Time Average number of days from the date a probation monitor is assigned to the date the monitor	Probation data recorded and submitted quarterly through Performance Measure Workbook	<i>6 days</i>	30 days
PM 8: Cycle Time Average number of days from the time a violation is reported to the program to the time the probation monitor responds.	Probation data recorded and submitted quarterly through Performance Measure Workbook	<i>8 days</i>	7 days



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STATE AND CONSUMER SERVICES AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: September 9, 2010

To: Enforcement Committee

Subject: Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery Programs

Agenda Item 7

Background

SB 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

To facilitate implementation of these standards, the DCA created a workgroup consisting of staff from each of the healing arts boards to draft recommended standards for the SACC consideration during public meetings. The recommended standards were vetted during public meetings akin to an informational hearing. The draft standards were then presented during a public meeting to the SACC for consideration and action.

Business and Professions Code sections 4360 thru 4373 establish the Pharmacists Recovery Program (PRP) and establish some of the functions of the program as well as program participation criteria. The board contracts with a vendor, currently Maximus, Inc. to administer the PRP. However, under current law, this program only available to pharmacists and interns.

Initially on November 16, 2009, the SACC approved the standards as required by SB 1441. The standards were later corrected in December 2009.

Recent Update

On April 6, 2010, the committee met to discuss action on amending four standards (1, 2, 8 and 10) as well as discuss and action on non-substantive edits recommended for all of the standards. The committee discussed and revised the four standards and discussed the additional non-substantive edits.

On August 4, 2010, a subcommittee convened to further discuss uniform standard four dealing with drug testing. The subcommittee did not complete its revision of this standard and a future meeting will be set.

Below is a brief description of each of the 16 standards. Because of the ongoing work with standard four, this standard could be changed during a future committee meeting.

1. Clinical diagnostic evaluation

- Specifies that if a licensee in a diversion program or on probation is required to undergo a clinical evaluation it shall comply with :
 - i. Qualifications for the licensed practitioner performing the evaluation
 - ii. Acceptable standards for such evaluations
 - iii. Identified elements of the report
 - iv. Timeframes to complete the process and prohibition of the evaluator having a financial relation, etc. with the licensee.

2. Temporary removal of practice for clinical evaluation

- Specifies that board will issue a cease practice order during the evaluation and review of the results by board staff.
- Specifies that the licensee will be subject to random drug testing at least two times per week.
- Sets forth the evaluation criteria that must be considered by the diversion or probation manager when determining if a licensee is safe to return to work and under what conditions.

3. Communication with a licensee's employer, if applicable

- Requires a licensee to notify the board of the names, physical addresses, mailing addresses and telephone numbers of all employers.
- Requires a licensee to give written consent authorizing the board and employers and supervisors to communicate regarding the licensee's work status, performance and monitoring.

4. Drug testing

- Sets forth a minimum testing frequency of 104 random drug tests per year for the first year and a minimum of 50 random drug tests per year (from then on.)
- Specifies that testing shall be observed; conducted on a random basis, as specified; and may be required on any day, including weekends or holidays.
- Requires licensees to check daily to determine if testing is required and specifies that the drug test shall be completed on the same day as notification.
- Establishes criteria for the collection sites and laboratories processing the results.

5. Group meeting attendance

- Sets forth the evaluation criteria that must be considered when determining the frequency of group support meetings.
- Specifies the qualifications and reporting requirements for the meeting facilitator.

6. Type of treatment

- Sets for the evaluation criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.

7. Worksite monitoring

- Allows for the use of worksite monitors.
- Specifies the criteria for a worksite monitor
- Establishes the methods of monitoring that must be performed by the worksite monitor.
- Sets forth the reporting requirements by the worksite monitor; specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day; and specifies that a written report must be provided to the board within 48 hours of the occurrence.
- Requires the licensee to complete consent forms and sign an agreement with the worksite monitor and board to allow for communication.

8. Positive drug test

- Requires the board to issue a cease practice order to a licensee's license and notify the licensee, employee and worksite monitor that the licensee may not work.
- Specifies that after notification, the board should determine if the positive drug test is evidence of prohibited use and sets forth the criteria the board must follow when making such a determination.
- Specifies that if the board determines that it was not a positive drug test, it shall immediately lift the cease practice order.

9. Ingestion of a banned substance

- Specifies that when a board confirms a positive drug test as evidence of use of a prohibited substance, the licensee has committed a major violation.

10. Consequences for major and minor violations

- Specifies what constitutes a major violation including: failure to complete a board ordered program or undergo a clinical diagnostic evaluation; treating patients while under the influence of drugs/alcohol, and drug/alcohol related act which would constitute a violation of the state/federal laws, failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
- Specifies the consequences for a major violation including: issuing a cease practice order to the licensee; requiring a new clinical evaluation; termination of a contract/agreement; referral for disciplinary action.
- Specifies what constitutes a minor violation including: untimely receipt of required documentation; unexcused group meeting attendance; failure to contact a monitor when required; any other violations that does not present an immediate threat to the violator or the public.
- Specifies the consequences for a minor violation including: removal from practice; practice restrictions; required supervision; increased documentation; issuance of a citation and fine or working notice; re-evaluation/testing; other actions as determined by the board.

11. Return to full time practice

- Establishes the criteria to return to full time practice, including demonstrated sustained compliance, demonstrated ability to practice safely, negative drug

screens for at least six months, two positive worksite monitor reports and compliance with other terms and conditions of the program.

12. Unrestricted practice

- Establishes the criteria for a licensee to request unrestricted practice including sustained compliance with a disciplinary order, successful completion of the recovery program, consistent and sustained participation in recovery activities, demonstrated ability to practice safely and continued sobriety of three to five years, as specified.

13. Private-sector vendor

- Specifies that the vendor must report any major violation to the board within one business and any minor violation within five business days.
- Establishes the approval process for providers or contractors that work with the vendor consistent with the uniform standards.
- Requires the vendor to discontinue the use of providers or contractors that fail to provide effective or timely services as specified.

14. Confidentiality

- For any participant in a diversion program whose license is on an inactive status or has practice restrictions, requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed.
- Specifies that the disclosure will not include that the restrictions are as a result of the licensee's participation in a diversion program.

15. Audits of private-sector vendor

- Requires an external independent audit every three years of a private-sector vendor providing monitoring services.
- Specifies that the audit must assess the vendor's performance in adhering to the uniform standards and requires the reviewer to provide a report to the board by June 30 of each three year cycle.
- Requires the board and department to respond to the findings of the audit report.

16. Measurable criteria for standards

- Establishing annual reporting to the department and Legislature and details the information that must be provided in the report.
- Sets forth the criteria to determine if the program protects patients from harm and is effective in assisting licensees in recovering from substance abuse in the long term.

Following this memo is a copy of the April 2010 Uniform Standards, a copy of the Business and Professions Code that establishes the Pharmacists Recovery Program, a copy of the implementation grid developed with staff counsel and a report submitted to the department documenting the board's efforts to implement these standards.

Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

Senate Bill 1441 (Ridley-Thomas)

Implementation by
Department of Consumer Affairs,
Substance Abuse Coordination Committee



Brian J. Stiger, Director

April 2010 (Corrected Version)

November Corrections shown underlined

December Corrections shown double underlined

April Corrections shown *italics and underlined*



Substance Abuse Coordination Committee

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Director, Department of Consumer Affairs

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CA Department of Alcohol & Drug Programs

Janelle Wedge
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Joanne Allen
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#1 SENATE BILL 1441 REQUIREMENT

Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

#1 Uniform Standard

~~Any licensee in a board diversion program or whose license is on probation, who the board has reasonable suspicion has a substance abuse problem shall be required to undergo a clinical diagnostic evaluation at the licensee's expense. The following standards apply to the clinical diagnostic evaluation.~~

If a healing arts board orders a licensee who is either in a diversion program or whose license is on probation due to a substance abuse problem to undergo a clinical diagnosis evaluation, the following applies:

~~1. The clinical diagnostic evaluation shall be paid for by the licensee;~~

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:
 - holds a valid, unrestricted license, which includes scope of practice to conduct a clinical diagnostic evaluation;
 - has three (3) years experience in providing evaluations of health professionals with substance abuse disorders; and,
 - is approved by the board.
2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.
3. The clinical diagnostic evaluation report shall:
 - set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem;
 - set forth, in the evaluator's opinion, whether the licensee is a threat to himself/herself or others; and,
 - set forth, in the evaluator's opinion, recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice.

Uniform Standards

April 2010

The evaluator shall not have a financial relationship, personal relationship, or business relationship with the licensee within the last five years. The evaluator shall provide an objective, unbiased, and independent evaluation.

If the evaluator determines during the evaluation process that a licensee is a threat to himself/herself or others, the evaluator shall notify the board within 24 hours of such a determination.

For all evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.

#2 SENATE BILL 1441 REQUIREMENT

Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

#2 Uniform Standard

The following practice restrictions apply to each licensee who undergoes a clinical diagnostic evaluation:

1. ~~His or her license shall be automatically suspended placed on inactive status~~ The Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the diversion program/board staff.
2. While awaiting the results of the clinical diagnostic evaluation required in Uniform Standard #1, the licensee shall be randomly drug tested at least two (2) times per week.

After reviewing the results of the clinical diagnostic evaluation, and the criteria below, a diversion or probation manager shall determine, whether or not the licensee is safe to return to either part-time or fulltime practice. However, no licensee shall be returned to practice until he or she has at least ~~one (1) month~~ 30 days of negative drug tests.

- the license type;
- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the scope and pattern of use;
- the treatment history;
- the licensee's medical history and current medical condition;
- the nature, duration and severity of substance abuse, and
- whether the licensee is a threat to himself/herself or the public.

#3 SENATE BILL 1441 REQUIREMENT

Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status or condition.

#3 Uniform Standard

If the licensee who is either in a board diversion program or whose license is on probation has an employer, the licensee shall provide to the board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.

#4 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomness, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

#4 Uniform Standard

The following drug testing standards shall apply to each licensee subject to drug testing:

1. Licensees shall be randomly drug tested at least 104 times per year for the first year and at any time as directed by the board. After the first year, licensees, who are practicing, shall be randomly drug tested at least 50 times per year, and at any time as directed by the board.
2. Drug testing may be required on any day, including weekends and holidays.
3. The scheduling of drug tests shall be done on a random basis, preferably by a computer program.
4. Licensees shall be required to make daily contact to determine if drug testing is required.
5. Licensees shall be drug tested on the date of notification as directed by the board.
6. Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.
7. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.
8. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.
9. Collection of specimens shall be observed.
10. Prior to vacation or absence, alternative drug testing location(s) must be approved by the board.
11. Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

#5 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

#5 Uniform Standard

If a board requires a licensee to participate in group support meetings, the following shall apply:

When determining the frequency of required group meeting attendance, the board shall give consideration to the following:

- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the recommendation of the clinical evaluator;
- the scope and pattern of use;
- the licensee's treatment history; and,
- the nature, duration, and severity of substance abuse.

Group Meeting Facilitator Qualifications and Requirements:

1. The meeting facilitator must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or other nationally certified organizations.
2. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years.
3. The group meeting facilitator shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.
4. The facilitator shall report any unexcused absence within 24 hours.

#6 SENATE BILL 1441 REQUIREMENT

Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

#6 Uniform Standard

In determining whether inpatient, outpatient, or other type of treatment is necessary, the board shall consider the following criteria:

- recommendation of the clinical diagnostic evaluation pursuant to **Uniform Standard #1**;
- license type;
- licensee's history;
- documented length of sobriety/time that has elapsed since substance abuse;
- scope and pattern of substance use;
- licensee's treatment history;
- licensee's medical history and current medical condition;
- nature, duration, and severity of substance abuse, and
- threat to himself/herself or the public.

#7 SENATE BILL 1441 REQUIREMENT

Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

#7 Uniform Standard

A board may require the use of worksite monitors. If a board determines that a worksite monitor is necessary for a particular licensee, the worksite monitor shall meet the following requirements to be considered for approval by the board.

1. The worksite monitor shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
2. The worksite monitor's license scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional if no monitor with like practice is available.
3. The worksite monitor shall have an active unrestricted license, with no disciplinary action within the last five (5) years.
4. The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
5. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.

Reporting by the worksite monitor to the board shall be as follows:

1. Any suspected substance abuse must be verbally reported to the board and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
2. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;
 - any indicators that can lead to suspected substance abuse.

The licensee shall complete the required consent forms and sign an agreement with the worksite monitor and the board to allow the board to communicate with the worksite monitor.

#8 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee tests positive for a banned substance.

#8 Uniform Standard

When a licensee tests positive for a banned substance, ~~the board shall:~~

1. ~~The licensee's license shall be automatically suspended; Place the licensee's license on inactive status~~ The board shall order the licensee to cease practice; ~~and~~
2. ~~Immediately~~ The board shall contact the licensee and instruct the licensee to leave work; and
3. The board shall notify the licensee's employer, if any, and worksite monitor, if any, that the licensee may not work.

Thereafter, the board should determine whether the positive drug test is in fact evidence of prohibited use. If so, proceed to Standard #9. If not, the board shall immediately lift the ~~suspension of reactivate the license~~ cease practice order.

In determining whether the positive test is evidence of prohibited use, the board should, as applicable:

1. Consult the specimen collector and the laboratory;
2. Communicate with the licensee and/or any physician who is treating the licensee; and
3. Communicate with any treatment provider, including group facilitator/s.

#9 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

#9 Uniform Standard

When a board confirms that a positive drug test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Uniform Standard #10 and the board shall impose the consequences set forth in Uniform Standard #10.

#10 SENATE BILL 1441 REQUIREMENT

Specific consequences for major and minor violations. In particular, the committee shall consider the use of a “deferred prosecution” stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

#10 Uniform Standard

Major Violations include, but are not limited to:

1. Failure to complete a board-ordered program;
2. Failure to undergo a required clinical diagnostic evaluation;
3. Multiple minor violations;
4. Treating patients while under the influence of drugs/alcohol;
5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;
6. Failure to obtain biological testing for substance abuse;
7. Testing positive and confirmation for substance abuse pursuant to Uniform Standard #9;
8. Knowingly using, making, altering or possessing any object or product in such a way as to defraud a drug test designed to detect the presence of alcohol or a controlled substance.

Consequences for a major violation include, but are not limited to:

1. ~~Inactivation-Automatic-Suspension~~ Licensee will be ordered to cease practice.
 - a) the licensee must undergo a new clinical diagnostic evaluation, and
 - b) the licensee must test *negative* for at least a month of continuous drug testing before being allowed to go back to work. ~~(, and)~~
2. Termination of a contract/agreement.
3. Referral for disciplinary action, such as suspension, revocation, or other action as determined by the board.

Minor Violations include, but are not limited to:

1. Untimely receipt of required documentation;
2. Unexcused non-attendance at group meetings;
3. Failure to contact a monitor when required;
4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to:

1. Removal from practice;
2. Practice limitations;
3. Required supervision;
4. Increased documentation;
5. Issuance of citation and fine or a warning notice;
6. Required re-evaluation/testing;
7. Other action as determined by the board.

#11 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

#11 Uniform Standard

“Petition” as used in this standard is an informal request as opposed to a “Petition for Modification” under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

1. Demonstrated sustained compliance with current recovery program.
2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee’s substance abuse.
3. Negative drug screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of the program.

#12 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

#12 Uniform Standard

“Petition for Reinstatement” as used in this standard is an informal request (petition) as opposed to a “Petition for Reinstatement” under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.
2. Demonstrated successful completion of recovery program, if required.
3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.
4. Demonstrated that he or she is able to practice safely.
5. Continuous sobriety for three (3) to five (5) year.

#13 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, (1) standards for immediate reporting by the vendor to the board of any and all noncompliance with process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; (3) standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and (4) standards for a licensee's termination from the program and referral to enforcement.

#13 Uniform Standard

1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.
2. A vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors is as follows:

Specimen Collectors:

- a) The provider or subcontractor shall possess all the materials, equipment, and technical expertise necessary in order to test every licensee for which he or she is responsible on any day of the week.
- b) The provider or subcontractor shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.
- c) The provider or subcontractor must provide collection sites that are located in areas throughout California.
- d) The provider or subcontractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for drug testing.
- e) The provider or subcontractor must have or be subcontracted with operating collection sites that are engaged in the business of collecting urine, blood, and hair follicle specimens for the testing of drugs and alcohol within the State of California.
- f) The provider or subcontractor must have a secure, HIPAA compliant, website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

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- g) The provider or subcontractor shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory drug test results, medical histories, and any other information relevant to biomedical information.
- h) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.
- i) Must undergo training as specified in Uniform Standard #4 (6).

Group Meeting Facilitators:

A group meeting facilitator for any support group meeting:

- a) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;
- b) must be licensed or certified by the state or other nationally certified organization;
- c) must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years;
- d) shall report any unexcused absence within 24 hours to the board, and,
- e) shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

Work Site Monitors:

1. The worksite monitor must meet the following qualifications:
 - a) Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
 - b) The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional, if no monitor with like practice is available.
 - c) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

- d) Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
2. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.
 3. Any suspected substance abuse must be verbally reported to the contractor, the board, and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
 4. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;
 - any indicators that can lead to suspected substance abuse.

Treatment Providers

1. Treatment facility staff and services must have:
 - a) Licensure and/or accreditation by appropriate regulatory agencies;
 - b) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;
 - c) Professional staff who are competent and experienced members of the clinical staff;

- d) Treatment planning involving a multidisciplinary approach and specific aftercare plans;
 - e) Means to provide treatment/progress documentation to the provider.
2. The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:
- a) The vendor is fully responsible for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them. No subcontract shall relieve the vendor of its responsibilities and obligations. All state policies, guidelines, and requirements apply to all subcontractors.
 - b) If a subcontractor fails to provide effective or timely services as listed above, but not limited to any other subcontracted services, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.
 - c) The vendor shall notify the appropriate board within five (5) business days of termination of said subcontractor.

#14 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

#14 Uniform Standard

The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.

- Licensee's name;
- Whether the licensee's practice is restricted, or the license is on inactive status;
- A detailed description of any restriction imposed.

#15 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

#15 Uniform Standard

1. If a board uses a private-sector vendor to provide monitoring services for its licensees, an external independent audit must be conducted at least once every three (3) years by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the vendor providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the board. The independent reviewer or review team must consist of individuals who are competent in the professional practice of internal auditing and assessment processes and qualified to perform audits of monitoring programs.
2. The audit must assess the vendor's performance in adhering to the uniform standards established by the board. The reviewer must provide a report of their findings to the board by June 30 of each three (3) year cycle. The report shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's monitoring services that would interfere with the board's mandate of public protection.
3. The board and the department shall respond to the findings in the audit report.

#16 SENATE BILL 1441 Requirement

Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

#16 Uniform Standard

Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program.

- Number of intakes into a diversion program
- Number of probationers whose conduct was related to a substance abuse problem
- Number of referrals for treatment programs
- Number of relapses (break in sobriety)
- Number of cease practice orders/license in-activations
- Number of suspensions
- Number terminated from program for noncompliance
- Number of successful completions based on uniform standards
- Number of major violations; nature of violation and action taken
- Number of licensees who successfully returned to practice
- Number of patients harmed while in diversion

The above information shall be further broken down for each licensing category, specific substance abuse problem (i.e. cocaine, alcohol, Demerol etc.), whether the licensee is in a diversion program and/or probation program.

If the data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of a program. It may also be used to determine the risk factor when a board is determining whether a license should be revoked or placed on probation.

The board shall use the following criteria to determine if its program protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

- At least 100 percent of licensees who either entered a diversion program or whose license was placed on probation as a result of a substance abuse problem successfully completed either the program or the probation, or had their license to practice revoked or surrendered on a timely basis based on noncompliance of those programs.

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- At least 75 percent of licensees who successfully completed a diversion program or probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

California Business and Professions Code
Article 21. Pharmacists Recovery Program

- 4360. Impaired Pharmacists: Legislative Intent
- 4361. Definitions
- 4362. Function of Program: Board Referrals; Voluntary, Confidential Participation
- 4364. Criteria for Participation to Be Established by Board
- 4365. Contracting with Employee Assistance Program: Selection
- 4366. Function of the Employee Assistance Program
- 4369. Board Referrals to Program: Written Information provided to Licensee; Termination for Non-compliance; Report to Board of Termination When Public Safety Threatened; Authority to Discipline
- 4371. Review of Activities of Program
- 4372. Confidential Records; Exception for Disciplinary Proceeding
- 4373. Immunity from Civil Liability

4360. The board shall operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.

4361. (a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.

(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacists.

4362. (a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

(1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.

(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on his or her entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

4364. (a) The board shall establish criteria for the participation of pharmacists and intern pharmacists in the pharmacists recovery program.

(b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.

(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

4365. The board shall contract with one or more qualified contractors to administer the pharmacists recovery program.

4366. The functions of the contractor administering the pharmacists recovery program shall include, but not be limited to, the following:

(a) To evaluate those pharmacists and intern pharmacists who request participation in the program.

(b) To develop a treatment contract with each participant in the pharmacists recovery program.

(c) To monitor the compliance of each participant with their treatment contract.

(d) To prepare reports as required by the board.

(e) To inform each participant of the procedures followed in the program.

(f) To inform each participant of their rights and responsibilities in the program.

(g) To inform each participant of the possible consequences of noncompliance with the program.

4369. (a) Any failure to comply with the treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the pharmacist's or intern pharmacist's participation in the pharmacists recovery program. The name and license number of a pharmacist or intern pharmacist who is terminated from the pharmacists recovery program and the basis for the termination shall be reported to the board.

(b) Participation in the pharmacists recovery program shall not be a defense to any disciplinary action that may be taken by the board.

(c) No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program.

4371. (a) The executive officer of the board shall designate a program manager of the pharmacists recovery program. The program manager shall have background experience in dealing with substance abuse issues.

(b) The program manager shall review the pharmacists recovery program on a quarterly basis. As part of this evaluation, the program manager shall review files of all participants in the pharmacists recovery program.

(c) The program manager shall work with the contractor administering the pharmacists recovery program to evaluate participants in the program according to established guidelines and to develop treatment contracts and evaluate participant progress in the program.

4372. All board records and records of the pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery, subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code. However, board records and records of the pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

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

Standard	RPH/Intern			TCH			DR		
	Contract	Regulation	Statute	Contract	Regulation	Statute	Contract	Regulation	Statute
1. Clinical Eval	X	X				X			X
2. Removal from Practice		X	X		X	X		X	X
3. Communication with Employer		X			X			X	
4. Drug Testing	X	X			X	X		X	X
5. Group Meetings	X	X				X			X
6. Treatment Requirements		X				X			X
7. Worksite Monitors	X	X				X			X
8. Positive Tests			X			X			X
9. Ingestion of Banned Substances*			X			X			X
10. Consequences			X			X			X
11. Full Time Practice	X		X			X			X
12. Unrestricted License			X			X			X
13. Private Sector Vendors	X			X		X	X		X
14. Public Discloure		X			X			X	
15. Audits of Vendor			X			X			X
16. Measurable Criteria	X			X			X		

*May depend on implementation of standard 10 and further guidance from the department.

Board of Pharmacy

Standard # 1 – Clinical Evaluation

Summary: The board's disciplinary guidelines include a provision requiring a clinical evaluation for certain conditions of probation. Additionally, the board uses the Pharmacists Recovery Program (PRP) to monitor pharmacists and interns with substance abuse violations, and a clinical evaluation is a key component of this program as well.

Administrative and Board Policy Changes Required:

Licensees: the board has incorporated the DCA requirements for the diagnostic report into its routine processes for probationers with substance abuse violations.

As the DCA is the contractor for the health care boards' monitoring program vendor, board staff will assist the DCA in securing this standard as a contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Pharmacists and Interns: the board will require a regulation and contractual change to make this a formal requirement.

Pharmacy Technicians and/or Designated Representatives: Statutory and regulation changes are required.

Standard # 2 – Removal from Practice

Summary: When negotiating stipulations, many times a provision is incorporated to require a licensee to undergo an evaluation by either a clinician or by the PRP to determine someone is safe to practice. The licensee is typically suspended from practice until such time as the evaluation is completed and the results are received. (This is typically used on pharmacists and interns, but could expand to other licensees as a probationary term should the case warrant.) Additionally, the PRP places a cease practice treatment contract term upon entry into the program or upon a confirmed positive drug screen while evaluations are underway.

Administrative and Board Policy Changes Required:

All Licensees: None

Statutory Changes and/or Regulation Changes Required:

All Licensees: SB 1172 (currently pending in the California Legislature) will provide the statutory authority for this DCA standard; the board will need to promulgate regulations if SB 1172 is enacted.

Standard # 3 – Communication with the Employer

Summary: The board's disciplinary guidelines includes a provision requiring employment notification and often also supervised practiced. As part of the PRP, participants are required to have a worksite monitor who is responsible to provide reports to the PRP. Further, a pharmacy technician, by virtue of their scope of practice, cannot work without a pharmacist also on duty.

Administrative and Board Policy Changes Required:

Pharmacists and interns: As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

All Licensees: Regulations are needed to secure the consent of the participant for the board's designee to speak with the worksite monitor. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Standard # 4 – Drug Testing

Summary: The board's disciplinary guidelines includes a provision requiring drug testing and specifies in many instances that a positive drug screen will result in the automatic suspension of the license. The board's current drug testing contract fulfills the requirements detailed in this standard. However, the testing frequency is determined on a case by case basis by the board.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required. Since the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

All Licensees: Statutory or regulatory change is required to standardize the testing frequency established in the DCA uniform standard.

Standard # 5 – Group Meeting Standards

Summary: The board's disciplinary guidelines includes a provision requiring attendance at support groups. Additionally, through the PRP, pharmacists and interns are required as part of their treatment contracts to attend support groups.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract amendment is required. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist this securing contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: A statutory or regulatory change is necessary to establish the financial relationship criteria specified in this uniform standard.

Standard # 6 – Treatment Evaluation Criteria

Summary: In putting someone on probation and/or in the PRP, these criteria are routinely considered, but on a case by case basis. Further, the board contracts with the PRP vendor, who employs licensed clinicians specializing in the monitoring of substance abuse and treatment, to obtain this type of consistent expertise and assessment.

Administrative and Board Policy Changes Required:

None

Statutory Changes and/or Regulation Changes Required

Licensees: Standardization of these requirements would require a statutory or regulatory change.

Standard # 7 – Worksite Monitoring requirements

Summary: The board's disciplinary guidelines includes a provision requiring employment notification and many times also supervised practiced. As part of the PRP, participants are required to have a worksite monitor, who is responsible to provide reports to the PRP. Further, a pharmacy technician, by virtue of his or her scope of practice cannot work without a pharmacist also on duty.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: Regulations are needed to secure the consent of the participant to authorize the worksite monitor to speak with the program. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Standard # 8 – Actions After Receiving a Positive Drug Test

Summary: In practice, after a positive drug is confirmed, the board requires the immediate removal of the licensee from practice if a participant in the PRP. The board's disciplinary guidelines includes a provision requiring drug testing and specifies in many instances that a positive drug screen will result in the automatic suspension of the license.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: SB 1172 (currently pending) will provide the statutory authority for this standard term.

Standard # 9 – Affirmation of Positive Drug Screen

Summary: In practice, after a positive drug is confirmed, the board requires the immediate removal of the licensee from practice if the positive drug screen is of a participant in the PRP. The board's disciplinary guidelines includes a provision requiring drug testing and specifies in many instances that a positive drug screen will result in the automatic suspension of the license.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required to effect this change. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: SB 1172 (currently pending in the CA Legislature) will provide the statutory authority for this standard.

Standard # 10 – Major Violations

Summary: The board's disciplinary guidelines detail which violations constitute a violation of probation. Further, some specific terms and conditions call for the automatic suspension of a license for failure to comply. In practice, unresolved non-compliance as well as egregious non-compliance with the PRP treatment contract provisions, results in removal of the licensee from practice if a participant in the PRP.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: To more formally and uniformly remove licensees from practice for major violations, statutory change is required.

Standard # 11 – Return to Full Time Practice

Summary: In practice, these requirements are followed in the PRP.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required to formally incorporate this standard. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Statutory Changes and/or Regulation Changes Required:

Licensees: To more formally and uniformly apply the standard, a statutory change is required.

Standard # 12 – Petition for Reinstatement of a Full License

Summary: In practice, these requirements are followed by the PRP.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required for formally incorporate this standard. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist this contract amendment (if pursued).

Statutory Changes and/or Regulation Changes Required:

Licensees: To establish this uniform standard, the board needs a regulation or statutory change.

Standard # 13 – Private Sector Vendors

Summary: The board contracts with a vendor for PRP administration. The board does not have the authority to use a vendor for these services for pharmacy technicians and designated representatives.

Administrative and Board Policy Changes Required:

None

Statutory Changes and/or Regulation Changes Required:

Pharmacy Technicians and Designated Representatives: A statutory change is required.

Standard # 14 – Public Disclosure for PRP Participation

Summary: The board publishes its disciplinary actions on its web site for all licensees. All terms and conditions of probation, including the term requiring participation in the PRP, are contained in this document.

Administrative and Board Policy Changes Required:

None

Statutory Changes and/or Regulation Changes Required:

A regulation change may be necessary per counsel's guidance.

Standard # 15 – Audit of Vendor

Summary: The DCA recently conducted an audit of the current vendor, with a report provided to the Legislature.

Administrative and Board Policy Changes Required:

The board would need funding to hire an independent auditor to comply with this standard.

Statutory Changes and/or Regulation Changes Required:

None.

Standard # 16 – Measurable Criteria

Summary: The board already receives information from the PRP vendor providing various statistical reports identified in this standard.

Administrative and Board Policy Changes Required:

Pharmacists and Interns: A contract change is required to formally incorporate all of the information contained in this standard. As the DCA is the contractor for the health care boards' monitoring programs, board staff will assist in securing this contract amendment (if pursued by the DCA).

Pharmacy Technicians and Designated Representatives: The board would need to secure funding for an AGPA to collect and analyze this data.

Statutory Changes and/or Regulation Changes Required:

None



California State Board of Pharmacy

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

Date: September 9, 2010

To: Enforcement Committee

Subject: GS1 Forum on Serialization and Track and Trace – Agenda Item 8

Since 2004, California has had statutory requirements to require all drug products sold in California to be electronically tracked back to the manufacturer, tracing every change in ownership – from the manufacturer, through wholesaler(s), to the pharmacy.

This secure, chain of custody system, is intended to safeguard California's pharmaceutical supply chain to prevent drug diversion, unauthorized resales into the supply chain, and the introduction of counterfeit drugs. These requirements model those of the FDA in their 2004 counterfeit task force report.

California's law has been amended twice since 2004 – in 2006 and 2008. The implementation of e-pedigree requirements in California is now on a phased-in schedule between 2015 and July 2017. Before these dates arrive, it was hoped that a federal law would be enacted to establish national standards for strengthening the supply chain.

Nevertheless, since the 2008 legislation, various companies in the supply chain have been working on the serialization piece to comply with CA's requirements.

In October, GS1, which is a worldwide standards-setting organization, will hold a forum on serialization and track and trace in California. A copy of information about this forum follows this page. Also included in this tab section are several recent articles on counterfeit drugs.

In the past, the board held its Workgroup to Implement E-Pedigree Requirements as a subcommittee of the Enforcement Committee.



2015 Readiness Workshop

Preparing for Serialization and Visibility within the U.S. Pharmaceutical Supply Chain

Join us for this new workshop and experience a post 2015 U.S. pharmaceutical supply chain world -- the beginning of serialization and Pedigree. The 2015 Readiness Workshop will help you to understand both the business and technical aspects of tracking and tracing serialized product through the supply chain and how to leverage this data to increase visibility into your processes.

This hands-on training session also provides participants a unique opportunity to utilize a new technique based on simulation methods to explore a number of real world supply chain scenarios that will help you to prepare for product serialization and make the decisions needed to be ready for 2015.

Key Benefits of Attending

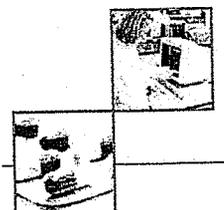
- Gain insights on the benefits of a fully implemented supply chain using GS1 Standards to support visibility-driven processes and technologies.
- Learn how to utilize the GS1 Healthcare US "U.S. Pharmaceutical Reference Model" developed and validated by industry members to support industry-wide implementation. The hands-on exercises will allow you to apply simulated supply chain processes using the Reference Model to:
 - Test business decisions needed to be ready for 2015
 - Practice with the FDA Standardized Numerical Identification (SNI)
 - Prepare for trading partner pilots
 - Generate GS1 standardized track and trace data
 - Test multiple scenarios specific for your organization
 - Test new concepts and data to discover additional benefits
- Discover advantages for new business opportunities that will help your organization beyond regulatory compliance.

Value to Your Organization

- You will be able to bring back a working knowledge of the tools and resources covered in the workshop to enable your organization to:
 - Resolve issues prior to implementation
 - Reduce implementation costs
 - Decrease the need for trading partner pilots
 - Provide confidence that your implementation is "trading partner ready"
 - Validate trading partner readiness

Who Should Attend

- Members of the U.S. pharmaceutical supply chain responsible for IT, government relations, logistics, packaging and supply chain operations, including contract manufacturers, contract packagers, disposers, hospital pharmacies, kitters, manufacturer, repackagers retail pharmacies, and wholesalers.



Workshop Overview

Business Focus – Day 1

This 1/2 day training session focuses on the business aspects and will explore the regulatory environment, the effect of business policy decisions, readiness checklist, conversations you will need to have with your technical staff and solution providers, and how your day to day business processes will change.

Hands-on exercises include: Operational decisions, working with regulators, product recall, drop shipment and repackaging.

Technical Focus – Day 2

This full day training session focuses on the technical aspects of managing serialized product and track and trace data. Key areas to be covered include GS1 Standards and the GS1 US™ Global Visibility Framework, using the “U.S. Pharmaceutical Supply Chain Reference Model” to generate EPCIS event and query XML, using the model to understand the technical aspects of tracking product through pre-defined business processes, and conversations you will need to have with the business process owners.

Hands-on exercises include: Operational decisions, working with regulators, product recall, drop shipment and repackaging.

2015 Readiness Workshop Preview Webinars - September 1st and September 16th

Learn more about the 2015 Readiness Workshop. GS1 Healthcare US is holding two webinars which will provide an overview of the Reference Model, workshop content details, and answer any questions.

Visit www.gs1us.org/hcedu and register for the “2015 Readiness Workshop Preview” webinar.

Workshop Fees

- Two Day Workshop: \$1,500
- Business/Regulatory Session Only (Day 1): \$800
- Group Discount: Register two from the same organization and receive 50% off the third registration fee. Use this opportunity to invite a government relations or business associates to take advantage of the information presented and help you champion these efforts within your organization. Note: All three attendees must register at the same time in order to receive discount.

Special GS1 Healthcare US Member Rate

- Two Day Workshop: \$1,000
- Business/Regulatory Session (Day 1 Only): \$600



Receive Event Announcements

If you would like to be notified of event updates, location confirmations, and registration availability for the upcoming 2015 Readiness Workshops, email GS1 Healthcare US at GS1HealthcareUS@gs1us.org.

Questions?

If you have any questions about the 2015 Readiness Workshop, email Bob Celeste, Director, Healthcare, GS1 Healthcare US at rceleste@gs1us.org

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2015 Readiness Program Workshops

The current California Board of Pharmacy regulation calls for 50 % of pharmaceuticals for sale in California to be uniquely identified by 2015 and that electronic pedigree data precede the product as it moves through the supply chain with the remainder to follow by 2016. Wholesalers are to manage both the serialized product and associated pedigree data by mid 2016, while pharmacies must follow suit by 2017. The 2015 Readiness Program workshop will help you understand business and technical aspects of tracking and tracing serialized product through the U.S. pharmaceutical supply chain while gaining more accurate and hopefully timely data than you may currently have.

The workshop is split into two sessions. The first session lasts ½ day and focuses on the business aspects of doing business post 2015. Key areas that we will explore are the regulatory environment, the effect of business policy decisions, conversations you will need to have with your technical staff and solution providers and how your day to day business processes will change.

The second session lasts a full day and focuses on the technical aspects of managing serialized product and track and trace data. Key areas that we will explore are the details of GS1 visibility standards, using the 2015 Reference Model to generate EPCIS event and query XML, using the model to understand the technical aspects of tracking product through pre-defined business processes and conversations you will need to have with the business process owners.

Planning Details

Dates:

October 12th – 13th: San Francisco, CA

November 10th – 11th: Washington, DC

Strategic Partners:

- HDMA ✓ - confirmed
- GPhA
- NACDS
- NCPDP
- NCPD ✓ - confirmed

Day 1 – Business focus

- Regulatory environment
 - Regulatory Perspective
 - San Francisco – Virginia Herold / Joshua Room , California Board of Pharmacy
 - Baltimore – Connie Jung, FDA
 - State Regulations
 - Florida Board of Pharmacy
 - California Board of Pharmacy
 - Federal environment
 - FDA
 - 2010 Joint Strategic Plan on Intellectual Property
- Business Policy decisions
 - Reporting level (GLN hierarchy) and impact on trading partners
 - Data sharing Policy
 - Internal and external information
 - Inference
 - Managing risk
- The world of 2015
 - Serialization and the impact on inventory management
 - Recall strategies and opportunities
 - Keeping product moving
- The state of the standards
 - Product and location standards
 - Drug Pedigree Messaging Standard
 - EPCIS / Core Business Vocabulary and Discovery Services
- Exercising the 2015 Reference Model
 - Operational decisions
 - Data capture points
 - Mapping the standards to your operations
 - Deciding who to share data with
 - Deciding how much data to share
 - Exercise 1: Working with regulators
 - State Board of Pharmacy visit / inspection
 - FDA visit / inspection
 - Exercise 2: Product Recall
 - Recall by Lot
 - Recall by Serial Number
 - Exercise 3: The Drop Shipment

- Exercise 4: Repackaging
- Business Readiness Checklist
- Things to discuss with your technical staff and solution provider
 - Technical aspects of the 2015 Reference Model
 - Data mining
 - Report structure
 - Mapping the standards to your operations
- Next steps
 - Business aspects of extending your implementation to support:
 - Proof of delivery
 - Cold Chain
 - Internal Asset tracking
 - Track and trace raw materials
 - Tracking to the patient bedside

DRAFT

Day 2 – Technical focus

- The state of the standards
 - Product and location standards
 - Drug Pedigree Messaging Standard
 - EPCIS / Core Business Vocabulary and Discovery Services
- Visibility Standards up close
 - GS1 Identifiers and visibility
 - EPCIS Capture Interface and XML Events
 - EPCIS Share and XML Queries
 - Core Business Vocabulary
 - Discovery Services
- Review of the 2015 Reference Model
 - Reference Model Overview
 - Input Parameters
 - Supply Chain Simulation
 - Data generated from the simulation
 - Master data supporting Visibility
 - Reports
 - Queries and Query strategy
 - Adjusting the Simulation input parameters
 - Generating EPCIS visibility events
 - Generating Reports
 - Comparing simulation runs
 - A closer look at the reference model business processes
 - Business process behavior, input and output
 - Mapping visibility standards to business processes
 - Understanding the Query strategy within the 2015 Reference Model
 - Using the 2015 Reference Model during you implementation
- Exercising the 2015 Reference Model
 - Operational decisions
 - Data capture points
 - Mapping the standards to your operations
 - Deciding who to share data with
 - Deciding how much data to share
 - Exercise 1: Working with regulators
 - State Board of Pharmacy visit / inspection
 - FDA visit / inspection
 - Generating pedigree data using the Reference Model

- Technical considerations
 - Understanding the generated XML Events and Queries
- Exercise 2: Product Recall
 - Understanding the business process via the Reference Model
 - Recall by Lot
 - Recall by Serial Number
 - Understanding the generated XML Events and Queries
- Exercise 3: The Drop Shipment
 - Understanding the business process via the Reference Model
 - Technical considerations
 - Understanding the generated XML Events and Queries
- Exercise 4: Repackaging
 - Understanding the business process via the Reference Model
 - Technical considerations
 - Understanding the generated XML Events and Queries
- Business Readiness Checklist
- Technical Readiness Checklist
- Things to discuss with your business staff
 - Data sharing Policy
 - Company hierarchy reporting level decisions
 - Trading Partner relations
 - Report structure
 - Mapping the standards to your operations
- Things to discuss with your solution providers
 - Technical aspects of the 2015 Reference Model
 - Data mining
 - Report structure
 - Mapping the standards to your operations
- Next steps
 - Technical aspects of extending your implementation to support:
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 - Internal Asset tracking
 - Track and trace raw materials
 - Tracking to the patient bedside

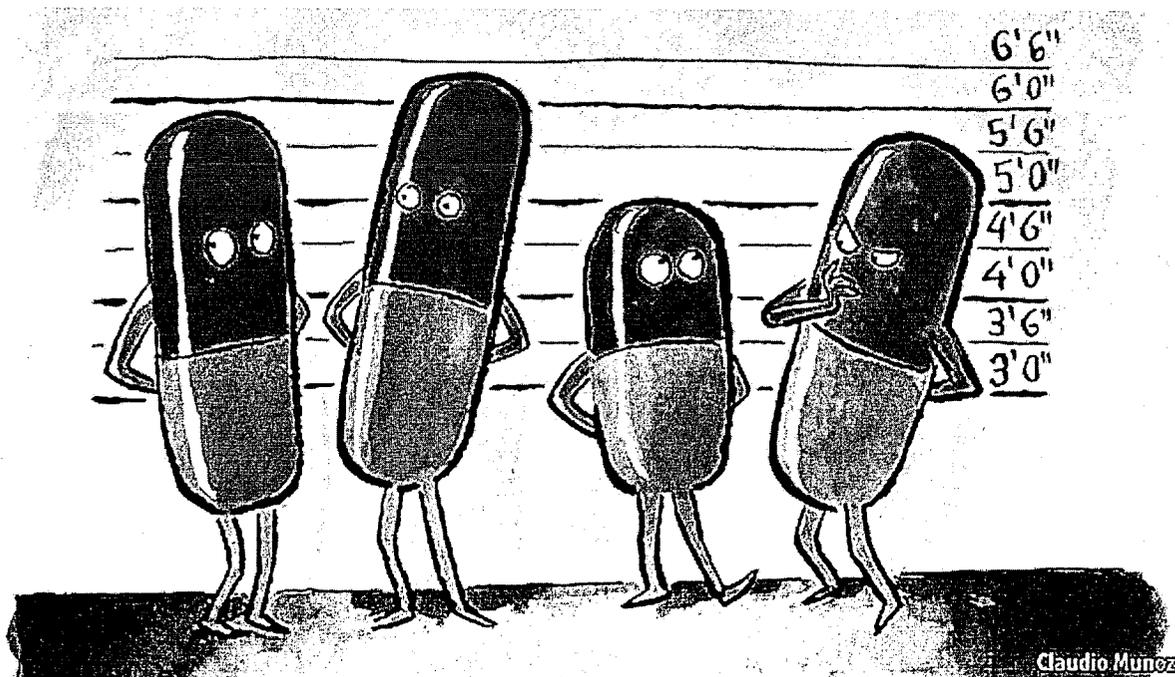
Virginia K. Herold

From: Karen Abbe
Sent: Tuesday, September 07, 2010 8:35 AM
To: Virginia K. Herold
Cc: Anne Sodergren; Carolyn Klein
Subject: The Economist: Poison pills – Counterfeit drugs used to be a problem for poor countries. Now they threaten the rich world, too



Poison pills – Counterfeit drugs used to be a problem for poor countries. Now they threaten the rich world, too

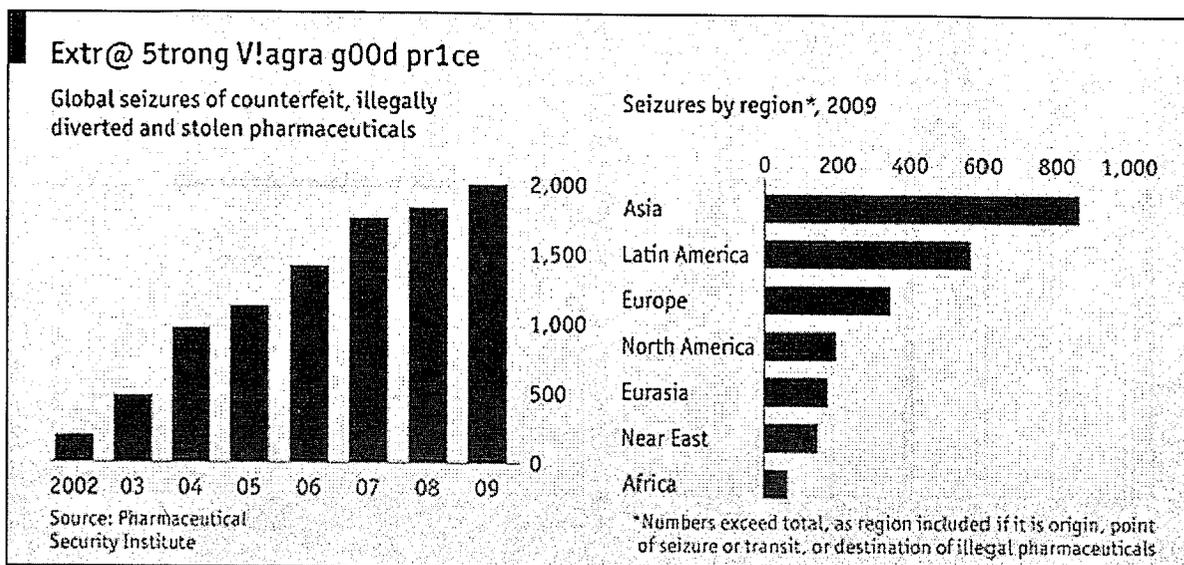
The Economist
September 2, 2010 | NEW YORK



DRUG smugglers can expect harsh penalties nearly everywhere—if the drugs in question are heroin or cocaine. Those who smuggle counterfeit medicines, by contrast, have often faced lax enforcement and light punishment. Some governments deem drug-counterfeiting a trivial offence, little more than a

common irritant. After all, whose spam filter does not groan with ads for suspiciously cheap “Viagra”?

This could be changing, however. The pharmaceutical industry has persuaded several governments to stiffen regulations against fake drugs and to conduct more aggressive raids (see chart). Companies are also devising novel technologies to outfox the criminals. Even the Catholic church is joining the cause, issuing a stern statement in August that it is in “the best interest of all concerned that smuggling of counterfeit drugs be fought against”.



The pope’s concern is justified. Counterfeit drugs can kill. Many are shoddily made, containing the wrong dose of the active ingredient. Taking them instead of the real thing can turn a treatable disease into a fatal one. It can also foster drug resistance among germs. This has been a big problem for a long time in developing countries. Studies of anti-infective treatments in Africa and South-East Asia have found that perhaps 15-30% are fakes. The UN estimates that roughly half of the anti-malarial drugs sold in Africa—worth some \$438m a year—are counterfeits.

Roger Bate of the American Enterprise Institute, a think-tank in Washington, DC, cautions that any such estimates should be treated with care. The countries with the most fakes may not be cracking down, so official figures will look rosy; in contrast, countries with a smaller counterfeit trade that are vigilant may end up with more seizures. The World Health Organisation agrees, and has recently taken its estimates off its website. Even so, Mr Bate says his field work has convinced him that counterfeits kill at least 100,000 people a year, mostly in the poor world.

Now it appears that fakes are taking off in the rich world too. Yes, Viagra still tops the list of knock-offs seen by Pfizer, says John Clark, the American drug firm’s global head of security; but fake versions of at least 20 of its products (including Lipitor, a blockbuster cholesterol drug) have been detected in the legitimate supply chains of at least 44 countries. Mr Clark’s intelligence comes from Pfizer’s global network of informants, consumer tip-offs and in-store inspections. He sees worrying trends.

Counterfeiters used to operate chiefly in developing countries, says Mr Clark, but now his firm sees fakes coming from such rich and well-regulated places as Canada and Britain. And the crooks are growing more technologically sophisticated: some can even counterfeit the holograms on packets that are meant to reassure customers that pills are genuine.

A consumer study funded by Pfizer recently found that nearly a fifth of Europeans polled in 14 countries had obtained medicines through illicit channels. That, the firm reckons, makes for a grey market in the EU of over €10 billion (\$12.8 billion). Terry Hisey of Deloitte, a consultancy, thinks the global market for fakes could be worth between \$75 billion and \$200 billion a year. Those staggering sums, he argues, help explain the emergence of a flurry of new technologies and companies hoping to help the drugs industry “secure its global supply chain”.

In July Oracle, an American software giant, unveiled Pedigree, a programme that helps drugs firms “track and trace” pills all the way from the factory to your fingers. IBM has a rival offering, as well as one using radio-frequency identification (RFID) chips, which are embedded in packaging to detect tampering and allow precise tracking. 3M, a materials company, and Abbott Laboratories, an American medical firm, are also rolling out an RFID-based product. A division of Johnson & Johnson, a drugs giant, has developed web-based software to help customs officials quickly verify whether drugs are fake or real.

Poor countries find it hard to take advantage of such technologies. Sophisticated radio tags and database software are not much use in places where street hawkers peddle fakes with impunity. Still, even in such difficult circumstances, a combination of political will and business ingenuity can make a difference.

Bottom-up battle

A Ghanaian start-up firm, mPedigree, has come up with a clever way to use mobile phones in this fight. Participating drugs companies emboss a special code onto packages, which customers find by scratching off a coating. By sending a free text with that code, they can find out instantly if the package is genuine or a fake.

Bright Simons, the firm’s boss, argues that technologies like his can be a useful bottom-up complement to top-down enforcement. Having successfully completed initial trials, he says, mPedigree is ready to expand its service in the region. The government of Nigeria, where fakery is rife, recently declared its intention to adopt such a text-based validation system.

Thomas Kubic of the Pharmaceutical Security Institute, an industry-funded outfit, gives warning that this war will be hard to win. After more than 30 years as an investigator, he is sure that crooks will eventually find a way around any defence.

Even so, he thinks novel approaches such as mobile-based validation may “harden the target”, just as a burglar alarm makes your home somewhat trickier to rob. If the cost and complexity of faking drugs goes up, crooks may choose to fake Gucci handbags instead. This would still be theft, not to mention a crime against fashion. But it will not kill anyone.

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Virginia K. Herold

From: Karen Abbe
Sent: Tuesday, September 07, 2010 8:48 AM
To: Virginia K. Herold
Cc: Anne Sodergren; Carolyn Klein
Subject: S.F. Examiner: Fed prosecutors accuse Wisconsin businesswoman, man of importing, selling counterfeit drugs



Fed prosecutors accuse Wisconsin businesswoman, man of importing, selling counterfeit drugs

By TODD RICHMOND
Associated Press
09/03/10 10:42 AM PDT

MADISON, WIS. — Federal prosecutors have accused a prominent Madison pharmacist and a Middleton man of importing and selling counterfeit Viagra and other drugs.

Marla Ahlgrimm, the 55-year-old founder of Women's Health America and a member of the University of Wisconsin Foundation's board of directors, and her alleged coconspirator, 63-year-old Balbir Bhogal, each face two counts of conspiring to deliver counterfeit controlled substances in federal court in New York.

Both were arrested Wednesday in Wisconsin, Assistant U.S. Attorney Elizabeth Altman said, although she did not know specifically where. Ahlgrimm's attorney, Timothy Edwards, told the Wisconsin State Journal newspaper that Ahlgrimm was taken into custody when she walked into her Madison office and discovered investigators executing a search warrant.

Edwards and Bhogal's attorney, federal defender Erika Bierma, didn't immediately return telephone messages from The Associated Press on Friday morning. The lead prosecutor in New York, Evan Williams, also didn't immediately return a message from the AP.

According to a criminal complaint unsealed in New York last week, an FBI informant who was running an online pharmacy ordered millions of anti-anxiety and appetite suppressants from Ahlgrimm and Bhogal in 2008 and 2009 through e-mails sent to Ahlgrimm - even though the informant didn't hold a federal license to purchase prescription drugs from U.S. manufacturers.

The informant told investigators Ahlgrimm said Bhogal had connections with manufacturers in India.

The drugs arrived directly from India, the complaint said. Some of the tablets were broken and weren't labeled.

Ahlgrimm told the informant to divide payment between her bank account in Green Bay and Bhogal's account in India. The complaint doesn't say how much money was transferred.

This past spring, a second FBI informant ordered pain killers Oxycodone and Hydrocodone and Viagra, Pfizer Inc.'s erectile dysfunction drug, from Bhogal, the complaint said. Bhogal also offered the informant generic Viagra, which isn't legally available in the United States because Pfizer holds an exclusive patent.

Bhogal told the informant to wire money to an account he had in Madison.

Investigators intercepted five packages Bhogal sent to the informant, the complaint said. Two of the packages, both from India, contained about 1,700 counterfeit Oxycodone tablets.

The third package, from an address just a few doors away from Women's Health America, contained about 1,100 unlabeled tablets of what appeared to be generic Viagra. Tests showed the tablets didn't contain the same levels of sildenafil, the active ingredient in Viagra, as the Pfizer brand.

The fourth package, from the same address as Women's Health America, contained nearly 2,050 pills that resembled generic Viagra but also didn't contain the same levels of sildenafil as Pfizer's brand.

The fifth package, this one from China, contained about 2,040 tablets of Viagra marked with the Pfizer logo. Tests showed the tablets weren't Viagra.

The UW Foundation handles fundraising and donations to the university. A telephone message The Associated Press left at the foundation's offices on Friday wasn't immediately returned.