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DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

## **Enforcement Committee Report**

Randy Kajioka, PharmD, Chair  
Greg Lippe, Public Board Member  
Ramón Castellblanch, PhD, Public Board Member  
Tappan Zee, Public Board Member

### ***ENFORCEMENT COMMITTEE REPORT AND ACTION***

Report of the meeting held on September 14, 2010.

#### **a. FOR ACTION:**

#### **Part 1: Request from Omnicare to Modify Existing Requirements in Pharmacy Regulations at 16 California Code of Regulations Section 1745 Regarding Partial Filling of Schedule II Prescriptions**

#### **Attachment 1**

**MOTION:** Enforcement Committee: Amend section 1745(c)(2) to read:  
1745(c)(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

Earlier this year, the board received two requests for modifications of requirements in board regulations from Omnicare.

The first request is:

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 a rulemaking process by the board. Existing section 1745 reads as follows:

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.

Committee Discussion:

During the September committee meeting, Dr. Huhn of Omnicare reviewed federal CFR section 1306.13(b) which 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."

Dr. Huhn stated that Omnicare is requesting that § 1745(c)(2) be amended to incorporate this alternative allowance from CFR § 1306.13(b), to allow for the option of electronic records and eliminate the need to document on the hard copy of the prescription each partial fill. He explained that it can be cumbersome to retrieve and document the hard copy for each partial fill over the course of 60 days.

If approved, the original prescription would only contain the initial information and the electronic record would include all updated information.

The committee discussed the option of allowing pharmacies to maintain electronic records or document on the original prescription. This option would be consistent with existing federal regulations, and would eliminate the need for pharmacists to

refer back to the paper copy of the prescription. Dr. Huhn stated that nothing else within the current process for partially filling a C-II prescription will change.

Action: The board should vote on the Enforcement Committee's motion.

**FOR DISCUSSION:**

**Part II: Provide Omnicare with 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.**

**Also Attachment 1**

Request:

Omnicare also made a second request: to allow a waiver of requirements in section 1793.7(a) to allow a pharmacy technician, and not a pharmacist, to perform the final check of medication if the container is bar coded.

In making its request to the board, 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 dispensed under conditions 1 and 2.

Background:

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

**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.

There is no authority to waive 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.

**Attachment 1** also provides several related articles on this topic from prior issues of *The Script*.

Committee Discussion:

During the September Enforcement Committee Meeting, Omnicare stated that the goal of this request is to improve pharmaceutical care for patients, reduce medication errors, and allow pharmacists to focus on patient-centered activities such as medication therapy management. Pharmacists can be better used if they do not have to check medication that has been bar coded. Omnicare stated that 12 states have approved this process. He stated that bar code verification confirms that the prescription was filled according to the practitioner's order.

One board inspector 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.

During the meeting, Dr. Kajioka advised Omnicare that the board does not have the authority to waive a regulation unless the procedure is part of an experimental program conducted with a school of pharmacy.

The committee asked for legal clarification from board counsel on this matter and suggested that if Omnicare intended to pursue this proposal, that they develop an experimental program with a school of pharmacy, and then return to the board.

**b. FOR INFORMATION AND POSSIBLE ACTION: Question and Answer Document Explaining the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound and Sections 1751-1751.8 Pharmacies that Compound Sterile Injectable Medications**

**Attachment 2**

During the Enforcement Committee Meeting, Chair Kajioka reminded attendees that at the June Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July 2010. He indicated that the answers to these and other submitted questions have been compiled into a document and posted on the board's Web site. Chair Kajioka stated that the board is responding to these questions to aid pharmacies in complying with the new requirements.

During the meeting there were some additional questions on compounding requirements from attendees of the meeting, which were answered by Supervising Inspector Ratcliff.

Dr. Ratcliff requested that any additional questions from the public be submitted in writing so they can be added to the compounding question and answer document that is provided in **Attachment 2**.

Committee Discussion/Action:

Chair Kajioka suggested that a small subcommittee be created to address questions regarding the compounding regulations. Dr. Kajioka expressed his willingness to participate as a member.

**c. FOR INFORMATION: Update on California's Drug Take Back Programs from Patients, and Comments Submitted to CalRecycle Pursuant to Requirements in SB 966 (Simitian, Statutes of 2007)**

Committee Discussion:

Chair Kajioka noted that at the 2010 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.

At the July Board Meeting, staff was directed to provide comments on this draft. These comments were submitted to CalRecycle in mid-August, and are provided in **Attachment 3**.

Post Meeting Update:

During the week of October 11, 2010, the President signed the Secure and Responsible Drug Disposal Act of 2010, which amends the Controlled Substances Act to expand the ability of families to dispose of unwanted controlled substances. Below is a summary of the federal legislation. Expect some federal regulations for this in the future.

**SUMMARY AS OF:**

9/29/2010--Passed House amended.

Secure and Responsible Drug Disposal Act of 2010 - Amends the Controlled Substances Act to allow an ultimate user of a controlled substance (or, if deceased, any person lawfully entitled to dispose of the ultimate user's property) who has lawfully obtained such substance to deliver that substance to another person, without being registered, for disposal if: (1) the person receiving the controlled substance is authorized to engage in such activity; and (2) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

Requires the Attorney General, in developing regulations under this Act, to consider the public health and safety, as well as the ease and cost of program implementation and participation by various communities.

Permits the Attorney General to authorize long-term care facilities to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such facilities in a manner that will provide effective controls against diversion and that is consistent with public health and safety.

Directs the United States Sentencing Commission to review and, if appropriate, amend its guidelines and policy statements to ensure an appropriate penalty increase

for persons convicted of a drug offense involving receipt of a controlled substance for disposal.

d. **FOR INFORMATION: Presentation by the Drug Enforcement Administration on Regulations for E-Prescribing of Controlled Substances, National Drug Take Back Day, and Drug Diversion of Controlled Substances in California**

**Attachment 4**

At the September Enforcement Committee Meeting, Mike Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles, provided information on DEA activities and objectives aimed at preventing drug diversion and prescription drug abuse.

Mr. Lewis provided an overview of the DEA regulations to permit e-prescribing of controlled substances. He discussed parties involved in this process including application providers, prescribing practitioners, and pharmacies.

Mr. Lewis also discussed DEA concerns about abuse of prescription drugs by teens who increasingly have attitudes that prescription drugs are “much safer” than illegal drugs. He stated that teenagers are reporting that prescription drugs are more readily available than illegal drugs and can often be found in the medicine cabinets within their homes.

Mr. Lewis discussed the increasing frequency and volume of drug diversion of controlled substances in California. He stated that diversion involves many groups including practitioners, pharmacists, employees, and patients and involves various motivations such as addiction, physical dependence, resale for money and/or illegal drugs, power, control or importance, and sex. Commonly diverted drugs include oxycontin, hydrocodone, xanax (alprazolam), codeine cough syrup, amphetamines, and valium.

The DEA continues to work closely on California drug diversion cases with the board. Also discussion included mention that the DEA is conducting investigations regarding gangs attempting to purchase pharmacies or “working” with pharmacists.

Mr. Lewis stated that the DEA would host a National Drug Take Back Day on September 25, 2010. He explained that the DEA will be providing collection boxes and will transport and incinerate the collected drugs. He advised that needles and sharps containers will not be collected. Depending upon the success of the program, there may be a second drug take back day in about 6 months.

Post Committee Meeting Update:

By all accounts, the DEA's drug take back event was successful and over 242,000 pounds of prescription drugs were collected nationally. The board provided several subscriber alerts in advance of September 25, and DCA distributed a board press release to consumer reports. **Attachment 4** contains photos of the event.

**e. FOR INFORMATION: Presentation by Supervising Inspector Judi Nurse on Thefts of Drugs from Pharmacies**

Supervising Inspector Judi Nurse will provide a presentation at this Board Meeting regarding the increase in thefts and robberies of drugs from California pharmacies and from various entities in the pharmaceutical supply chain (e.g., common carriers). Dr. Nurse supervises the board's inspectors who investigate drug diversion.

Dr. Nurse provided a similar presentation to the Enforcement Committee that included discussion about: (1) the need for increased awareness among pharmacists about diversion, (2) prevention of diversion and theft from pharmacies, and (3) the importance of dispensing responsibly using corresponding responsibility. During this meeting she noted the increase in diversion from pharmacies and indicated that the board's diversion cases have increased by 40 percent over the past few years.

Pharmacists are responsible for the security of the drugs and are the last line of defense against diversion of drugs to the streets, either by theft from the pharmacy or inappropriate dispensing of controlled substances. The board's responsibility includes education of licensees and the protection of the consumer by aggressively pursuing those who do not comply with federal and state pharmacy laws.

Vicodin products represent the largest volume of diverted drugs. Oxycontin and Ambien are also commonly diverted. California Business and Professions Code § 4059.5 requires that all dangerous drugs or devices be delivered to a licensed pharmacy and signed for and received by a pharmacist. This requirement is an important security measure to ensure that pharmacists are aware of what drugs are coming in and out of the pharmacy.

**f. FOR DISCUSSION AND POSSIBLE ACTION: Implementation of Components of DCA's Consumer Protection Enforcement Initiative**

**Attachments 5- 8**

**MOTION:** Enforcement Committee: Direct staff to initiate review of the Disciplinary Guidelines and report back on recommended changes for future committee and board discussion and action.

**Background**

Since July 2009 the Department of Consumer Affairs has been working with health care boards to improve their capabilities to investigate and discipline errant licensees to protect the public from harm. These results yielded the Consumer Protection Enforcement Initiative (CPEI). The CPEI was comprised of a three pronged solution designed to ensure that: (1) investigations were completed and final action taken against a licensee within 12 – 18 months, (2) legislative changes designed to remove barriers to investigations, and (3) a new computer system be installed 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. Subsequently, 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 in 2010, but are elsewhere on the agenda for this October Board Meeting for sponsorship next year.

During the June 2010 Board Meeting, the board discussed proposed regulatory language developed by counsel, designed to implement some of 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 following items.

- Amendment to Section 1760 – Disciplinary Guidelines. The proposed amendment would specify that any proposed decision that includes findings of fact that include that a licensee engaged in sexual contact with a patient, client or customer, or a licensee convicted of a sexual offense shall contain an order of revocation. The proposed change provides an exception to this and also defines sexual contact. The board took no action on this proposal, and asked that it be brought back to a future board meeting for discussion.

At this October Meeting, the board will discuss this possible amendment (see below). **Attachment 5.**

- Amendment to Section 1762 – Unprofessional Conduct. The proposed amendment to this section would specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and failure to notify the board about an arrest, indictment, conviction or discipline as specified. The section also would specify that the board is authorized to revoke a license or deny an application for an act requiring an individual to register as a sex offender. It was the consensus of the board to bring this issue back to a future meeting for discussion.

At this October Meeting, the board will discuss this possible amendment (see below). **Attachment 6.**

- Amendment to Section 1769 – Application Review and Criteria for Rehabilitation. The proposed amendment would allow the board to request that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice. The board voted to require that once it has been determined that an

At this October Meeting, the board will consider the language drafted for these proposed amendments (see below). **Attachment 7.**

- Amendment to Section 1770 – Substantial Relationship Criteria. The proposed amendment would specify that a crime or act that resulted in a licensee being required to register as a sex offender would be considered substantially related to the functions and qualification of the license. The board did not take action on this proposal, and indicated it did not wish to discuss this amendment again.

At this meeting, there are multiple potential action items:

1. The board needs to vote on the Enforcement Committee's Sept. 2010 motion to direct that staff work on the Disciplinary Guidelines of the Board, to augment the guidelines with changes to implement those components from the CPEI (SB 1111) and SB 1441 guidelines that can be pursued without separate statutory or regulation activities.
2. The board may wish to review, refine and approve amendments to section 1760 regarding standardized disciplinary guidelines for violations dealing with sexual contact. The board started initial review of this during the June Board Meeting. **Attachment 5.** A motion and second for this action will be needed.
3. The board may wish to review, refine and approve amendments to section 1762 regarding the proposed amendments to this section that would specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and failure to notify the board about an arrest, indictment, conviction or discipline as specified. The section also would specify that the board is authorized to revoke a license or deny an application for an act requiring an individual to register as a sex offender. **Attachment 6.**
4. Amendment to Section 1769 – Application Review and Criteria for Rehabilitation. The proposed amendment would allow the board to request that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice. The board voted to require that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days. Within 60 days of the evaluation, the report must be received from the evaluator.

At this October Meeting, the board will consider the language drafted by staff into the proposed amendments. **Attachment 7.**

5. The board may wish to review and act on the performance standards developed by staff to conform to the department's online reporting of major enforcement milestones.

These performance standards are provided in **Attachment 8**. A motion and second for this action will be needed.

The executive officer notes that several challenges impact the board as a result of the current budget situation including a hiring freeze preventing the filling of the positions allocated by the CPEI, overtime prohibitions, and furloughs. It will be a challenge for the board to meet the measuring standards and to ensure that investigations are completed and final action is taken against a licensee within 12 – 18 months without the needed staffing.

**g. FOR DISCUSSION AND POSSIBLE ACTION: Implementation of DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program**

**And: DCA Audit of Maximus**

**Attachments 9 and 10**

Background:

Senate Bill 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 in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for the SACC consideration during public meetings.

California 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. Dr. Kajioka advised that under current law, this program is only available to pharmacists and interns.

At the September 2010 Enforcement Committee:

Assistant Executive Officer Anne Sodergren provided an overview of each of the SB 1441 uniform standards regarding substance-abusing healing arts licensees.

The Enforcement Committee was advised that on August 4, 2010, a DCA subcommittee convened to further discuss Uniform Standard 4 dealing with drug testing. The subcommittee did not complete its revision of this standard and a future meeting will be set to complete this discussion.

The committee discussed Standard 1, dealing with requirements for a clinical evaluation. The committee supported the requirement that a probationer must undergo a clinical diagnostic evaluation as a standard requirement for any substance abusing probationer.

The committee suggested that the board may want to include amending into the disciplinary guidelines that certain probationers undergo a clinical diagnostic evaluation.

However, it was the consensus of the committee to defer discussion of the remaining SB 1441 standards to a future meeting after all the standards have been finalized. The committee requested that Ms. Herold communicate to the SB 1441 subcommittee the Enforcement Committee's interest in the standards and that it believes the clinical diagnostic evaluation is a strong and worthwhile tool.

The remaining standards were discussed during Ms. Sodergren's PowerPoint. A summary of these standards is provided in **Attachment 9**.

The consensus of the committee is to cluster the remaining standards into grouped topics for future discussion. This will be done for discussion at the next Enforcement Committee Meeting.

#### Maximus Audit by the DCA

DCA recently completed its contract and performance audit of Maximus for its diversion services. Maximus provides contracted services to six healing arts boards and one committee, including this board. Each program operates differently according to specifics in their underlying statutes. A copy of the audit report is provided in **Attachment 10**.

Mr. Lippe expressed concern regarding some of the deficiencies noted in the program regarding records and documentation, and asked for what follow-up will be done in response to the audit findings.

The Senate Business and Professions Committee has also expressed concern with the audit, and requested that the department's auditors take a closer look at certain items.

The committee requested an update on the audit response at a future meeting.

#### **h. FOR INFORMATION: GSI's October 2010 Forum in San Francisco on Serialization and Track and Trace in the Pharmaceutical Supply Chain**

The committee was updated on a conference in San Francisco by the standards setting organization GS1. The executive officer will speak on California's e-pedigree standards.

#### **i. Minutes of the Meeting Held September 14, 2010**

#### **Attachment 11**

A summary of the meeting held on September 14, 2010 is provided in **Attachment 11**.

#### ***OTHER ENFORCEMENT ITEMS***

j. **FOR POSSIBLE ACTION: DEA's Policy Statement on the Role of Authorized Agents in Communicating Controlled Substances Prescriptions to Pharmacies, 21 CFR Part 1305 (Docket No. DEA 3395)**

**Attachment 12**

Background

In early October, the DEA issued its policy statement regarding the role of an authorized agent in transmitting an order for a controlled substances prescription to a pharmacy.

Under the federal Controlled Substances Act, a valid prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice (and who is authorized to prescribe controlled substances). "While the core responsibilities pertaining to prescribing controlled substances may not be delegated to anyone else, an individual practitioner may authorize an agent to perform a limited role in communicating such prescriptions to a pharmacy " to make the process more efficient. However the DEA requires that only a prescriber may make the medical determination to prescribe a controlled substance, not by an agent.

This issue has been the cause of DEA enforcement activities in other states where in a skilled nursing home an RN has requested a controlled substance for a patient as an "agent" of a prescriber who is not present at the time of the order. In the policy explanation provided by the DEA, there are at least two violations if an agent (e.g., nurse) provides an emergency order to a pharmacy for a C-II drug and then calls it into the pharmacy.

The policy statement restates the DEA policies and federal laws in this area. Essentially the statement provides that:

1. An authorized agent of a prescriber (prescriber equals practitioner) may transmit a Schedule III-V prescription, pursuant to a written or oral prescription of a practitioner, but the practitioner cannot delegate to an agent or any other person the practitioner's authority to issue a prescription. The practitioner must personally sign the prescription manually or electronically. The agent is not authorized to make a medical determination nor can the prescriber delegate his or her signature authority to the agent.
2. A pharmacy may dispense a Schedule III and IV drug pursuant to an electronic or written prescription (a) signed by practitioner or a (b) a facsimile of a signed paper prescription that is transmitted by an agent.
3. A pharmacy may dispense a C-III-V medication pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist, containing all valid information required for the prescription, except for the signature of the practitioner. An agent may orally communicate such a prescription to a pharmacist. The pharmacist may have a duty to inquire into the legitimacy of the prescription, based on the circumstances.
4. A prescription for a C-II drug must be in writing, and must be signed by the practitioner, except in an emergency (see #5 below).
5. In an emergency, a C-II drug may be ordered orally by a practitioner, in an amount needed to care for the patient during the emergency period and it must be followed up within 7 days by a practitioner-signed, written prescription to the dispensing pharmacy. Such an oral order must be immediately reduced to writing by the pharmacist and must contain all the information required in a prescription except for the signature of the practitioner. The

prescribing practitioner must personally communicate the emergency oral prescription to the pharmacist. "An agent may NOT call in an oral prescription for a Schedule II controlled drug on behalf of a practitioner even in an emergency circumstance."

6. A valid agent relationship with a prescriber will NOT usually exist outside of an employer-employee relationship (page 61616, paragraph1).
7. There is also a detailed delegation form for the prescriber to designate and delegate permitted functions to an agent at the close of the policy statement.

**k. FOR ACTION: Formation of an Ad Hoc Task Force to Develop Guidelines on Implementing the DEA Electronic Prescribing Requirements for Controlled Substances**

Last spring, the DEA issued its "interim" rule on its electronic prescribing requirements for controlled substances. This rule is contained in a document over 300 pages in length that is very technical and difficult to comprehend. Following release of this rule, the board submitted comments to the DEA requesting an extension in the adoption of the final rule until pharmacy, prescribers and other interested parties could review and provide comments. No response to these comments has been received.

Despite the technical challenges of the interim rule, the board may wish to assume leadership in this area by advising pharmacies what is expected under the DEA's requirements. For this, staff suggests the formation of an ad hoc task force, appointed by the president, to develop guidance for California pharmacies, with the participation of interested stakeholders.

**I. FOR INFORMATION: Availability of Two Ethics Courses to comply with 16 CCR 1773.5**

Several years ago the board developed regulation requirements for an in-depth, extensive ethics course for pharmacists and interns who are being disciplined for ethical lapses. The regulation took effect in September 9, 2009. For over a year, requirements to complete a detailed ethics course have been one optional component in the settlement of board disciplinary cases.

This fall, two course providers offering this course, the Institute for Medical Quality and Professional Boundaries Incorporated. According to Board Counsel Schieldge, the board does not need to approve any course directly; however, the provider must ensure that its course complies with the requirements in the board's regulations. A copy of these requirements is provided below.

**1773.5 Ethics Course Required as Condition of Probation.**

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

- a. The board will consider for approval an ethics course that at minimum satisfies the following requirements:
  - (1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.

- (2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.
- (3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.
- (4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.
- (5) Content. The course shall contain all of the following components:
  - (A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.
  - (B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.
  - (C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.
  - (D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.
  - (E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.
  - (F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.
- (6) Class Size. A class shall not exceed a maximum of 12 participants.
- (7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.
- (8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.
- (9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

**m. FOR DISCUSSION: Compliance Achieved in Reporting Disciplinary Actions to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank**

Under federal law, state licensing bodies are required to report to a specified federal data bank within 30 days any adverse licensing actions they take against their licensees. This board is one such agency that is required to report this information to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank. The intent is a central repository of information on all US health care practitioners. The requirement has existed for a number of years, and the vast majority of agencies in each state required to report to it apparently did not do so.

The California Board of Pharmacy did submit this disciplinary information to the data bank for a number of years, but discontinued doing so in the early 2000s in response to severe budget reductions and hiring freezes impacting board staff. However, in 2009, the board dedicated one part-time employee to submitting the required information to the data bank and getting our information caught up.

I am pleased to report that as of October 1, 2010, this board has been deemed as compliant.

n. **FOR INFORMATION: Enforcement Statistics 2010/11**

**ATTACHMENT 14**

**Attachment 14** includes the enforcement statistics for first quarter 2010/11.

o. **FOR INFORMATION: First Quarterly Report of the Committee's Goals for 2010/11**

**ATTACHMENT 15**

**Attachment 15** contains the first quarter's status of Enforcement Committee Goals.

# **Attachment 1**

# Proposal 1

Scott R. Huhn PharmD  
Omnicare  
879 Second Street  
Santa Rosa, CA 95404  
707-486-7801  
[scott.huhn@omnicare.com](mailto: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](mailto: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.

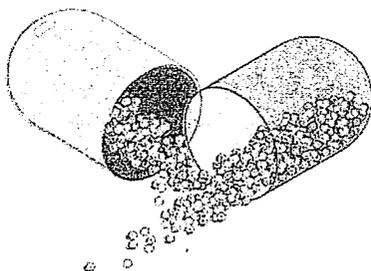
Pharmacy Law is violated where a prescription is dispensed in an insufficiently or inaccurately labeled

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.

# **Attachment 2**

## Compounding Questions and Answers, September 14, 2010

**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.

For 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 pharmacy (NRP) is a pharmacy located in another state that furnishes dangerous drugs to patients in CA, and is required to be licensed with the board. Part of the licensure requirement is that 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 thus 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. So the master formula record 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 the record-keeping exemption in 1735.3(a)(b) 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 NRPs.**

However, NRPs 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 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 seem 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, 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 its 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 required information as is available. If there is no expiration date on a device, there would be no expiration date 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 maintained together as long as they are readily retrievable and available for inspection. These records may be maintained in a paper or electronic manner.

However 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)

# **Attachment 3**



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

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](mailto: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 it 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.

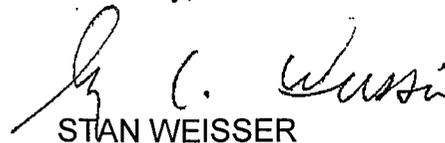
The board also notes that mail return by patients of unwanted drugs may offer additional advantages that are not greatly emphasized in the guidelines. This option warrants further review and discussion.

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 Hagen 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, Hagen 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)

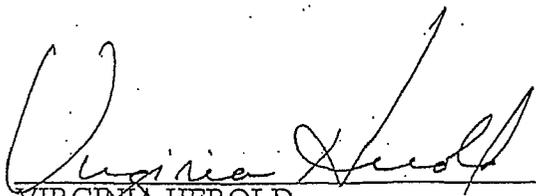
3 19. Respondent is subject to disciplinary action under section 810, subdivision  
4 (a)(2) for preparing and presenting false claims for payment, which constitutes a specifically  
5 identified form of unprofessional conduct. In or about the year 2000, Respondent fraudulently  
6 presented false claims 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

1 EDMUND G. BROWN, JR., Attorney General  
of the State of California  
2 ARTHUR TAGGART  
Supervising Deputy Attorney General  
3 STERLING A. SMITH,  
Deputy Attorney General, State Bar # 84287  
4 California Department of Justice  
1300 I Street, Suite 125  
5 P.O. Box 944255  
Sacramento, CA 94244-2550  
6 Telephone: (916) 445-0378  
Facsimile: (916) 327-8643

7 Attorneys for Complainant  
8

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

12 In the Matter of the Accusation Against:

Case No. 3234

13 **MICHELLE H. MAI**  
15837 E. Palomino Blvd.  
14 Fountain Hills, Arizona 85268

**AMENDED ACCUSATION**

15 Pharmacy License No. RPH 58012

16 Respondent.  
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 ///

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 unless otherwise indicated.

5           4.       Section 490 of the Code states, in pertinent part, that:

6           “(a) In addition to any other action that a board is permitted to take against a  
7 licensee, a board may suspend or revoke a license on the ground that the licensee has been  
8 convicted of a crime, if the crime is substantially related to the qualifications, functions, or duties  
9 of the business or profession for which the license was issued.

10           (b) Notwithstanding any other provision of law, a board may exercise any  
11 authority to discipline a licensee for conviction of a crime that is independent of the authority  
12 granted under subdivision (a) only if the crime is substantially related to the qualifications,  
13 functions, or duties of the business or profession for which the licensee’s license was issued.

14           (c) A conviction within the meaning of this section means a plea or verdict of  
15 guilty or a conviction following a plea of nolo contendere.”

16           5.       Section 493 of the Code states, in pertinent part, that:

17           “Notwithstanding any other provision of law, in a proceeding conducted by a  
18 board within the department pursuant to law to deny an application for a license or to suspend or  
19 revoke a license or otherwise take disciplinary action against a person who holds a license, upon  
20 the ground that the applicant or the licensee has been convicted of a crime substantially related to  
21 the qualifications, functions, or duties of the licensee in question, the record of conviction of the  
22 crime shall be conclusive evidence that the conviction occurred, but only of that fact, and the  
23 board may inquire into the circumstances surrounding the commission of the crime in order to fix  
24 the degree of discipline or to determine if the conviction is substantially related to the  
25 qualifications, functions, or duties of the licensee in question.”

26           6.       Section 4301 of the Code states:

27           “The board shall take action against any holder of a license who is guilty of  
28 unprofessional conduct or whose license has been procured by fraud or misrepresentation or

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(l) 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 ///



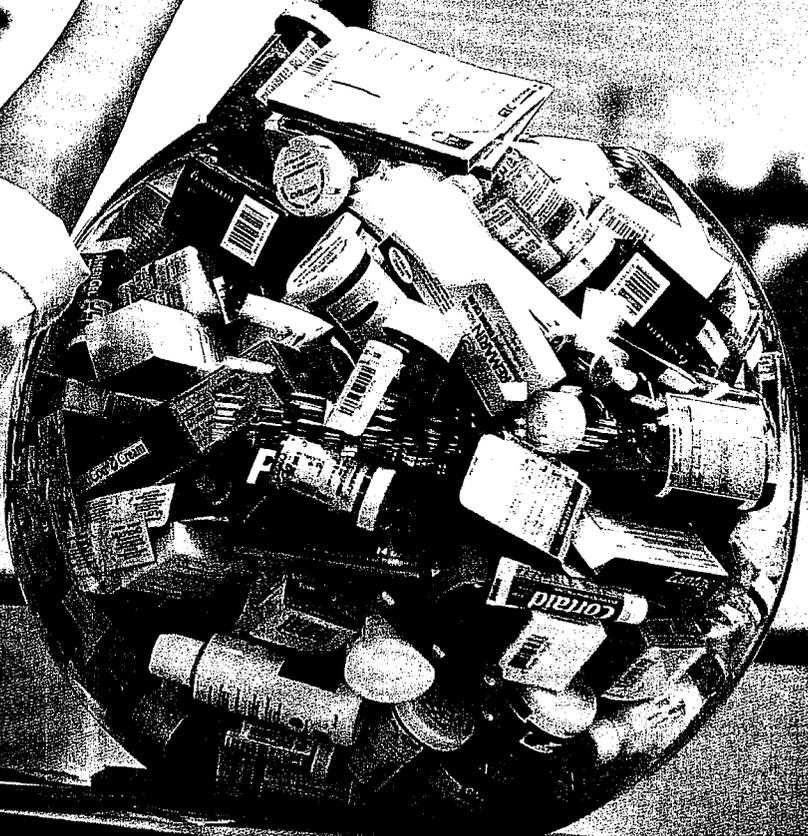
# Attachment 3



consultation



**Take-Back Program**  
The time has come again to help you  
keep your pharmacy safe. The 2007  
FDA Drug Enforcement Administration  
has announced that it will be  
conducting a nationwide sweep of  
pharmacies to ensure that they  
are properly disposing of controlled  
substances. The DEA has announced  
that it will be conducting a  
nationwide sweep of pharmacies  
to ensure that they are properly  
disposing of controlled substances.



# Attachment 4

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

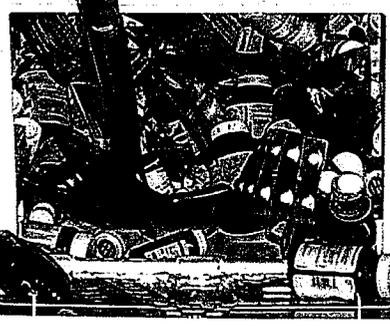
SAN MATEO COUNTY  
ENVIRONMENTAL HEALTH DEPARTMENT



PHARMACEUTICAL DISPOSAL  
ONLY



DESCHUROS 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](mailto: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

# **Attachment 4**

-- From WWW. DEA.GOV--

## American Public Overwhelmingly Responds to DEA Prescription Drug Take-Back Effort

**OCT 05** -- WASHINGTON, D.C. -- The United States Drug Enforcement Administration today announced the overwhelmingly successful results of the first-ever national prescription drug "Take-Back" campaign. The American public turned in more than 242,000 lbs of prescription drugs for safe and proper disposal. More than 4,000 take back sites were available in all 50 states this past Saturday, and Americans responded in huge numbers.

"The Take-Back Campaign was a stunning nationwide success that cleaned out more than 121 tons of pills from America's medicine cabinets, a crucial step toward reducing the epidemic of prescription drug abuse that is plaguing this nation," said DEA Acting Administrator Michele M. Leonhart. "Thanks to our state and local law enforcement and community partners—and the public—we not only removed these dangerous drugs from our homes, but also educated countless thousands of concerned citizens about the dangers of drug abuse."



DEA personnel unload boxes of prescription drugs into a front-end loader prior to incineration in Kennedale, Texas.



DEA held the first-ever Prescription Drug Take-Back Day on September 25, 2010.



A DEA Agent helps a citizen unload her unused prescription drugs in Woodbridge, Virginia.



DEA Acting Administrator Michele Leonhart speaks to media outside a drop-off location in Washington D.C.



A University of Maryland Police Officer helps a DEA Agent seal up a bag of dropped off drugs in College Park, MD.



Cars lined up in Allen, Texas to drop off prescription drugs at a collection site.



DEA personnel unload boxes of prescription drugs into a front-end loader prior to incineration in Kennedale, Texas.



For one gentleman from Troy, Missouri, it was easier to remove the kitchen drawer to carry his unwanted meds.



Arizona residents turned in over three tons of prescription drugs which were stored in a warehouse prior to incineration.



New Jersey residents turned in over 7 tons of prescription drugs, some of which are displayed here in Newark.



Pills being dropped off at the Central Fire Dept. in Laredo, TX,



DEA's Seattle Field Division and Washington State Patrol used a fish tank to display some of the prescription drugs that were collected.



A mom takes time out of her busy day to drop off some unneeded prescription drugs at Colorado State University in Fort Collins, CO.



A Scottsdale, Ariz. couple drop off unused prescription drugs at the Scottsdale Fashion Square Mall on Saturday, Sept. 25<sup>th</sup>.



DEA's Cleveland office collected 16 pallets (foreground) of prescription drugs. The pallets weighed in at 9,225 pounds.



A bus driver gives his unwanted prescription drugs to a DEA agent in Scripps Carlsbad, California.



Puerto Rico Radio and TV talk show personality Rony “The Hyper” Campos turns in all unused and expired medications from his family at the DEA Take Back collection site at Plaza Las Americas in San Juan.

# **Attachment 5**

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.

# **Attachment 6**

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.

# **Attachment 7**

§1769. *Application Review and Criteria for Rehabilitation*

**Proposed Amendments**

(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 board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date of the examination is completed. The report of the examiner shall be made available to the applicant.

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.

# **Attachment 8**

Board / Bureau / Program Name:		Pharmacy	
Measure Type / Name	Collection Method	Example	Your Program's Target
<b>PM 1: Volume</b> Number of complaints received	Extracted from CAS and submitted quarterly through the Performance Measure Workbook	<i>N/A</i>	<i>No target required</i>
<b>PM 2: Cycle Time</b> 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
<b>PM 3: Cycle Time</b> 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
<b>PM 4: Cycle Time</b> 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
<b>PM 5: Efficiency (Cost)</b> 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>
<b>PM 6: Customer Satisfaction</b> 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
<b>PM 7: Cycle Time</b> 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
<b>PM 8: Cycle Time</b> 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

# **Attachment 9**

## SB1441 Uniform Standard Summary

### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change
    - Regulation change (disciplinary guidelines)

### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Regulation change (disciplinary guidelines)

### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants

- Regulation change (disciplinary guidelines)
- Other individuals
  - Statutory change (establish program)
  - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change (establish program)
    - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change (establish program)
    - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns

- Contract change for PRP participants
- Regulation change (disciplinary guidelines)
- Other individuals
  - Statutory change (establish program)
  - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change
    - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change (establish program)
    - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change
    - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
  - Other individuals
    - Statutory change

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
  - Other individuals
    - Statutory change

#### 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.
- Changes needed for implementation:

- Pharmacists/Interns
  - Statutory change
  - Contract change for PRP participants

#### 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.
  - Changes needed for implementation:
    - Pharmacists/Interns
      - Statutory change
      - Contract change for PRP participants
    - Other individuals
      - Statutory change

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants

#### 16. Measurable criteria for standards

- Establishes 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants

# **Attachment 10**

Enforcement

**Contract Compliance and  
Performance Audit of The  
Department of Consumer Affairs  
contract with Maximus, Inc. for  
the Health Professionals  
Diversion Program**

Contract # 014-0511-3

Audit No. 2009-101  
June 2010



Internal Audit Office

**INTERNAL AUDIT OFFICE**

1625 North Market Blvd., Ste. N-324, Sacramento, CA 95834  
P (916) 574-8190 F (916) 928-7986 | [www.dca.ca.gov](http://www.dca.ca.gov)



April 30, 2010

Brian Stiger, Director  
Department of Consumer Affairs  
1625 North Market Blvd. Ste. S-308  
Sacramento, CA 95834

Dear Mr. Stiger,

Enclosed is the DCA Internal Audit Office's report on the DCA's contract with Maximus, Inc. for the Health Professionals Diversion Program, contract # 014-0511-3. The audit period was 7/1/2007 through 6/30/2009. We issued our draft report on April 15, 2010. We received Maximus' response to the draft audit report on April 22, 2010 and have incorporated the reply into this report. If you have any questions, please call me at (916) 574-8190.

Sincerely,

*Original signed by:*

Cathleen Sahlman  
Audit Chief

Attachment

cc: Virginia L. Matthews, Maximus Program Manager

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## Report Summary

### Results in Brief

Since 2003 Maximus is the contractor that has provided Diversion services on behalf of six healing arts boards and one committee that fall under the administrative authority of the Department of Consumer Affairs (DCA). The purpose of the Diversion contract was to implement a confidential, comprehensive chemical dependency and mental illness monitoring and referral program for health care professionals. There are six boards and one committee authorized by statute to administer a Diversion program for eligible licensees. The six boards and one committee covered under the contract are:

- Board of Pharmacy
- Board of Registered Nursing
- Dental Board of California
- Osteopathic Medical Board
- Physical Therapy Board
- Veterinary Medical Board
- Physician Assistant Committee

The audit was conducted pursuant to Senate Bill 1441, chaptered September 28, 2008. The purpose of the audit was to review Maximus' effectiveness, efficiency, and overall performance in managing Diversion programs. The audit test period was from July 1, 2007 through June 30, 2009. The audit was performed in accordance with the *Standards for the Professional Practice of Internal Auditing*.

The audit scope closely followed the audit requirements set forth in SB 1441, and included detailed interviews with Maximus personnel to describe all processes, and subsequent case file testing to determine if Maximus had complied with provisions of the contract and had performed in accordance with these provisions. We tested a sample of 177 case files, representing all six boards and one committee.

Although we noted a number of areas for improvement, overall, we concluded that Maximus is operating in compliance with contract provisions. Senate Bill 1441 also asked that the audit "make recommendations regarding the continuation of the **programs**..." It should be noted that the scope of the audit encompassed only contract compliance and performance of the administrative vendor, Maximus, and not the DCA boards' performance as a broader aspect of the DCA's overall Enforcement **program**. It follows that the recommendations in the report address only the administrative vendor and not the program as a whole. Decisions regarding the continuation of the programs are policy level decisions appropriately made by DCA management and the legislature once audits of the boards' Enforcement programs taken as a whole have been completed, and are beyond the scope of this review.

We noted the following areas for improvement:

- Maximus currently provides the individual boards/bureaus with monthly and quarterly summary reports of the overall Diversion program, however, the DCA executive management team does not currently receive comparable reports. With the current emphasis on standardizing enforcement practices and the interrelated nature of the Diversion program with the enforcement process, it follows that the executive management team would benefit from customized reports providing high level detail that reflect their needs related to executive management decisions regarding these programs.

Recommendation: Maximus should work with DCA's executive management team to develop high level summary reports of the program that provides executive management with the information most useful in making department-wide decisions related to the Diversion program.

- Maximus Diversion records in some cases lack the required documentation of treatment, aftercare, and monitoring services received by recipients. Of the thirty or so individual participant contract terms found in any participant's case file, two items were not well documented. Documentation was missing for outpatient programs (mainly aftercare) and quarterly reports from therapists in 65% of files tested. Maximus was accepting monthly self-reports provided by the participants themselves as proof that these terms had been fulfilled.

Recommendation: Maximus should require reliable third party documentation proving that 100% of individual contract terms are compliant. Maximus should increase its monitoring of all required reports for individual recovery contracts for all participants, ensuring aftercare and therapist reports are included in the case file documentation.

- Maximus' timeliness could be improved for positive urine test results reporting to the boards. Maximus subcontracts with FirstLab for laboratory testing services. Maximus assigns each participant a unique identifying number which they are supposed to provide to the collection site at the time of testing. Some participants are not using the unique identifier and instead provide the collection site with their social security numbers. This creates a situation in which FirstLab must manually reconcile the different identifiers before providing Maximus with positive test results. This results in about a one-day delay in Maximus receiving positive test results.

Recommendation: Maximus should work with FirstLab to speed up the reporting of positive test results. Maximus and FirstLab should consider the use of donor identification cards to provide collection sites with official

information regarding the participants and would eliminate the extra day required to match identifiers and social security numbers.

- Maximus failed to adequately monitor one participant's compliance with bodily fluid testing, resulting in a participant who was not testing for more than two months. This participant was terminated from the program for ceasing to call and test. A note in the Maximus case log stated "no one knew he had not called in or tested for two months."

Recommendation: Maximus should ensure it adequately monitors each and every participant in accordance with the Diversion contract.

- Maximus had combined some of the records for certain licensees with multiple participations within the program, in one case, resulting in the erroneous purging of treatment records. Because there were no identifiers in these cases distinguishing old from new case files, a new file could be purged along with old information.

Recommendation: Maximus should ensure it keeps separate files for each participation when a participant has been in the program more than one time.

- Worksite monitoring (WSM) needs to be improved. Worksite monitor agreements do not provide enough information to determine if Worksite monitors meet required criteria. Worksite monitors are supposed to be in a position to observe the participant at work, and it is essential that the WSM not be a subordinate of the program participant.

Recommendation: Maximus should increase its oversight over worksite monitoring. No WSM should be a subordinate of the participant.

- Clinical Assessments may not be done timely due to limited availability of licensed therapists. One participant's clinical assessment was not done within four weeks of application to the program. Some participants are in inpatient programs during this 4 week time frame and Maximus has relied upon the in-house clinical staff to provide the required assessment. However, this could be viewed as a conflict of interest if the treating clinician were to recommend further treatment in its own facility.

Recommendations: Maximus should have alternate licensed therapists in cases where a licensed therapist assigned to a participant is unavailable.

Maximus should ensure the completion of the clinical assessment required for proper treatment. Maximus should limit the reliance on treatment facility in-house therapists to conduct the clinical assessment to avoid the appearance of conflict of interest.

- Discrepancies were noted in participant's initial call dates existing in Maximus' database. The audit found 12% of initial call dates did not match the date noted in the case log and what was recorded in the participant's history and profile (H & P) report. It may appear that the participant called earlier or later than noted in the H & P report. For participants who are board-ordered into the program, the report may not accurately reflect the correct date when the participant applied for the program.

Recommendations: Maximus should better define what date to use for the initial call date when preparing the History & Profile report for each participant.

## **Background**

Maximus, Inc. was the contractor chosen in 2003 by the Department of Consumer Affairs (DCA) to provide Diversion services on behalf of six healing arts boards and one committee that fall under its administrative authority (Contract # 014-0511-3 and eight amendments extending the contract through December 31, 2009). The purpose of the contract was to implement a confidential, comprehensive chemical dependency and mental illness monitoring and referral program for health care professionals. The contract was originally designed to accommodate approximately 700+ participants. The six boards and one committee are:

- Board of Pharmacy
- Board of Registered Nursing
- Dental Board of California
- Osteopathic Medical Board of California
- Physical Therapy Board of California
- Physician Assistant Committee
- Veterinary Medical Board

Each of the above entities is authorized by statute to administer a Diversion program for their eligible licensees. As described by the Request for Proposal (RFP) for the contract, the goal of each Diversion program is to protect the public by early identification of these licensees and by providing them access to appropriate intervention programs and treatment services so they can return to practice in a manner that will not endanger the public health and safety. Since there were features, standards, and services common to each of the six boards and one committee, the contract with Maximus was chosen to address all seven entities as one client. The contract also specifies board specific requirements for each board and the committee. We also reviewed these board specific requirements to determine whether or not Maximus had appropriately addressed each board's specific requirements. The contract with Maximus covers the period July 1, 2003 through December 31, 2009 over 6.5 years.

The DCA Internal Audit Office (IAO) performed an audit of the DCA's contract with Maximus to fulfill the audit requirement in Senate Bill 1441, chaptered September 28, 2008. The purpose of the audit was to review Maximus' effectiveness, efficiency, and overall performance in managing diversion programs for substance abusing licensees. The audit test period was from July 1, 2007 through June 30, 2009. Case files selected for testing within the audit period extended both before and after the initial period of audit due to the multiple year nature of the program (i.e. if an active case file from 2008 was selected for testing, relative case file information may have extended as far back as the late 1990's, and may have extended forward to current day if still an active case).

**Objectives, Scope and Methodology**

The audit was performed in accordance with the *Standards for the Professional Practice of Internal Auditing*. The objective of the audit was to provide DCA management, boards and the California legislature with an audit of the effectiveness, efficiency, and overall performance of the vendor chosen by the department to manage diversion programs for substance-abusing licensees of health care licensing boards, as required by Senate Bill 1441. The Senate Bill also requested the audit make recommendations regarding the continuation of the programs and any changes or reforms required to ensure that individuals participating in the programs are appropriately monitored, and the public is protected from health care practitioners who are impaired due to alcohol or drug abuse or mental illness.

The audit scope has been designed to closely follow the audit requirements set forth in SB 1441. The following grid identifies the applicable SB 1441 audit requirement, a cross-reference to the applicable report narrative addressing the senate bill requirement, and a cross-reference to any related findings and recommendations addressing the requirement.

Senate Bill 1441 Requirement	Report Narrative Location	Related Finding # If applicable
Identify percentage of participants that were: <ul style="list-style-type: none"> <li>• Self-referred</li> <li>• Board-referred</li> <li>• Board-ordered</li> </ul>	Exhibit A, page 6	N/A
Describe all aspects of bodily fluids testing <ul style="list-style-type: none"> <li>• Frequency of testing</li> <li>• Randomicity</li> <li>• Method of notice to participants</li> <li>• Number of hours between the provision of notice and the test</li> <li>• Standards for specimen collectors</li> <li>• Procedures used by specimen collectors</li> <li>• Location of testing</li> <li>• Average timeframe from date of the test to the date the result becomes available</li> </ul>	Begins on page 9 Pgs. 10-11  Pg. 10  Pg. 11  Pg. 12  Pg. 13  Pg. 13	Finding 2

Senate Bill 1441 Requirement	Report Narrative Location	Related Finding # If applicable
Describe group meeting attendance <ul style="list-style-type: none"> <li>• Required qualifications for group meeting facilitators</li> <li>• Frequency of required meeting attendance</li> <li>• Methods of documenting and reporting attendance or non-attendance by program participants</li> </ul>	Pg. 14 Pg. 14 Pg. 14	
Describe standards used in determining whether inpatient or outpatient treatment is necessary	Pg. 15	
Describe worksite monitoring requirements and standards	Pg. 15	Findings 5,6
Timeliness of diversion services provided by the vendor	Pg. 16	Findings 8,9
Thoroughness of <i>documentation</i> of treatment, aftercare, and monitoring services received by participants	Pg. 17	Finding 1
Thoroughness of <i>documentation of the effectiveness</i> of the treatment and aftercare services received by participants	Pg. 17	Finding 1
Evaluate vendor's approval process for providers or contractors that provide diversion services, including specimen collectors, group meeting facilitators, and worksite monitors	Pg. 17  Pg. 14 Pg. 15	Finding 6
Evaluate the vendor's disapproval of providers or contractors that fail to provide effective or timely diversion services	Pg. 17	
Evaluate the vendors promptness in notifying the boards when a participant fails to comply with the terms of his or her diversion contract or the rules of the board's program	Pgs. 20-33 case file testing	Finding 2
Recommend whether the vendor should be more closely monitored by the <b>department</b> , including: <ul style="list-style-type: none"> <li>• Whether the vendor should provide the <b>department</b> with periodic reports demonstrating</li> <li>• the timeliness and thoroughness of documentation of non-compliance with diversion program contracts; and,</li> <li>• Its approval and disapproval of providers</li> <li>• and contractors that provide diversion services.</li> </ul>	Pg. ii, Page 19	Report Summary
Recommendations regarding continuation of the programs and any changes or reforms necessary.	Pg. ii, Pg. 19	Report Summary

We applied the following specific procedures in conducting this audit:

1. Reviewed the RFP and contract, including all amendments, between the DCA and Maximus.
2. Reviewed each board's specific contract provisions and incorporated this into our audit testing.
3. Interviewed each board and committee's Diversion Program Manager (DPM) to obtain an understanding of their interaction with Maximus, and any concerns they felt should be addressed in the audit.
4. Reviewed each board's statutes and regulations applicable to the Diversion program.
5. Interviewed the Maximus Diversion Program Manager and Operations Manager regarding all aspects of the program. Also interviewed clinical case managers and compliance monitors working for Maximus. Tested case files to validate procedures described during the interview process.
6. Observed a Diversion Evaluation Committee meeting of the Dental board in order to understand how a DEC works.
7. Obtained and reviewed Department of Transportation Drug Testing Standards required by the contract.
8. Interviewed the client business manager for FirstLab, the sub-contractor that administers laboratory testing services for Maximus.
9. Visited a First Lab collection site and interviewed staff on-site about their procedures to determine compliance with contract requirements.
10. Interviewed a clinical assessor under contract with Maximus.
11. Interviewed a group meeting facilitator under contract with Maximus.
12. Obtained read-only access to the Max-CMS computer system containing the automated case files for all participants. Tested a sample of case files (both automated and hard copy) for all six boards and one committee. Case files were tested for timeliness of critical services, completeness, and accuracy, compliance with contract terms and conditions, and thoroughness of documentation of treatment. A more detailed description of the case file testing is found prefacing the Findings and Recommendations section of this report.

## **Description of the Diversion Program**

As discussed in the background section of this report, the Diversion program was designed to be a confidential, comprehensive chemical dependency and mental illness monitoring and referral program for health care professionals.

There are six boards and one committee participating in the Maximus contract. Each board and committee has its own statutes and is organized according to these statutes. Exhibit A shows each board or committee, what statutes apply, and whether or not a Diversion Evaluation Committee (DEC) is utilized (some boards have statutes authorizing a DEC, but do not use one). In addition, the exhibit shows the percentages of self-referred participants, board-referred participants, and board-ordered participants, as required by SB 1441.

Exhibit A provides an overview of each board's program.

Exhibit A – Board summaries

	B & P Codes pertaining to Diversion/ Recovery Program	Number of applicants/ participants during period of review	Self-referrals	Board referrals***	Board Ordered referrals****	Unknown referral method*****	Authorized Diversion Evaluation Committee
Dental Board of CA	1695-1699	75	7 (9%)	36 (48%)	32 (43%)	0	Yes
Osteopathic Medical Board of CA	2360-2370	17	10 (59%)	1 (6%)	6 (35%)	0	Yes
Pharmacy, Board of	4360-4373	122	30 (25%)	20 (16.33%)	64 (52%)	8 (6.66%)	No
Physical Therapy Board of CA	2662-2669	20	0	19 (95%)	1 (5%)	0	Yes
Physician Assistant Committee	3534-3534.10	30	11 (37%)	9 (30%)	10 (33%)	0	Yes
Registered Nursing, Board of	2770-2770.14	853	280 (33%)	566 (66%)	0	7 (1%)	Yes
Veterinary Medical Board and Registered Veterinary Technician Examining Committee	4860-4873	12	7 (58.3%)	3 (25%)	1 (8.3%)	1 (8.3%)	Yes

\*\*\*Board Referrals are Informal Board Referrals.

\*\*\*\*Board Ordered Referrals are known as Probation Referrals, which are mandated referrals to the Diversion Program with successful completion as a term and condition of probation.

\*\*\*\*\*Unknown referral method- unable to determine how participant was referred to the program. This may account for those participants who were in the program before 2003 (the year Maximus took over as Diversion vendor). However, Maximus should make every attempt to classify the type of referral as self, board-referred, or board-ordered, contacting each board as necessary to obtain the information.

The audit period was July 1, 2007 through June 30, 2009, but includes many cases that started before 2007 due to the multi-year nature of participation in the program.

As shown in exhibit A, there are three methods of entry into the Diversion program. The first is self-referral. A participant is designated as a self-referral when the licensee contacts the contractor directly and is not in the program as a result of disciplinary action by the board. A self-referral is confidential, and is not disclosed to the public. Some self-referrals become board referrals or board-ordered referrals at a later date.

The second type of admission to the Diversion program is board-referred. In a board referral, the board may refer a licensee to the Diversion program, but it is not yet a condition of formal probation.

The third type of referral is a board-ordered referral. This occurs usually as a condition of probation.

Regardless of the method of entry or type of referral, the process followed by Maximus is the same. The potential participant does a phone intake with Maximus, reached through their 24-hour telephone number, which is manned by clinical case managers (CCMs). The CCM mails the participant program information and sets them up for immediate urine screening. An appointment is scheduled for a clinical assessment.

### **Clinical Assessment**

After the initial intake assessment is completed, a face-to-face meeting is scheduled between the applicant and a Clinical Assessor (CA). The CA is required to provide a comprehensive assessment, including a complete psychosocial history, drug history, and a five Axis diagnosis per standards of the DSM IV-TR Multiaxial Assessment Clinical Evaluation. They are also asked to provide treatment recommendations.

The written assessment is due to Maximus within 30 calendar days of completing the assessment. A CA will set an appointment with an applicant, review intake notes and collect history information during a diagnostic interview. With this information, the CA will identify any concerns for the applicant's safety, or recommend immediate inpatient treatment if necessary, as well as provide any specific recommendations for treatment. Although CAs do not make the ultimate determination whether an applicant is fit for the program, their assessment is considered in the decision-making process. Clinical judgement is never made by only one person. It is always done in conjunction with the DEC or DPM. Dental Board requires all participants to go into inpatient treatment (95% do go into inpatient treatment but for various reasons the other approximate 5% do not; sometimes insurance will not cover it, etc.). These participants go to a treatment center that specializes in health care professionals, such as Betty Ford in Southern California or Hazelden in Oregon. For the Nursing Board, almost 100%

go into inpatient treatment at first. Other boards vary. If a participant is actively using at the time of entry into the program they need a medically supervised detoxification. Some have already checked themselves into one; if this is the case, then Maximus needs to determine whether or not the program is adequate. Some participants have already started treatment based upon what their insurance coverage will cover.

Intensive outpatient treatment is for those further along in their program. It is 9 hours per week for 9 weeks minimum. Aftercare is usually 1 hour per week, normally at the same facility where the participant received their inpatient or intensive outpatient treatment.

If a determination is made that an applicant seek immediate inpatient treatment, the CA is required to notify Maximus within one business day. At that time a Clinical Case Manager will contact the applicant immediately to facilitate entry into the appropriate level of care. The Diversion Program Manager (DPM) or the Diversion Evaluation Committee if also notified with 24 hours of the CA's recommendation.

Once out of initial inpatient or intensive outpatient treatment, a participant is set up for either a DEC meeting or board committee meeting to determine acceptance to the program (if not already previously accepted). An initial intake with the Clinical Case Manager will be held, in which the terms of a pre-entry agreement are determined by the applicant's individual case. The applicant is given an opportunity to respond, clarify, and is asked to agree to the terms. The agreement is then mailed to the applicant, and they are asked to sign and return it. Once the DEC or committee meets, a customized agreement is prepared and signed by the participant. There are normally about thirty terms to the agreement, including random drug testing, group therapy, individual therapy, Alcoholics Anonymous or 12 step meetings, quarterly DEC or committee meetings, aftercare, intensive outpatient treatment, worksite monitoring, monthly self-reporting, etc. In addition, the agreement will place restrictions on the participant's ability to work. The customized terms are based upon the DEC or DPM's assessment of the participant's needs, as well as public protection. As of January 1, 2009 Business and Professions Code was amended to state that the Diversion Program Manager has primary responsibility to review and evaluate recommendations of the DEC, so that all decisions rest with the DPM.

### **Ongoing Monitoring by Clinical Case Managers and Compliance Monitors**

Once the participant's program has been set up, there is ongoing monitoring and assessment of progress provided by Maximus. Each participant is assigned to a Clinical Case Manager (CCM). The CCM is supported by one or more compliance monitors (CM). Clinical Case Managers are experienced clinicians. Many hold certifications in addiction nursing specialties. CCMs work in teams

with CMs and are assigned to the Boards and groups of participants. The CMs provide support to the CCMs and are dedicated solely to a CCM when the caseload exceeds 100 participants.

We interviewed both a Clinical Case Manager and a Compliance Monitor about their roles, and also reviewed their job descriptions found in the Maximus contract. The CCM position requires a licensed psychologist, social worker or registered nurse. Primary duties include conducting assessment and reassessment of impaired health professional licensees, including evaluating incoming information submitted by treatment providers, facilities, participants, and labs to monitor participant's progress and compliance with the recovery contract. They develop the immediate plan of care for each participant, then monitor how it is going by obtaining feedback from all parties. Initially, they set up the clinical assessment, set up drug testing with FirstLab, and require the participant to call once per week. If the participant fails to call, they are considered non-compliant. They also set up the participant with support group meetings. They consult with the DEC on the recovery contract terms. In the event the participant has a positive drug test or relapse, it is the CCM who makes the call to notify the board DPM and/or DEC.

The compliance monitor position requires a bachelor's degree in Behavioral Science or a related field, plus three years of experience in a behavioral health care setting related to chemical dependency or mental illness. Their primary responsibilities are to collect incoming data and reports from treatment providers, facilities, participants, labs, worksite monitors, support group facilitators, and other team members. They input necessary information into the case management system (Max-CMS). Auditors noted there could be multiple case log notes for each participant during a single day. They alert the CCM of any issues of non-compliance or special circumstances on a prompt basis. They produce the monthly compliance/non-compliance letters, as well as other reports and correspondence. It is the CM who initially (7 a.m. each morning) logs into Max-CMS to see any missed calls, missed tests, etc. One of the CMs runs a report each morning of the Random bodily fluids testing results and sends the information to all other CMs. They also fax the boards when there is non-compliance.

### **All Aspects of Random Bodily Fluids Testing (RBFT)**

At the end of 2008 and the beginning of 2009, Maximus found performance issues with the vendor contracted to perform drug testing on participants. As a result, in February 2009, Maximus changed drug testing vendors. FirstLab is the subcontracted vendor responsible for the arranging, collecting, processing and accounting for all drug testing related to this program. Included in the services provided by FirstLab are the random selection of participants, notification, specimen collection, testing, electronic reporting and billing of participants. First

Lab only uses certified labs. First Lab is a third party contractor to the actual labs, and provides neutral oversight of these facilities.

### Frequency/Randomicity

FirstLab has a random selection system that can generate customized test frequencies based on the monitoring needs of any given participant. The tests are scheduled by computer annually and the frequency of the testing can be changed if necessary. Also, the Board Diversion Program Manager (DPM) and/or the Clinical Case Manager (CCM) have the ability to add additional tests or revise the schedules as the need arises. Under the contract audited, the "default" or minimum number of tests conducted was 18 times per year. Any board or DEC could request a different frequency if warranted. Some participants' frequency has been as high as 52 times per year (Dental, Pharmacy participants).

FirstLab is responsible for the call-in notification system. That is, participants are required to call-in each day to find out if they are required to be tested. Not only is a call-in system available, but also an online log-in system. If a participant is unable to go to their regular site due to work schedule conflicts, arrangements can be made for the participant to test at an alternate site.

Although the call-in and log-in systems are available 24 hours a day, participants are limited to calling or logging in between the hours of 5 a.m. and 8 p.m. No notice is given before 5 a.m. or after 8 p.m. Participants must test the **same business day** they call in. This means that if a participant called in at 5 a.m. and determined they had to test that day, they would have at most 19 hours to get the test done, in order to meet the same business day requirement, because they would have to test before midnight. This measure was put into place in order to limit the participants' ability to flush his or her system before testing and also to meet the schedule of most collection sites. Maximus limits the number of hours between provision of notice of the test and the test itself by utilizing limited call-in hours and the requirement to test the same business day.

The program uses a standardized lab panel on all participants that includes the use of Ethyl Glucuronide (EtG), a direct metabolite of alcohol, to detect alcohol ingestion. EtG testing can detect the ingestion of alcohol for up to 72 hours after consumption. Since alcohol has the highest frequency of relapse (due to its availability) the urine test using EtG is the preferred alternative. Urine testing also picks up drug metabolites for several days after use. There are exceptions, such as very short-acting drugs that can only be detected on the same day. If the use of such drugs is suspected by the CCM, they can recommend additional tests to the DEC for a particular individual.

A participant can not be excused from testing on a given day without the approval of the DPM, Diversion Evaluation Committee (DEC) or DEC Consultant.

If a participant is traveling for some reason, approval must be obtained in advance and an alternate testing site identified in the locale traveled to.

Testing provided by FirstLab is for the basic panel. This consists only of urine testing. If other non-standard testing is required, such as hair follicle, Maximus will obtain approval of the DPM. One board requires the hair follicle test as a condition of graduation from the program. The hair test will show evidence of drug use if used in the past 90 days (window of results). The test is performed by taking a sample of hair close to the scalp that is about the diameter of a drinking straw. Several panels are available to test the hair, and Maximus uses the panel with the most capability. There is no provision in the contract under audit requiring Maximus to do this, nor is it in the new contract now in effect (after January 1, 2010), however Maximus provides this service as an add-on.

### **Specimen Collection**

Specimen collectors are approved by the sub-contractor for lab service, FirstLab.

Specimen collectors used by FirstLab are certified according to the most recent version of the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Specimen collectors employ the standards and procedures as outlined in the DOT Urine Specimen Collection Guidelines for the U.S. Department of Transportation (DOT) Workplace Drug Testing Programs. The DOT does not allow anyone else to use its chain of custody forms however, the chain of custody form utilized by FirstLab contains the same information as the federal form.

Collection sites are located throughout the United States, making it convenient for participants to be tested when required. Also, field staff is available to perform collections on the weekend if necessary.

Auditors selected a collection site in Sacramento to do a site visit, view the facilities and speak to the personnel on-site about their procedures applicable to the Maximus contract. All drug testing procedures were confirmed to conform to DOT drug testing standards. The site selected was an urgent care center. The site, as is typical, served many other customers besides FirstLab. They provided a sample of the chain of custody form used by FirstLab, which contained specific instructions as to how the collection should be handled. A participant reporting to provide a specimen is required to provide positive identification with a picture ID.

The manager on-site described how the form is used, and how the facilities are prepared for specimen collection. The lab must place a bluing agent into the toilet used, and also secure the faucets so that no source of liquid is available to the participant.

If a collection is required to be observed, collections are observed by same-gender collectors. Participants are notified by FirstLab that they will be subject to observed collections as a condition of monitoring. Under the contract currently under audit, not all collections had to be observed, but many were. Approximately 50% of dental board collections were observed, and 100% of Pharmacy collections. The new contract effective in 2010 now requires all collections to be observed.

To ensure that a specimen has not been adulterated, substituted or diluted, the laboratory will conduct specimen validity testing on every specimen. A Chain of Custody form accompanies every specimen and is initialed by the participant and the collector. If for some reason the chain of custody has been broken, the specimen is discarded. A participant is considered noncompliant if it is found that his or her specimen has been adulterated, substituted or diluted.

The following procedures are employed at the time of specimen collection:

- After washing hands, the donor shall remain in the presence of the observer and not have access to any water fountain, tap, soap dispenser, cleaning agent or any other materials that might be used to adulterate the specimen.
- The donor shall provide the specimen under the direct supervision of an observer (partially applicable under contract audited).
- Upon receiving the specimen, the observer shall determine that there is sufficient sample to enable all required testing to be performed. If a nonsufficient sample is provided, the participant will be asked to provide another sample of sufficient volume.
- After the specimen is collected, the observer shall inspect the urine specimen to determine its color and look for any indication of adulterants or dilutents. The specimen temperature is taken and should be in the range of 33°C and 38°C. Any unusual findings should be noted in the observer's record.
- When it has been determined that the specimen is valid, the observer will ask the donor to observe the transfer of the specimen and the placement of the tamper-proof seals over the bottle cap and down the sides of the bottles. The donor will sign the seals.

The specimen is prepared using the following procedures:

- Both the observer and the donor shall be present.
- The observer shall place labels on the bottle. The label should note the date of collection and a minimum of two identifiers for the donor, such as a name and date of birth.
- The observer shall enter the date and time of the supervised collection into their record and sign the record.
- The donor shall be asked to read and counter-sign the record.

- The observer shall complete the chain-of-custody form.
- All specimens are shipped to the laboratory via secure, overnight courier service as soon as possible after collected and will be securely stored in a refrigerated environment until it is shipped.

Audit observation at the collection site determined the collection is being performed according to the contract requirements. FirstLab reports to Maximus on monitoring regarding lab turn around times, errors, and broken chain of custody as these conditions occur. FirstLab maintains a log of collection site errors and provide immediate written and verbal corrective action in the event of a flaw. In the event that problems are identified at a collection site, FirstLab may recommend a change in the site.

### **Specimen Processing**

Specimens are processed within two business days of receipt by Clinical Reference Laboratories or other subcontracted laboratory. If a specimen is received on a Friday, it may not be tested until the following Tuesday allowing the participant to work as many as 5 or 6 additional days before a positive test is determined.

Presumptive positive tests will be confirmed by gas chromatography/mass spectrometry (GC/MS). Each specimen will be examined for the presence of compounds at the detection levels indicated in each panel. Positive screening results will be confirmed prior to reporting. This is a provision of laboratory certification. Positive test results must be confirmed by GC/MS prior to being reported as a positive. Thus for a confirmed positive test, average timeframe from the date of the test to the date the result becomes available will be longer than the time taken to report a negative result.

### **Testing Results and Information**

Certified Medical Review Officers are made available by FirstLab to review and evaluate drug testing results, if deemed necessary. FirstLab is able to provide web-based result retrieval, management reports and early warning indicators of participant noncompliance.

Audit testing of lab results imported to Maximus identified a recommendation for improvement in the timeliness of drug testing results. The issue is due to program participants using social security numbers rather than the Maximus unique identifier number at the collection site. Maximus no longer uses social security numbers due to federal requirements (HIPAA). Many collection sites still accept the SSN as the unique identifier for a participant. When a program participant gives a collection site their SSN, rather than their Maximus unique identifier number, a difficulty is created until First Lab manually reconciles the

results, matching up the SSN used with the Maximus unique identifier number. This can create a one-day delay in importing lab results to the Maximus system. A more complete description of this issue is found in Finding # 2 on page 22.

### **Support Groups**

There are approximately 70 nurse and health professional support group providers in California. Maximus maintains a list of support groups throughout the state. The list is used to refer participants to support group meetings which are required as a part of their recovery contracts. Providers of Nurse Support Groups are required to hold a California license as a registered nurse. Health Professional Support Group providers must hold a California license as a registered nurse, a marriage family therapist, a clinical social worker, a psychologist or psychiatrist. Providers must be clinically competent and have at least 3 years of experience providing chemical dependency, mental illness treatment, and referrals and monitoring for health care professionals. Group meeting facilitators have been selected by the boards. The Board of Nursing already had group meeting facilitators selected and Maximus has continued with the use of these, adding only one since taking over the contract. The approval process consists of verifying the facilitator's credentials, and the other components of the application.

All participants are required to attend health support groups or nurse support groups at least weekly until they enter the transition phase, which is typically the final year of program participation. Registered nurses are required to attend 1 time per week and health professionals are required to attend either 1 or 2 times per week. Although Maximus is not responsible for the delivery of the support group content (program), Clinical Case Managers make site visits to the meeting locations at least once per year. During the visits, the CCM completes an evaluation of the site and reports on any feedback obtained. These evaluations are maintained by Maximus and the information is summarized and provided to the Diversion Program Managers on a monthly basis. A support group may be subject to removal from the referral list if evaluations find that they are noncompliant, ineffective or have quality of care issues. The final decision to remove a support group from the referral list is made in conjunction with the Board(s). Support group sites may be visited more often if problems or concerns are identified.

The support group facilitators provide monthly reports to Maximus that indicate a participant's progress and attendance. Group facilitators will contact Maximus within 24 hours if a participant is absent from a meeting without having contacted the facilitator or if the facilitator suspects a participant has relapsed. Group facilitators do not determine if a participant's absence is excused or not. Non-attendance at group support is cause for a letter of non-compliance to be sent to the participant.

## **Determination of Inpatient/Outpatient Treatment**

As discussed in the Clinical Assessment Section of this report, starting on page 7, recommendations for inpatient or outpatient treatment are made by the clinical assessor, based upon their diagnostic tools and assessment of the participant's needs. Maximus makes a recommendation for treatment based upon these factors. Admission criteria at each treatment facility is generally standardized. However, it is possible for Maximus to make a referral which is then rejected by the treatment facility. Maximus is sometimes forced to accept another alternative which is not as preferable. The "old" standard for inpatient treatment was 28 days; however, many insurance companies stopped paying for the full 28 days. Therefore, a participant's insurance coverage may determine what type of treatment they receive. If it is found that intensive outpatient treatment does not result in any benefit, Maximus will recommend inpatient treatment. Inpatient treatment may be recommended to an applicant after the initial intake has been completed. In making this determination, the standard criteria that is followed includes whether an applicant is a danger to himself/herself, is a danger to others, or is unable to care for himself/herself.

The contract in force during the audit period contained no criteria for whether a participant should go into inpatient or outpatient treatment, and it would appear Maximus does not have full control over which type of treatment a participant receives.

## **Worksite Monitoring**

In order to ensure the safety of the public, as well as ensure compliance from participants, the Maximus Diversion Program uses Worksite Monitors (WSM) to monitor and document how participants conduct themselves in the workplace. A worksite monitor is a person who is also employed at the participant's worksite. The WSM is an observer of the participant's personal behavior and professional performance. A WSM is required to be in a position to have regular daily and ongoing contact with the participant and a willingness to contact Maximus to discuss any concerns. Reportable concerns would include attendance, behavior, and general attitude or competency. Likewise, a WSM will be notified by the clinical case manager that a participant must stop working if he or she tests positive for alcohol or drugs. Furthermore, the WSM must maintain confidentiality in the work environment.

As a condition of the participant returning to the workplace, a WSM must be designated by the participant and approved by Maximus. To become a WSM, the WSM applicant must be in a position to provide supervision for the Diversion Program participant. Qualification requirements may vary from board to board. Additionally, supervision requirements may vary from participant to participant

depending upon their perceived level of need during a given period of time. Maximus has established the following minimum criteria for approving Worksite Monitors:

1. The WSM must be available to the applicant or participant, preferably working the same shift/hours, for randomly scheduled contact.
2. The WSM must be a colleague or in a supervisory capacity to the participant, at least one management step above on the organization chart.
3. If no such person is available in the current work setting, the board can approve another person, perhaps within the same building.
4. The WSM must be comfortable with and willing to confront the participant when addressing unusual or outstanding behaviors.
5. This person must also be willing to notify Maximus immediately if a suspected relapse or unusual behavior is exhibited by the participant and comfortable knowing that these concerns will be immediately discussed with the participant.
6. If a WSM is in recovery, they should have at least five years of current and continuous sobriety.
7. The WSM may not be a current participant in the Diversion program. If the WSM was a previous Diversion participant, they shall have successfully completed the Diversion program.
8. The WSM may not be a relative of the participant.
9. Reports must be submitted to Maximus monthly for the first three months and quarterly thereafter.

A WSM is notified within 10 business days that they have been approved by the Clinical Case Manager. The new WSM is educated on their responsibilities and the process for identifying relapse behaviors and detecting whether an applicant or participant is a danger to themselves or the public. The WSM is also provided information about reporting. WSMs were required to submit quarterly reports to Maximus under the contract audited.

The audit determined that not all of the above criteria have been enforced. WSMs do not always work the same shift as the program participant. Worksite monitors are not always in a supervisory capacity. We also found, during the case file testing portion of the audit, weaknesses existed in some cases in the worksite monitoring area. See Finding 6 on page 29 for a description of the issues.

### **Timeliness of Diversion Services Provided by the Vendor**

Timeliness is covered in the case file testing, described on page 17 of the report. Findings 7 and 8, on pages 30 and 31 describe timeliness issues found.

## **Review the Thoroughness of Documentation of treatment, aftercare and monitoring services received by participants**

Thoroughness of Documentation of treatment, aftercare and monitoring services received by participants was determined during case file testing, described on page 17 of the report. Finding 1 describes a thoroughness of documentation issue found.

## **Maximus' Process for Approval/Disapproval of Providers/Contractors**

SB 1441 required the audit cover the vendor's disapproval process of providers or contractors that fail to provide effective or timely diversion service. During the period under audit Maximus replaced the sub-contractor providing lab services. The reason given is that the lab did not have national certification. Therefore, Maximus replaced the subcontractor with FirstLab, who uses only certified labs to conduct testing. First Lab is a third party contractor to the actual labs, and provides neutral oversight of these facilities.

Maximus also sub-contracts with about 70 clinical assessors. They apply and Maximus validates their licenses and ensures they have malpractice insurance. Typically these positions are licensed by the Board of Behavioral Sciences or the Board of Psychology as marriage and family therapists, licensed clinical social workers, or psychologists. All clinical assessors are evaluated quarterly in written reports based upon the parameters of 1) adhering to the scope of their contracts 2) the quality of their services, and 3) their communication with clients. Every two years, Maximus checks to re-certify each provider's license is current and insurance is up to date.

## **Case File Testing**

### **Max-CMS Tracking System**

Maximus created the Max-CMS computer system to assist with monitoring each participant. Creation of this database was a condition of the original contract, and has been fully complied with. This comprehensive database tracks all activity of a participant in the program. All board/committee Diversion program managers have access to the system, and can use it to monitor participant activity. The system contains many useful reports, including a history and profile report, clinical information, the customized recovery compliance terms, the compliance recovery plan, report of compliance/non-compliance, work restrictions, DEC reassessments, monthly self-reports, fee payments, whether or not phone check-in for drug testing is compliant, transition information, and more. Max-CMS capability has been enhanced continuously since Maximus took over the Diversion contract, and can produce some customized reports useful for monitoring. Max-CMS was created in 2004 therefore, for some long-term

Diversion participants there are some documents that needed to be accessed through the old, paper case files.

Case file testing was performed for all six boards and one committee as follows:

- Board of Registered Nursing (43)
- Physical Therapy Board of California (10)
- Board of Pharmacy (16)
- Osteopathic Medical Board (7)
- Veterinary Medical Board (6)
- Physicians Assistant Committee (25)
- Dental Board (26)

Files were selected using a random selection method. All files were subjected to the same procedures, including an examination of:

- Timeliness of diversion services provided by Maximus
- Determination that each board's specific contract provisions were incorporated into each board's cases and are appropriately documented as addressed by Maximus
- Documentation of the clinical assessment
- Date the DEC or committee met to consider applicant's entrance
- Whether or not applicant was accepted and why
- Documentation of non-compliance
- Whether or not the participant was deemed a public threat
- Whether or not the participant was terminated, is currently participating, or completed the program
- Evidence of ongoing monitoring by clinical case manager and/or compliance monitor
- Thoroughness of documentation of treatment, aftercare, and monitoring services received by participants
- Thoroughness of documentation of effectiveness of the treatment
- Compliance with each participant's individual contract terms, such as worksite monitoring, group meeting attendance, 12-step program attendance, aftercare, etc.
- Maximus' promptness in notifying the boards when a participant failed to comply with the terms of his or her individual Diversion contract or the rules of the board's program

Results of the case file testing follow in the Findings and Recommendations section. The Findings and Recommendations section also includes some issues applicable to contract performance without regard to any specific case or board, intended to provide changes or reforms necessary, as required by SB 1441.

## **SB 1441 Recommendations**

SB 1441 required this audit make recommendations regarding the continuation of the programs and any changes or reforms required to ensure that individuals participating in the programs are appropriately monitored. The scope of the audit encompassed only contract compliance and performance of the administrative vendor, Maximus, and not the DCA boards' performance as a broader aspect of the DCA's overall Enforcement program. Therefore, the recommendations in this report address only the administrative vendor and not the program as a whole. Decisions regarding the continuation of the programs are policy level decisions appropriately made by DCA management and the legislature once audits of the boards' Enforcement programs taken as a whole have been completed, and are beyond the scope of this review.

Maximus' monitoring of participants is described in the preceding several pages describing the Diversion program in general. Monitoring was specifically evaluated during the case file testing. Any instances in which participants were not adequately monitored are found in the Findings and Recommendations section of this report, beginning on page 20.

SB 1441 also required the audit to determine whether Maximus should provide the Department with periodic reports demonstrating the timeliness and thoroughness of documentation regarding non-compliance with the program. While Maximus currently provides the individual boards/bureaus with monthly and quarterly summary reports of the overall Diversion program, the DCA executive management team does not currently receive comparable reports. With the current emphasis on standardizing enforcement practices and the interrelated nature of the Diversion program with the enforcement process, it follows that the executive management team would benefit from customized reports providing high level detail customized to reflect their needs related to executive management decisions regarding these programs. Further, these reports should be structured to provide a mechanism to alert DCA management, first hand, to changes and issues as they arise, rather, than having to rely on board management to relay this information. Maximus' Diversion Program management has expressed a willingness to work with DCA's executive management to develop reports that would meet their specific needs.

Maximus should work with DCA's executive management team to develop high level summary reports of the program that provides the executive management with the information most useful in making department-wide decisions related to enforcement and Diversion programs.

Copies of the Diversion Program Manager monthly meeting agendas and minutes should be provided to the DCA executive management to allow them the ability to attend a meeting if necessary and to review the issues and concerns raised during the meetings.

## Findings and Recommendations

### **Finding 1 - Maximus Diversion records in some cases lack the required documentation of treatment, aftercare, and monitoring services received by participants.**

Samples of participants requiring aftercare were randomly selected for testing. Participant files were reviewed for specific recovery contract requirements. Some simply required aftercare or other treatment, whereas others required aftercare or treatment with reporting from the treatment provider at regular intervals. We noted an exception whenever there was a requirement and no documentation existed. A total of 63 files were tested for the attributes noted above, covering all 7 boards. Of the 63 tested, 41 (65%) files were found to have exceptions to the requirements. Many of the files requiring quarterly reports from treating therapists did not contain all required reports. Further, Maximus has acknowledged that they have been accepting the monthly self reports in which the participants state that they are participating in the aftercare programs or therapy sessions in lieu of the quarterly status reports from the providers as required by the respective contracts.

As a result, some of the participants' required treatment is not documented in accordance with the individual contracted terms. Further, Maximus cannot fully monitor the participant's treatment if they are not requiring updates from the treatment providers. Relying on the word of the participants does not adequately replace the status updates from these providers.

Senate Bill 1441 required this audit to review "...the thoroughness of documentation of treatment, aftercare, and monitoring services received by participants..."

Contract # 014-0511-3, contract term 7/1/03 – 12/31/09 Scope of Work, general requirements section 1.5, states that the contractor should, "Reassess and evaluate participants' recovery, and monitor compliance with recovery contracts."

It should be noted that additional treatment and aftercare are not required of all participants. The requirement is specific to each participant recovery contract, and there may be various requirements in any given recovery contract (i.e., Aftercare is just one of possibly 30 terms in a recovery contract). Within the contracts progress reports may not be required in the same intervals for all participants.

Although Maximus does in many cases require the documentation through the contractual agreements, they have admittedly not been enforcing the reporting requirements.

**Recommendation:**

Maximus should collect all required reports and information as required by the individual recovery contracts for all participants. Maximus should consider standardizing this requirement in participant recovery contracts to increase the efficiency of Maximus' monitoring of the participant treatment, as currently not every recovery contract requires written status reports for treatment provided.

## Finding 2 – Positive Lab Result Reporting- Timeliness Issues

Compliance information contained within the participant files regarding the out of range, dilute, or positive urine tests were mostly Maximus' own internally generated documents, consisting of non-compliance letters and "occurrence reports". Maximus was using the occurrence reports to document the date they received notification from FirstLab of a positive test result. The contract in force during our testing period of 7/1/2006 through 6/30/2009 requires Maximus to report to the board within one business day of the receipt of the results by Maximus, cases in which bodily fluid results were positive.

To test the timeliness of the reporting of positive urine results by Maximus to the boards we had to first ascertain whether we could obtain reliable third party information documenting when lab results were actually available to Maximus.

We contacted FirstLab, Maximus' subcontractor for laboratory testing. FirstLab told us that there is an "import date" that can be easily accessed by Maximus on FirstLab's website. The import date is the date the testing lab imports the results into FirstLab's system. However, upon testing the dates in the system, we noted that some test results seemed to be one day off. In some cases Maximus clearly did not have access to the results data on the "import date" but rather about one day later. FirstLab's account manager in charge of the Maximus account stated that there are exceptions in the system when a participant profile does not exactly match up with the information given by the participant, and this causes a delay in the viewing of results on the system by Maximus. The exceptions are commonly caused by the participant using a social security number at the collection site rather than their unique Maximus identifier. When this happens FirstLab must manually match up the participants SSN to the Maximus identifier before results are available to Maximus on the system. FirstLab does this at least once per day, which may account for the one day delay seen in the dates results were available to Maximus.

We tested 100% of positive results for a six month period for each board (except BRN, for which we tested only one month due to the larger volume of participants). The chart below identifies the number of positive test results for the six month (or one month in the case of BRN), and the time frames it took for the board to receive notification of the positive result.

Because the contract requires Maximus to report within one business day **after** obtaining the results, we took exception to all positive tests that were reported to the boards more than two days after the "import date". This threshold provided Maximus with the one business day requirement and one additional day to account for the lag between the import date and their ability to view the information. Our specific testing to determine Maximus' timeliness in reporting positive tests results to the boards are as follows:

Board	Number of Positive Results	Exceptions	% of Exceptions to Total Tested	Could Not Determine <sup>1</sup>
Dental Board	10	0	0%	2
Physicians Assistants Committee	6	2	33%	2
Board of Pharmacy	2	0	0%	n/a
Veterinary Medicine Board	4	0	0%	n/a
Board of Osteopathic Medicine	1	0	0%	n/a
Physical Therapy Board	No + results	0	0%	n/a
Board of Registered Nursing	13	2	15%	n/a

<sup>1</sup> Could Not Determine represents those files reviewed that did not have fax receipt dates confirming the actual delivery of the test results to the board on the date noted as the "Date Board Notified" on the occurrence reports.

As shown in the chart above, notification of positive test results contained exceptions for the Physicians Assistant Committee and the Board of Registered Nursing for the sample months selected. In the case of the Board of Registered Nursing, the two exceptions consisted of one that took one extra business day to notify, and one that took three extra days to notify. For the Physicians Assistant Committee, one exception took one extra business day to notify, and one exception took 3 extra business days to notify. The Physical Therapy Board had no positive results during the period selected for testing.

Further, we met with a clinic manager for a collection site used by Maximus participants. This manager stated that the normal practice for their facility is to require social security numbers unless the donor has a donor ID card. She stated that they do not feel comfortable accepting donor IDs without one. As noted above, this is likely a contributing factor to the delay in Maximus' ability to view the results as soon as they are imported. Providing participants with a donor ID card will provide official information to the collection sites to check against the information on the collection forms and serve to reduce the number of data exceptions that cause delays in Maximus actually obtaining the results.

Contract # 014-0511-3, contract term 7/1/03 – 12/31/09, Scope of Work, general requirements section 1.6, states that the contractor should, "Report in writing, within one business day, to the DEC and/or DPM any applicant or participant

who is unsuccessful in maintaining recovery, is non-compliant with contract requirements, or presents a threat to the public health and safety or themselves.”

The current process does not provide the boards with the source information needed to monitor compliance with the reporting timeframes required by the contract. Further, participants providing their SSNs rather than their Maximus unique identifier numbers to the collection sites are causing delays in Maximus’ ability to view lab results.

**Recommendations:**

The boards should be provided with regular reports similar to those provided to us by Maximus that allowed us to choose our sample for testing. With these reports and the occurrence reports already provided to the boards upon a non-negative test result by a participant, the boards will be better equipped to monitor Maximus’ compliance with the contract terms related to timely reporting on an ongoing basis.

Additionally, Maximus should carefully monitor its reporting of test results to the boards to ensure they are meeting the reporting timeframes.

Maximus and FirstLab should consider utilizing donor ID cards to provide collection sites with official information regarding the participant, including the unique identifier used in the FirstLab system, in an effort to reduce the number of exceptions in the system, which will allow Maximus to view the results earlier.

**Finding 3 - Maximus failed to adequately monitor one participant's compliance with the bodily fluid testing, resulting in a participant who was not testing for more than two months, being allowed to continue in the program unabated.**

One participant was terminated for non-compliance for ceasing to call and test for more than two months. A note on the participant's case log by Maximus' compliance monitor assigned to the board stated that "no one knew he had not called in or tested for two months." There were no non-compliance letters regarding this situation until more than two months after the participant stopped calling in and testing. Maximus is normally notified of missed calls and tests by the laboratory subcontractor shortly after the missed call or test via the internet site that Maximus says they check daily, so the lack of information does not make sense and presents a concern regarding the effectiveness of Maximus' monitoring of this participant's case.

As a result, a participant was allowed to continue virtually un-monitored as far as urine testing is concerned for over two months.

The contract in force during our testing period of 7/1/2006-6/30/2009 requires Maximus to report within one business day participant non-compliance with contract terms. Maximus stated in its bid that missing more than two tests within any three month period will be considered chronic and will be reported the next business day after the third missed test.

The cause is unknown, however, it seems that there was a lapse in monitoring for this particular participant.

This severe non-compliance was noted in only 1 of the 177 case files tested.

**Recommendation:**

Maximus should ensure that it adequately monitors each of its participants in accordance with the diversion contract.

**Finding 4 - Maximus has combined some of the records for certain licensees with multiple participations within the program, in one case, resulting in the erroneous purging of treatment records.**

There were several licensees that have participated in the program previously, and in some of these cases information from previous participation was included in the current files. This blending of files becomes a problem if Maximus begins to purge old cases. Because there are no identifiers on the case files distinguishing an old participation from the current, a new file could be purged along with the old information. In fact, this happened in two of the tested files. In one instance, the participant had been in the program previously and the old case had been flagged to be purged. Initially, Maximus could not find the current file with the exception of some of the very recent information. After some searching they were able to find part of the current case file which had been erroneously placed in the archived storage boxes. However, even this information was not complete. The support group reports, self reports, treatment information, and 12-step cards have seemingly been purged from the physical files. However, this information is still contained in the max-cms system.

In the other case, a case log note from the wrong participant was placed into another participant's case log. This compromises participant confidentiality and increases the risk that case decisions could be made based upon inaccurate information, as both case files were affected. One was missing a case log note it should have had, while the other included erroneous information.

Further, another case that was closed as a public risk contained information on all three participations in the program, when only the most current was relevant to the public risk closure. This case is sent to the board, whose enforcement investigators use the information for the enforcement action to be taken on the licensee.

As a result, each participation in the program is not being provided with separate case files, making the chances of erroneous purging, file misplacement, and improper disclosure of information more likely.

Maximus has acknowledged this problem and has stated they are already taking steps to correct it.

The contract in force during our testing period of 7/1/2006-6/30/2009 requires Maximus to maintain documents and records for a period of three years after final payment under the contract.

In some cases, Maximus' staff has combined case files, for unknown reasons, however, Maximus stated they will devise a procedure to prevent this from happening.

This exception occurred in 3 (2%) of the 177 case files tested.

**Recommendation:**

Maximus should ensure that it keeps separate files for each participation when a participant has been in the program more than one time.

**Finding 5 - A participant had multiple noncompliance issues**

One participant's 12-step meeting cards for May-July 2006 were received late in mid-August 2006. There was no signed copy of the pre-entry agreement in the file. The participant did not have a Worksite Monitor Agreement in place. There was no documentation of timely notification to the Board of these issues.

There was no indication of the reason that the noncompliance occurred or that the noncompliance was not timely reported to the Board.

All noncompliance should be monitored and the participant should be compelled to comply or be terminated from the program.

**Recommendation:**

We recommend that Maximus document noncompliance and report noncompliance to the Board in a timely manner. In addition, if a participant's contract calls for a worksite monitor and none is obtained, the participant should not be allowed to practice.

**Finding 6: One participant initially did not have a worksite monitor in place. When a worksite monitor was subsequently put in place, the worksite monitor agreement did not provide enough information to determine if the worksite monitor was not a subordinate employee of the participant.**

A participant's case log notes initially stated that the participant does not have a worksite monitor in place. When a new worksite monitor was put in place, it was noted that a "new Employee" is the participant's new worksite monitor. Because the Worksite Monitor Agreement does not require a worksite monitor to indicate a license number or a job title, it is difficult to determine whether the worksite monitor was a superior or a subordinate employee of the participant.

Business and Professions Code Section 4870 states that, "Each veterinarian and registered veterinary technician who requests participation in a diversion program shall agree to cooperate with the treatment program designed by a diversion evaluation committee. Any failure to comply with the provisions of a treatment program may result in termination of the veterinarian's or registered veterinary technician's participation in the program."

Maximus stated that a job title is not required at this time on the worksite monitoring agreement. However, the new contract effective January 2010 requires that a worksite monitor agreement include the worksite monitor's job title as well as a copy of the organizational chart.

A worksite monitor that is independent and not a subordinate employee of the participant helps ensure that worksite monitor activities and reports are accurate and unbiased.

**Recommendation:**

Worksite Monitor agreements should have the monitor's official title stated on the form to document they are not a subordinate of the participant.

**Finding 7: Clinical assessments were not done timely due to limited availability of licensed therapists, and for some participants entering inpatient treatment facilities upon application into the diversion program.**

In one case, we found a participant's clinical assessment was not done within four weeks of application into the program. It appears that the delay was due to the assigned licensed therapist. The case log shows that Maximus made numerous attempts to contact the licensed therapist to schedule the clinical assessment. However, because the licensed therapist did not return the phone call timely, the clinical assessment was not done within four weeks of the participant's application. Maximus may not have had an alternate licensed therapist available to conduct the required clinical assessment.

Additionally, we found that in 16 of the 98 cases (16%) reviewed, the participant's clinical assessment was not done within four weeks after the initial intake interview. However, we note that in some cases, the participant was in an inpatient treatment facility. Therefore, the participant's availability to schedule the clinical assessment may have been problematic.

Contract #014-0511-3-8, contract term 7/1/03 – 12/31/09, General requirements, section 1.3 requires that Maximus conduct comprehensive, confidential, in-person assessments of applicants within four weeks of application. Further, Scope of Work, general requirements section 2.2 requires that Maximus evaluate and monitor treatment providers and other resources for adherence to the Diversion Program's criteria.

**Recommendation:**

We recommend that Maximus have alternate licensed therapists in cases when the licensed therapist assigned to a particular participant is not available.

For board referred participants, Maximus should institute procedures addressing when the assessor or participant is unreachable, so that the lack of progress in scheduling the clinical assessment is reported to the board.

**Finding 8: Maximus placed reliance on a third party administrator to conduct the required clinical assessment; however, it was not done. As a result, the participant's recovery contract may not properly reflect the treatment required for a successful recovery.**

An applicant was in a 90-day in-patient treatment facility when the applicant initially applied to enter the Diversion program. During the intake interview, Maximus decided that because the facility has a licensed therapist, it would rely on the facility to conduct the clinical assessment. However, we found that the clinical assessment that includes the required diagnosis was not provided by the facility.

Contract #014-0511-3-8, contract term 7/1/03 – 12/31/09, Scope of Work, general requirements section 2.2 states that Maximus evaluate and monitor treatment providers and other resources for adherence to the Diversion Program's criteria. Moreover, a board specific requirement, section 1.3 states that a comprehensive in-person assessment will be completed within four weeks of the initial intake.

Maximus relied on the treatment facility to conduct the required clinical assessment. However, it appears that Maximus did not ensure that the clinical assessment was performed.

As a result, the participant's clinical assessment was not done timely. Moreover, because the clinical assessment is a factor in determining appropriate treatment, the participant's recovery contract may not properly reflect the treatment required for a successful recovery. In addition, it may represent a conflict of interest for a third party administrator to conduct a clinical assessment and recommend treatment to be provided, when in fact they are being paid to provide treatment to a participant.

**Recommendation:**

Maximus should follow-up timely with any third party/sub-contractors to ensure completion of the clinical assessment required for proper treatment and successful recovery.

To limit the appearance of conflict of interest issues, Maximus should limit reliance on in-house licensed therapists to conduct the clinical assessment. Because the assessment could recommend continual treatment in the facility where the licensed therapist is employed, it might be interpreted by someone from outside the facility that the licensed therapist is recommending such treatment for continual employment or continued business for its employer (treatment facility).

**Finding 9: Discrepancy in participant's initial call dates exist in Maximus' database.**

Maximus' database keeps track of all correspondence with either the board or participant. During our review, we found 36 instances of 133 cases reviewed (27%) where the initial call date with the participant did not match the date noted in the case log and what was reported in the participant's History & Profile report.

Contract #014-0511-3-8, contract term 7/1/03 – 12/31/09, Scope of Work, general requirements section 3. the contractor should, "Provide, maintain and upgrade as necessary a computer database system for the effective and efficient monitoring of Diversion Program applicants and participants and production of statistical reports."

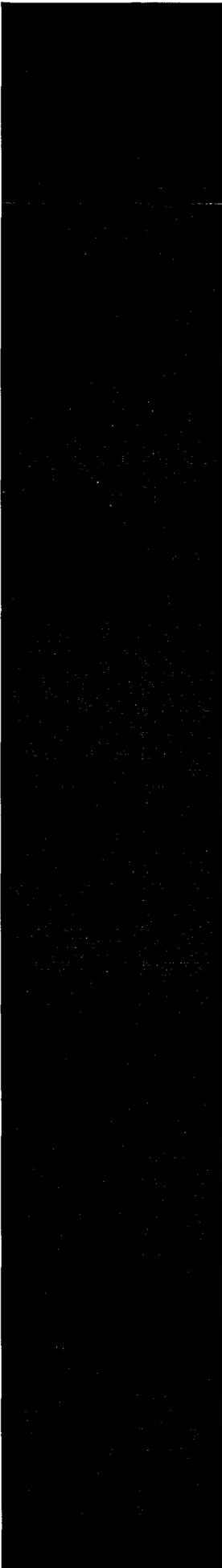
The difference in when the initial call was received by Maximus could be due to a programming error.

It may appear that the participant called to apply for the program earlier or later depending on what was reported in their History & Profile report. As a result, for those participants who are board ordered to be in the program, the report may show that the participant called Maximus later than they should have.

**Recommendation:**

Maximus should better define what date to use for the initial call date when preparing the History & Profile report.

Maximus should ensure the database reporting function is programmed correctly to ensure correct dates are reported on the participant's History & Profile report.



# **ATTACHMENT I**

## **Maximus' Response to the Draft Report**

**MAXIMUS Response to the DCA audit of the  
California Health Professionals Diversion Program  
April 2010**

**EXECUTIVE SUMMARY**

MAXIMUS appreciates the opportunity to participate in this audit and respects the decision of the Department of Consumer Affairs (DCA) to conduct such an audit. We understand the importance of an agency to audit and confirm that an Administrative Vendor is in compliance with contract requirements and the program is operated as designed. This audit includes the start of the MAXIMUS and DCA partnership which began in 2003 and continues today. Most recently, we are pleased to be working closely with the respective Diversion Program Managers (DPMs) to implement the terms of the new agreement beginning on January 1, 2010.

We applaud the DCA for the incorporation of key elements contained in SB1441 into the program before the legislation was enacted. As noted in our responses, the new contract has resulted in several improvements to processes and procedures that further strengthen the program. Quality and continuous improvement are core tenets of the services MAXIMUS provides to its clients and stakeholders. We continue to stand ready to work closely with the DCA to continue to improve the processes which protect the safety of the healthcare consumers of California.

**FINDING #1**

**MAXIMUS diversion records in some cases lack the required documentation of treatment, aftercare, and monitoring services received by participants.**

**RECOMMENDATION:**

MAXIMUS should collect all required reports and information as required by the individual recovery contracts for all participants. MAXIMUS should consider standardizing this requirement in participant recovery contracts to increase the efficiency of MAXIMUS monitoring of the participant treatment, as currently not every recovery contract requires written status reports for treatment provided.

**MAXIMUS RESPONSE:**

Thank you for the recommendation for standardization in the requirements and collection of reports and information in support of the elements in the participant's *Recovery Contract*. In response to the recommendation, MAXIMUS has initiated a preventative action plan. Effective December 23, 2009 revisions were made to the *Recovery Contract* to include a participant contract term for the requirement for providing the *Treatment Provider Reports*, when appropriate, to their Clinical Case Manager. Additionally, a blank *Treatment Provider Report* is now mailed to the participants on a quarterly basis so they have it readily available. While the inclusion of this information is not a contractual requirement for MAXIMUS under the agreement with the Department of Consumer Affairs, if provided, the documentation increases consistency in monitoring participant treatment, standardization to the collection of reports and improves the communication between the MAXIMUS Clinical Case Manager and the Treatment Provider. *Treatment*



*Provider Reports* are one of many elements of recovery that are monitored to determine compliance with the terms of the Recovery Contract.

**FINDING # 2**

**Finding #2 was not summarized in the audit report.**

**RECOMMENDATION:**

The boards should be provided with regular reports similar to those provided to us by MAXIMUS that allowed us to choose our sample for testing. With these reports and the occurrence reports already provided to the boards upon a non-negative test result by a participant, the boards will be better equipped to monitor MAXIMUS compliance with the contract terms related to timely reporting on an ongoing basis.

Additionally, MAXIMUS should carefully monitor its reporting of test results to the boards to ensure they are meeting the reporting timeframes.

MAXIMUS and FirstLab should consider utilizing donor ID cards to provide collection sites with official information regarding the participant, including the unique identifier used in the FirstLab system, in an effort to reduce the number of exceptions in the system, which will allow MAXIMUS to view the results earlier..

**MAXIMUS RESPONSE:**

Thank you for the recommendations. MAXIMUS is always open to suggestions that further strengthen the communication between the Department of Consumer Affairs and the Diversion Program. We support this recommendation regarding the reports and view as a continuous improvement opportunity. We are prepared to initiate discussion with the department regarding their report needs. MAXIMUS will coordinate specifically with the Diversion Program Managers regarding this program enhancement via our regularly scheduled Status Meetings.

Beginning with the new contract term starting January 1, 2010, MAXIMUS has adopted new reporting requirements for positive lab results as prescribed by the Department of Consumer Affairs. These new requirements are monitored via an independent Quality Assurance review.

Donor ID cards are provided to applicants and participants at the time of registration with FirstLab. As an enhancement to the registration process, the applicants and participants are to be encouraged to use their Donor ID card, and not their Social Security Numbers. Additionally, MAXIMUS has opted to move away from the use Social Security Numbers in the program in an effort to further protect the Personal Health Information (PHI) of our program participants.

**FINDING #3**

**MAXIMUS failed to adequately monitor one participant's compliance with the bodily fluid testing, resulting in a participant who was not testing for more than two months, being allowed to continue in the program unabated.**

**RECOMMENDATION:**

MAXIMUS should ensure that it adequately monitors each of its participants in accordance with the diversion contract.

**MAXIMUS RESPONSE:**

MAXIMUS recognizes the importance of program monitoring specific to bodily fluid testing and agree that participant compliance is to be closely monitored. In this particular circumstance, the participant was in recovery from surgery and as a result unable to work. During recovery he was not working and was monitored by his Clinical Case Manager for the other applicable elements of his compliance terms. The participant did not call in for testing as he perceived he was not required to do so during the surgery recovery period and until active engagement in the program resumed.

Based on the circumstances of this participant as it relates to the finding, we respectfully submit that we do not concur that the participant was allowed to continue in the program unabated. We are also pleased to note that the audit identified only one case in a sample size of 177 that was noteworthy. We do, however, acknowledge that program monitoring in the area of bodily fluid testing should be periodically reviewed for opportunities to increase controls and the effectiveness of monitoring. As recent as August 2009, we have further refined our processes in response to participants who fail to call or test. This is also an aspect of the program that is discussed regularly with the Diversion Program Managers and we will continue to do so in efforts to further strengthen the monitoring of testing.

**FINDING #4**

**MAXIMUS has combined some of the records for certain licensees with multiple participations within the program, in one case, resulting in the erroneous purging of treatment records.**

**RECOMMENDATION:**

MAXIMUS should ensure that it keeps separate files for each participation when a participant has been in the program more than one time.

**MAXIMUS RESPONSE:**

Periodically, there are participants that return to the Diversion Program. In this case, the participant already has both an electronic and hard copy file. Upon return to the program, it is best to create a new hard copy file to ensure the purging cycle is appropriately applied. Upon the identification of this finding, MAXIMUS immediately implemented a corrective action plan that includes the paper file being sealed and filed in a separate location from active files within 30 days of the closure of the case. This practice was fully implemented on October 1, 2009.

**FINDING #5**

**One participant's 12-step meeting cards for May-July 2006 were received late in mid-August 2006. There was on signed copy of the pre-entry agreement in the file. The participant did not have a Worksite Monitor Agreement in place. There was no documentation of timely notification to the Board of these issues.**

**There was no indication of the reason that the noncompliance occurred or that the noncompliance was not timely reported to the Board.**

**All noncompliance should be monitored and the participant should be compelled to comply or be terminated from the program.**

**RECOMMENDATIONS:**

We recommend that MAXIMUS document noncompliance and report noncompliance to the Board in a timely manner. In addition, if a participant's contract calls for a worksite monitor and none is obtained, the participant should not be allowed to practice.

**MAXIMUS RESPONSE:**

MAXIMUS recognizes the critical nature of adequate supervision when a participant returns to work. The case circumstances associated with this finding are from one participant in 2006, therefore, we do not believe that this finding is representative of a systemic concern related to case documentation in need of a formal corrective action plan. However, we believe in continuous improvement in the operations of the Diversion program and in our role as your Administrative Vendor and we have recently enhanced our Diversion Quality Assurance (QA) program for the new contract period and its new requirements. We took this opportunity to also review the manner in which we review case documentation and reporting from a quality perspective. We have enhanced our QA checklist to increase the focus on this important element of the case record.

The Department of Consumer Affairs and its respective Boards has our commitment to continue the use our Quality Assurance methodology and continuous improvement initiatives to increase the effectiveness of the Diversion program in the new contract period.

**FINDING #6**

**One participant initially did not have a worksite monitor in place. When a worksite monitor was subsequently put in place, the worksite monitor agreement did not provide enough information to determine if the worksite monitor was not a subordinate employee of the participant.**

**RECOMMENDATION:**

Worksite Monitor agreements should have the monitor's official title stated on the form to document they are not a subordinate of the participant.

**MAXIMUS RESPONSE:**

As a component of the new contract implementation, the Worksite Monitor Agreement is being revised to include the information regarding position and license number of the Worksite Monitor. The approval

process for the Worksite Monitor now includes a request for the Organizational Chart to verify the position of the participant in relation to the Worksite Monitor.

**FINDING #7**

**Clinical assessments were not done timely due to limited availability of licensed therapists, and for some participants entering inpatient facilities upon application into the diversion program.**

**RECOMMENDATION:**

We recommend that MAXIMUS have alternate licensed therapists in cases when the licensed therapist assigned to a particular participant is not available.

For board referred participants, MAXIMUS should institute procedures addressing when the participant is unreachable, so that the lack of response is reported to the board.

**MAXIMUS RESPONSE:**

While we believe that these cases do not represent a systemic concern with delays in conducting assessments, MAXIMUS does agree there is a continuous improvement opportunity to review the current resource level of Assessors for any adjustments warranted.

The audit records show 16 findings of 98 cases reviewed. All 98 participants had an assessment completed; however, 16 were identified as not completed timely. One of the 16 cases met the contract requirement with an assessment completed 15 days after intake. With regard to six of the cases with this finding, the delays were related to participants who were in treatment. When in treatment, the participant is legitimately unavailable for the Assessment. In two additional cases, the assessment was conducted by an independent assessor while the participant was in treatment, either on a pass or as an excused absence from an intensive outpatient program. As a result, we respectfully submit that these cases were not findings in which a MAXIMUS response is required.

Concerning the remaining seven cases, in three of the seven, an assessment was conducted within 31 calendar days; the requirement is within four (4) weeks. During this timeframe the MAXIMUS staff was making contact with the Clinical Assessor to secure an appointment. The remaining three cases all had assessments conducted; however, delays were related to rescheduling the appointment times.

MAXIMUS understands the importance of the timely clinical assessments. In response to the new contract period, we engaged in securing the new Subcontractor Agreements for Clinical Assessors. This process creates an opportunity for MAXIMUS to further review timely response requirements when securing appointments for the participants.

**FINDING #8**

**MAXIMUS placed reliance on a third party administrator to conduct the required clinical assessment; however; it was not done. As a result, the participant's recovery contract may not properly reflect the treatment required for a successful recovery.**

**RECOMMENDATION:** MAXIMUS should follow up timely with any third party/sub contractors to ensure completion of the clinical assessment required for proper treatment and successful recovery.

To limit the appearance of conflict of interest issues, MAXIMUS should limit reliance on in-house licensed therapists to conduct the clinical assessment. Because the assessment could recommend continual treatment in the facility where the licensed therapist is employed, it might be interpreted by someone from outside the facility that the licensed therapist is recommending such treatment for continual employment or continued business for its employer (treatment facility).

**MAXIMUS RESPONSE:**

In the one case noted for this finding, MAXIMUS provided the auditor a copy of the treatment provider report dated 7/9/09. The report included a 5-Axis diagnosis, as is required. This report fulfills the requirement for timely completion of clinical assessment, and therefore, was accepted by the program.

With the terms of the contract beginning January 1, 2010, MAXIMUS agrees to obtain a clinical assessment from an independent third party for all new applicants.

**FINDING #9**

**Discrepancy in participant's initial call dates exist in MAXIMUS database.**

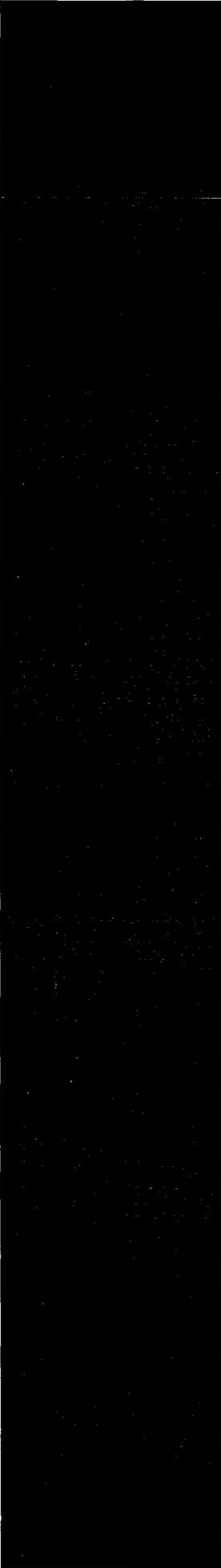
**RECOMMENDATION:**

MAXIMUS should better define what date to use for the initial call date when preparing the History and Profile report.

MAXIMUS should ensure the database reporting function is programmed correctly to ensure correct dates are reported on the participant's History and Profile report.

**MAXIMUS RESPONSE:**

During the time of the audit, which coincided with the start date of the new contract period, MAXIMUS identified that there were conflicting definitions and/or conditions being applied to the use of the data elements *date of initial contact* and *intake date*. As a result, date variances occurred. Please note, the database reporting functionality is correct, only the application of the definition of terms is applicable to the findings noted. MAXIMUS initiated discussion with the Diversion Program Managers (DPMs), on behalf of their respective Boards, to determine how best to proceed and obtain their direction. MAXIMUS has received clarification from the Boards and the Department of Consumer Affairs legal counsel regarding the definition of the point of initial contact. The History and Profile Report will be revised to meet the requirements related to initial call date as directed. We will keep the DPMs apprised of the progress of this effort during the regularly scheduled Status Meetings.



# **ATTACHMENT II**

## **Internal Audit Office Comments on Maximus' Response to the Draft Report**

## Internal Audit Office Comments on Maximus' Response to the Draft Report

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To provide our perspective on Maximus' response to our draft audit report, we are commenting on the issues below.

**Finding 3** - To ensure the proper context of this finding we must reiterate that Maximus stated in its case log notes that no one was aware that this participant had not called into the lab or tested for over two months. If Maximus is monitoring compliance with the drug testing requirements daily, it does not make sense that this issue would go unnoticed for over two months. Regardless of the reason the participant was not compliant with the testing requirements, this is still a non-compliance situation and should be dealt with in a timely manner.

**Finding 8** - The progress report provided to the auditor by Maximus dated 7/9/09 was not for the required clinical assessment, but was presumably for the aftercare treatment provided by the same facility to the participant. The dates of treatment did not correspond to the patient's in patient treatment period, and could not have fulfilled the requirement for the time period in question.

# **Attachment 11**



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

**STATE BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
ENFORCEMENT COMMITTEE  
MINUTES**

**DATE:** September 14, 2010

**LOCATION:** Samuel Greenberg Board Meeting Room  
Los Angeles International Airport  
1 World Way  
Los Angeles, CA 90045

**COMMITTEE MEMBERS**

**PRESENT:** Randy Kajioka, PharmD, Chair  
Greg Lippe, Public Member  
Ramón Castellblanch, Public Member  
Tappan Zee, Public Member

**STAFF**

**PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Robert Ratcliff, Supervising Inspector  
Judi Nurse, Supervising Inspector  
Tessa Fraga, Staff Analyst

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**Call to Order**

Chair Kajioka called the meeting to order at 9:51 a.m.

1. Request from Omnicare to Modify Existing Requirements in Pharmacy Regulations:
  - 16 California Code of Regulations Section 1745 Regarding Partial Filling of Schedule II Prescriptions
  - 16 California Code of Regulations Section 1793.7 Regarding Requirements of a Pharmacy Employing Pharmacy Technicians

Chair Kajioka provided that earlier this year, the board received two requests for modifications of requirements in board regulations from Omnicare. He advised that this meeting will be the first time the board or one of its committees has the opportunity to discuss these requests.

## Presentation to the Committee

Scott Huhn, PharmD, Regional Compliance Manager for Omnicare, provided a presentation to the board on each of the following requests.

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

#### Current Regulation

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.

## **Request**

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.

## **Discussion**

Dr. Huhn reviewed CFR section 1306.13(b) which 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."

Dr. Huhn stated that Omnicare is requesting that § 1745(c)(2) be amended to incorporate this alternative allowance from CFR § 1306.13(b). If amended, § 1745(c)(2) would read:

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original prescription (or on another appropriate record uniformly maintained and readily retrievable), also recording the initials of the pharmacist dispensing the prescription;

Dr. Huhn stated that this change would allow for the option of electronic records and would eliminate the need to retain and document a hard copy for each partial fill. He explained that it can be cumbersome to retrieve and document the hard copy for each partial fill over the course of 60 days.

Greg Lippe expressed concern that the electronic record will not be consistent with the original prescription.

Dr. Huhn provided that the original prescription would only contain the initial information and the electronic record would include all updated information.

Ramón Castellblanch requested clarification on the current standard.

Executive Officer Virginia Herold provided that the current regulation has remained unchanged since it was promulgated. She advised that at the time it was promulgated, computers were not used in pharmacies at the same level they are used today.

Supervising Inspector Robert Ratcliff added that the current regulation allows for better patient care for those people who may not live for an extended length of time. He recommended that a simple word change be made to change “and” to “or”:

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

Ms. Herold asked if this would create any confusion from an enforcement perspective.

Dr. Ratcliff indicated that this option would not be a problem for enforcement activities. He suggested that pharmacies develop policies and procedures to ensure that all staff pharmacists maintain records in the same manner.

Mr. Lippe expressed concern regarding this process in the event a pharmacy’s computer system crashes. He explained that if this were to happen, the information available on the hard copy would not be updated or accurate. Policies and procedures should be required to explain how records would be created and maintained.

Dr. Hunh provided that information is stored daily to either a disc or an external hard drive.

Mr. Lippe suggested that pharmacies be required to only use information on the electronic record if the original hard copy has been modified. He also suggested that pharmacies be required to only maintain electronic records if they have available technology.

Dr. Kajioka discussed that not all pharmacies have the same available technology. He cautioned the committee from being overly prescriptive in this area.

Ms. Herold suggested that the following be added to § 1745(c)(2):

A pharmacy that partially fills a prescription pursuant to this section shall do so according to policies and procedures developed by the pharmacy.

Mr. Zee expressed concern that allowing pharmacies to develop their own policies and procedures would lead to inconsistency.

Mr. Zee expressed concern that the committee is moving beyond reviewing and or modifying the section and is instead addressing the issue of how pharmacies maintain their data.

The committee further discussed the option of allowing pharmacies to maintain electronic records or document on the original prescription. This option would be consistent with existing federal regulations.

Dr. Ratcliff provided that Business and Professions Code section 4070(c) requires that changes to electronic records must be made by a pharmacist as well as all changes must be noted to indicate the type of change made. He advised that computer crashes will impact the entire pharmacy and all prescriptions to be dispensed. Mr. Ratcliff recommended that pharmacists be allowed to exercise their professional judgment in this type of situation in order to take care of the patient.

Ms. Herold asked what percentage of a prescription that is partially filled may not reach the patient in a long-term care facility.

Dr. Hunh provided that typically all of the prescription is used.

Dr. Ratcliff provided that this amendment will eliminate the need for pharmacists to refer back to the paper copy of the prescription. He stated that nothing else within the current process will change.

No public comment was provided.

**MOTION:** Recommend to the full board that section 1745(c)(2) be amended to read:

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

M/S: Zee/Lippe

Support: 4    Oppose: 0    Abstain: 0

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.

### **Current Regulation**

#### **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.

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 section 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.

### **Request**

Permit a waiver of 16 California Code of Regulations Section 1793.7(a) to authorize a pharmacy technician utilizing bar-code scan under supervision of a pharmacist to perform the medication label check prior to delivery to the patient.

### **Discussion**

Dr. Hunh stated that the goal of this request is to improve pharmaceutical care for patients, reduce medication errors, and allow pharmacists to focus on patient-centered activities such as medication therapy management.

Dr. Hunh provided that 12 states have approved this process. He stated that verification confirms that the prescription was filled according to the practitioner's order. Dr. Hunh explained that a pharmacist is actively supervising the medication verification process and is identified on the end of day reports in the operating system.

Dr. Hunh discussed the benefits of bar-code technology and added that it is recommended by the Institute for Safe Medication Practices and the National Association of Boards of Pharmacy (NABP).

Dr. Kajioka asked who would be indicated as the dispenser.

Dr. Hunh provided that both the technician and the pharmacist will be indicated as the dispenser.

Dr. Kajioka provided that the current regulation does not show that technicians have any ownership of the prescriptions that are dispensed.

Dr. Hunh sought clarification on how section 1793.8 would apply to this area.

Dr. Kajioka provided that he does not believe that the board has authority to waive a regulation unless the procedure is part of an experimental program conducted with a school of pharmacy. He requested that the board seek clarification on this issue from the board's legal counsel.

It was the consensus of the committee to seek legal clarification from board counsel and suggested that Omnicare develop an experimental program with a school of pharmacy.

Dr. Hunh asked if the board will provide any written notice to Omnicare to use to approach the schools of pharmacy.

Ms. Herold recommended that Omnicare develop a proposal to bring before the full board before approaching schools of pharmacy.

No public comment was provided.

2. Question and Answer Session on the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound, and Sections 1751-1751.8, Pharmacies That Compound Sterile Injectable Medications

Chair Kajioka provided that 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 2010. He indicated that the answers to these and other submitted questions have been compiled into a document and will be posted on the board's Web site. Chair Kajioka stated that the board is responding to these questions to aid pharmacies in complying with the new requirements.

Chair Kajioka requested any additional questions from the public.

### **Public Comment**

Howard Switzey, representing Kaiser Permanente, sought clarification regarding § 1735.6(a) – Compounding Facilities and Equipment with regards to the board's intent and enforcement of this requirement.

Dr. Ratcliff provided that the board will be ensuring that all equipment within the facility is calibrated and certified as required. He stated that ensuring that the facility itself meets building standards is not within the board's jurisdiction.

Dr. Ratcliff requested that all questions from the public also be submitted in writing to be added to the compounding question and answer document that will be made available on the board's Web site.

Mr. Switzey asked whether § 1735.3(b) requires that records be documented every time a product is used for compounding.

Dr. Ratcliff indicated that records for a product are to be updated with regards to use, acquisition, storage, and destruction.

Mr. Switzey provided that industry is seeking guidance regarding end product testing.

Dr. Ratcliff provided that the board expects each institution to implement process validation in this area.

Discussion continued regarding end product testing and the compounding requirements. Chair Kajioka provided that the board wants to allow flexibility in this area to allow pharmacists to exercise their professional judgment.

Chair Kajioka suggested that a small subcommittee be created to address questions regarding the compounding regulations.

There was no additional committee discussion or public comment.

### 3. Update on California's Drug "Take Back" Programs from Patients

Chair Kajioka provided that at the 2010 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.

Chair Kajioka provided that this report to the Legislature is required by SB 966 (Simitian, Chapter 562, Statutes of 2007), and is due December 1, 2010. He stated that 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.

Chair Kajioka provided that during the board meeting, staff was directed to provide comments on this draft. He indicated that these comments were submitted to CalRecycle in mid-August. Chair Kajioka added that these comments were provided in the committee's packet.

Chair Kajioka provided that on September 25, 2010, the federal Drug Enforcement Administration (DEA) will host a nationwide drug take back event so the public can dispose of its unwanted/unneeded medications.

### **Public Comment**

Steve Gray, representing Kaiser Permanente, asked for more detail regarding the DEA event.

Ms. Herold provided that more information will be provided by a DEA representative during the next agenda item.

There was no additional committee discussion or public comment.

4. Presentation by the Michael Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles

Chair Kajioka provided that 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.

**Presentation to the Committee**

Mike Lewis, Diversion Program Manager, Federal Drug Enforcement Administration, Los Angeles, provided information on DEA activities or objectives aimed at preventing drug diversion and prescription drug abuse.

Mr. Lewis provided an overview of the DEA Regulations to permit e-prescribing of controlled substances. He discussed parties involved in this process including application providers, prescribing practitioners, and pharmacies.

Mr. Lewis expressed concern that prescription drugs have impacted the attitudes of teenagers who believe that prescription drugs are “much safer” than illegal drugs. He stated that teenagers are reporting that prescription drugs are more readily available than illegal drugs and can often be found in the medicine cabinets within their homes.

Mr. Lewis discussed the increasing frequency and volume of drug diversion of controlled substances in California. He stated that diversion involves many groups including practitioners, pharmacists, employees, and patients and involves various motivations such as addiction, physical dependence, resale for money and/or illegal drugs, power, control or importance, and sex. Mr. Lewis reviewed commonly diverted drugs including oxycontin, hydrocodone, xanax (alprazolam), codeine cough syrup, amphetamines, and valium.

Mr. Lewis provided that the DEA will be hosting a National Drug Take Back Day on September 25, 2010. He explained that, together with the help of local and state law enforcement agencies, this event provides the public an opportunity to return unused controlled substances. Mr. Lewis indicated that the DEA will be providing collection boxes and will transport and incinerate the collected drugs. He advised that needles and sharps containers will not be collected.

## Public Comment

Steve Gray, representing Kaiser Permanente, asked if non-controlled substances will also be collected. He asked whether posters are available to help advertise the event.

Mr. Lewis indicated that non-controlled substances will be accepted. He provided that posters are available and that the DEA has asked law enforcement and community groups to help advertise for the event.

A member of the public asked if this will be a one time event.

Mr. Lewis provided that there are plans for a second drug take back day in about 6 months.

Dr. Castellblanch asked if there will be any publicity surrounding the events planned.

Mr. Lewis provided that the DEA planned an Open House for the media and will also be planning television spots, radio and morning show announcements, and electronic banner ads. He indicated that collection site information has been posted at [www.dea.gov](http://www.dea.gov).

Dr. Kajioka asked how other law enforcement groups can participate.

Mr. Lewis stated that the DEA has reached out to as many law enforcement agencies as possible. He indicated that some departments are unable to staff the event as it is scheduled for a Saturday and overtime is not permitted.

Ms. Herold provided that the board has already sent a subscriber alert and plans to send a second alert closer to the event.

Ms. Herold discussed the diversion cases investigated by the board. She indicated that the number of diversion cases has significantly increased over the last two years. She advised the committee that this is an important issue to be addressed by the board.

Mr. Lewis provided that the DEA would like to work closer with the board on cases and ways to prevent diversion.

Dr. Castellblanch asked if there are any available reports regarding organized crime and pharmacies.

Mr. Lewis provided that the DEA is conducting investigations regarding gangs attempting to purchase pharmacies or meet with pharmacists. He indicated that

the DEA has not produced a study or report regarding organized crime involved with pharmacies.

Orriette Quandt sought clarification on e-prescribing requirements regarding whether companies who authenticate prescriber's signatures have been identified.

Mr. Lewis provided that these companies are often working with a state regulatory board or some type of certification service. He stated that the DEA headquarters may be able to provide more information on this area.

Dr. Quandt discussed that prescribers are trying to electronically prescribe controlled substances and are being told by application providers that this practice is legal.

Mr. Lewis provided that this information should be reported to the DEA for further review.

Dr. Gray indicated that Kaiser has been notified that the Washington D.C. DEA office has a list of acceptable certifying agencies.

There was no additional committee discussion or public comment.

5. Presentation by Supervising Inspector Judi Nurse on Thefts of Drugs from Pharmacies

#### **Presentation to the Committee**

Supervising Inspector Judi Nurse provided an overview of the presentation that she and Executive Officer Virginia Herold gave in May regarding 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.

Dr. Nurse discussed three main areas: (1) increased awareness among pharmacists about diversion, (2) prevention of diversion and theft from pharmacies, and (3) the importance of dispensing responsibly using corresponding responsibility. She reviewed the increase in diversion in pharmacies and indicated that the board's diversion cases have increased by 40 percent over the past few years.

Dr. Nurse explained that pharmacists are responsible for the security of the drugs and are the last line of defense against diversion of drugs to the streets, either by theft from the pharmacy or inappropriate dispensing of controlled substances.

She stated that the board's responsibility includes education and the protection of the consumer by aggressively pursuing those who do not comply.

Dr. Castellblanch asked whether oxycontin is the most commonly diverted drug.

Dr. Nurse provided that Vicodin products represent the largest volume of diverted drugs. She indicated that oxycontin and Ambien are also commonly diverted.

Dr. Castellblanch sought clarification regarding diversion from manufacturers and wholesalers.

Dr. Nurse provided that the board does not regulate manufacturers.

Ms. Herold provided that wholesalers in California are taking steps to combat diversion from the drug distribution process. She provided that the board still has cases involving deliveries from a wholesaler that are not delivered directly to the pharmacist as required by law.

Dr. Nurse discussed Business and Professions Code § 4059.5 which requires that all dangerous drugs or devices be delivered to a licensed pharmacy and signed for and received by a pharmacist. She indicated that this requirement is an important security measure to ensure that pharmacists are aware of what drugs are coming in and out of the pharmacy.

Steve Gray, representing Kaiser Permanente, provided that the DEA law requires that all controlled substances are locked up in either a cage or vault within a wholesale facility. He stated that controlled substances within a hospital or pharmacy are often spread throughout inventory and are not required to be locked up. Dr. Gray provided comment on the role of common carriers with regards to the delivery of drugs. He indicated that pharmacies need help from the board, DEA, and Department of Justice to ensure that common carriers honor the law to ensure that all deliveries are delivered directly to the licensed pharmacy and are not left on a loading dock.

Dr. Castellblanch asked whether the board can enforce common carriers.

Ms. Herold provided that the board has no jurisdiction over common carriers.

Mr. Lippe asked whether it is typical to have camera surveillance over controlled substance storage areas.

Dr. Gray provided that this is not common. He indicated that Kaiser does lock up and have camera surveillance over Schedule II drugs storage areas.

There was no additional committee discussion or public comment.

The committee deferred discussion of agenda item 6 in order to discuss agenda item 7.

7. Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program

Dr. Kajioka provided that 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.

Dr. Kajioka provided that 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.

Dr. Kajioka provided that 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. He stated that the board contracts with a vendor, currently Maximus, Inc. to administer the PRP. Dr. Kajioka advised that under current law, this program is only available to pharmacists and interns.

### **Presentation to the Committee**

Assistant Executive Officer Anne Sodergren provided an overview of SB 1441 and the uniform standards regarding substance-abusing healing arts licensees.

Ms. Sodergren advised that on August 4, 2010, a subcommittee convened to further discuss uniform standard four dealing with drug testing. She indicated that the subcommittee did not complete its revision of this standard and a future meeting will be set.

Ms. Sodergren highlighted the first standard and reviewed changes needed prior to implementation.

#### **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.
- Changes needed for implementation:

- i. Pharmacists/Interns
  - 1. Contract change for PRP participants
  - 2. Regulation change (disciplinary guidelines)
- ii. Other individuals
  - 1. Statutory change (establish program)
  - 2. Regulation change (disciplinary guidelines)

Ms. Herold asked the committee to discuss whether or not it deems this standard appropriate for all individuals. She indicated that currently, participants in the PRP undergo a clinical diagnostic evaluation; however, probationers may not.

Mr. Zee suggested that the board wait until the standards are final prior to implementation of the requirements.

Ms. Herold provided that the department has asked all healing arts boards to move forward with implementation of the standards. She indicated that the board's legal counsel has advised the board not to move too far forward until all standards are final.

Dr. Castellblanch asked whether the current evaluations act as a deterrent for current PRP participants.

Ms. Sodergren provided that the evaluations are used as a step in the rehabilitation process and not as a deterrent. She indicated that the evaluations provide baseline information regarding a participant's level of recovery, severity of substance abuse, and any underlying dual diagnosis information including mental illness.

Mr. Lippe asked whether a second evaluation is performed after a participant completes the program.

Ms. Sodergren provided that most PRP participants will be assessed regularly by a health support group facilitator (a licensed clinician). She indicated that treatment contracts also allow for annual reassessments. Ms. Sodergren stated that the board's disciplinary guidelines permit additional evaluations at the request of the board.

Dr. Castellblanch asked how the cost of the evaluation will impact pharmacy technicians.

Ms. Herold provided that the current model disciplinary guidelines do not include evaluations for technicians. She indicated that if ordered, this cost would be born by the technician. Ms. Herold suggested that the committee could recommend that evaluations be included in the model disciplinary guidelines if deemed an integral probation monitoring tool.

Mr. Lippe provided comment in support of requiring an evaluation as part of probation requirements. He stated that the evaluation would be beneficial in providing baseline information as well as identifying any risks if the individual reenters the program or has future discipline issues.

Chair Kajioka provided that an evaluation post program/probation completion would provide valuable information as to whether or not the individual is likely to relapse.

Chair Kajioka suggested that the committee revisit the standards after they have been finalized.

It was the consensus of the committee to discuss the standards at a future meeting when more information is available and the standards have been finalized. The committee requested that Ms. Herold communicate to the subcommittee the committee's interest in the standards and that it believes the clinical diagnostic evaluation is a strong and worthwhile tool.

Ms. Sodergren advised that there may be timing issues with implementing the standards as statutory changes may be needed. She indicated that regulation changes will be easier to implement.

Steve Gray, representing Kaiser Permanente, provided comment with respect to costs for pharmacy technicians. He advised that the cost of the evaluation may be covered by health insurance policies depending on what type of practitioner is required to administer the evaluation. Dr. Gray provided comment in support of the evaluations as a tool to provide baseline information when limiting a licensee's practice. He added that employers should be advised of a licensee's limited practice.

Mr. Lippe cautioned the board from focusing on the cost to a violator as a determining factor when considering whether an evaluation should be added as a requirement.

Ms. Sodergren advised that currently the board is required to post licensees' work restrictions; however, the reason for the restrictions cannot be disclosed.

Ms. Herold provided that standard discipline terms include that a licensee notifies all present and prospective employers of the terms, conditions and restrictions imposed by their decision.

Ms. Herold provided that the board may want to consider amending the disciplinary guidelines in the future to include a requirement for probationers to undergo a clinical diagnostic evaluation.

Ms. Sodergren reviewed each of the following standards and any changes needed in order to implement the requirements.

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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change
    - Regulation change (disciplinary guidelines)

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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Regulation change (disciplinary guidelines)

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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals

- Statutory change (establish program)
- Regulation change (disciplinary guidelines)

Ms. Herold provided that the board currently does not test PRP participants or probationers at this high of a frequency except in extreme cases.

Ms. Sodergren provided that the subcommittee is evaluating how this standard applies to cases where a person has already progressed into recovery at the time of his or her entrance into the program and whether this high frequency is needed. She stated that there is also a concern regarding whether it is more beneficial in terms of consumer protection to test at a higher frequency to catch noncompliance or less frequently to maintain randomness.

Ms. Herold provided that drug testing can be costly and could be burdensome especially for pharmacy technicians and pharmacist interns.

Dr. Kajioka provided that he believes the frequency to be an excessive amount. He stated that he believes that removing a practitioner from work who tests positive during random testing is achieving public protection.

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change (establish program)
    - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change (establish program)
    - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change (establish program)
    - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change
    - Regulation change (disciplinary guidelines)

#### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change (establish program)
    - Regulation change (disciplinary guidelines)

## 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
    - Regulation change (disciplinary guidelines)
  - Other individuals
    - Statutory change
    - Regulation change (disciplinary guidelines)

## 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
  - Other individuals
    - Statutory change

## 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.
- Changes needed for implementation:

- Pharmacists/Interns
  - Statutory change
  - Contract change for PRP participants
- Other individuals
  - Statutory change

### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants

### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants
  - Other individuals
    - Statutory change

### 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Statutory change
    - Contract change for PRP participants

## 16. Measurable criteria for standards

- Establishes 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.
- Changes needed for implementation:
  - Pharmacists/Interns
    - Contract change for PRP participants

Ms. Herold discussed challenges that the board may encounter when implementing the standards. She recommended that the board divide the standards into related categories for further evaluation. She discussed that once implemented, it will be more difficult to monitor probationers as their restrictions are decreased and lifted in a progressive fashion – probationary terms usually do not change during progression through probation.

Discussion continued regarding the standards. It was the consensus of the committee to wait for further clarification before making a recommendation to the board. It was requested that the standards be broken down into categories for a future discussion.

Ms. Herold discussed the department's contract and performance audit of Maximus for its diversion services. She indicated that a copy of the audit report will be posted on the board's Web site.

Mr. Lippe expressed concern regarding some of the deficiencies noted in the program regarding records and documentation.

Ms. Sodergren provided that the report focuses on the services provided by Maximus to six healing arts boards and one committee. She advised that the programs are not run the same and that the PRP reviews participants quarterly to ensure that the systematic checks are in place.

Mr. Lippe asked what follow-up will be done in response to the audit findings.

Ms. Herold provided that Maximus has had an opportunity to respond to the findings and has indicated that it will address the deficiencies.

Ms. Sodergren provided that the standards will require that the vendor be audited every three years.

Ms. Herold provided that board staff will be meeting with the department to discuss necessary follow-up action by the department.

The committee requested an update on the audit response at a future meeting.

No public comment was provided.

6. Update on the Board's Efforts to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative

Background

Beginning in July 2009, the Department of Consumer Affairs has been working with health care boards 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. Subsequently, 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.

Ms. Herold recommended that this issue be discussed by the full board. She provided that the department is working towards standardizing performance measures to be posted on board and department Web sites.

Ms. Herold discussed several challenges impacting the board as a result of the current budget situation including a hiring freeze preventing the filling of the positions allocated by the CPEI, overtime prohibition, and furloughs. She stated that it will be a challenge for the board to meet the measuring standards and to

ensure that investigations are completed and final action is taken against a licensee within 12 – 18 months without the needed staffing.

Chair Kajioka referenced to the case timelines provided within the board packet.

Ms. Sodergren provided that the board's disciplinary guidelines have not been updated since 2008. She stated that the committee may wish to direct staff to initiate this review and bring recommendations back to the committee for evaluation.

No public comment was provided.

**MOTION:** Direct staff to initiate review of the disciplinary guidelines and report back recommended changes for future committee and board discussion and action.

M/S: Lippe/Kajioka

Support: 3    Oppose: 0    Abstain: 0

8. GS1 Schedules October 2010 Forum in San Francisco on Serialization and Track and Track in the Pharmaceutical Supply Chain

Background

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 California's requirements.

Chair Kajioka provided that in October 2010, GS1, which is a worldwide standards-setting organization, will hold a forum on serialization and track and trace in California.

No public comment was provided.

9. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 1:34 p.m.

# **Attachment 12**

this rule effective within less than 30 days.

#### List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airmen, Airports, Aviation safety.

#### The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends Chapter I of Title 14, Code of Federal Regulations, as follows:

#### PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 1155, 40103, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180).

■ 2. Amend Appendix D to Part 91 by revising section 1 introductory text to read as follows:

#### Appendix D to Part 91—Airports/ Locations: Special Operating Restrictions

*Section 1.* Locations at which the requirements of § 91.215(b)(2) and § 91.225(d)(2) apply. The requirements of §§ 91.215(b)(2) and 91.225(d)(2) apply below 10,000 feet MSL within a 30-nautical-mile radius of each location in the following list.

\* \* \* \* \*

Issued in Washington, DC, on October 1, 2010.

**Pamela Hamilton-Powell,**

*Director, Office of Rulemaking.*

[FR Doc. 2010–25102 Filed 10–5–10; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1306

[Docket No. DEA–339S]

#### Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Statement of policy.

**SUMMARY:** The Drug Enforcement Administration (DEA) is issuing this statement of policy to provide guidance under existing law regarding the proper role of a duly authorized agent of a DEA-registered individual practitioner

in connection with the communication of a controlled substance prescription to a pharmacy.

**FOR FURTHER INFORMATION CONTACT:** Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; telephone (202) 307–7297.

#### SUPPLEMENTARY INFORMATION:

##### Legal Authority

DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 through 1321. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. Controlled substances are drugs that have a potential for abuse and dependence; these include substances classified as opioids, stimulants, depressants, hallucinogens, anabolic steroids, and drugs that are immediate precursors of these classes of substances. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity.

##### Background

Under longstanding Federal law, controlled substances are strictly regulated to ensure a sufficient supply for legitimate medical, scientific, research, and industrial purposes and to deter diversion of controlled substances to illegal purposes. The substances are regulated because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under proper circumstances. To minimize the likelihood that pharmaceutical controlled substances would be diverted into illicit channels, Congress established under the CSA a closed system of drug distribution for

legitimate handlers of controlled substances. The foundation of this system is the concept of registration. The only persons who may lawfully manufacture, distribute and dispense controlled substances under the CSA are those who have obtained a DEA registration authorizing them to do so. 21 U.S.C. 822. Thus, the prescribing of controlled substances may be carried out only by those practitioners who have obtained a DEA registration authorizing such activity.

To be eligible for a DEA registration as a practitioner under the CSA, one must be a physician, dentist, veterinarian, hospital, or other person licensed, registered, or otherwise permitted by the United States or the State in which he or she practices to dispense controlled substances in the course of professional practice. 21 U.S.C. 802(21), 823(f). Thus, State licensure to prescribe controlled substances is generally a prerequisite to obtaining a DEA registration to do so. The term “individual practitioner” excludes institutions such as hospitals, which are themselves DEA registrants and are permitted to administer and dispense, but not prescribe, controlled substances under their registration. 21 CFR 1300.01(b)(17).

By longstanding statutory requirement, a valid prescription issued by a DEA-registered practitioner is required for dispensing a controlled substance. To be effective (*i.e.*, valid), a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *United States v. Moore*, 423 U.S. 122 (1975); 21 CFR 1306.04(a). Thus, the practitioner must determine that a prescription for a controlled substance is for a legitimate medical purpose. While the core responsibilities pertaining to prescribing controlled substances may not be delegated to anyone else, an individual practitioner may authorize an agent to perform a limited role in communicating such prescriptions to a pharmacy in order to make the prescription process more efficient. Nonetheless, it is important to understand that any agency relationship must also preserve the requirement that medical determinations to prescribe controlled substances be made by a practitioner only, not by an agent. Accordingly, this statement of policy outlines DEA’s existing statutory and regulatory requirements as to the proper role of duly authorized agents of individual practitioners. DEA anticipates the utilization of electronic prescribing by practitioners for

controlled substance prescriptions will reduce the role of agents over time.

*Medical Determination of Need for a Controlled Substance Prescription Cannot Be Delegated*

DEA regulations state: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a). Accordingly, the practitioner must determine that a prescription for a controlled substance is for a legitimate medical purpose. This determination is the sole responsibility of the practitioner and may not be delegated.

*Elements of a Valid Prescription Must be Specified by the Practitioner and Cannot be Delegated*

Controlled substance prescriptions are orders for medication to be dispensed to an ultimate user and are required to contain specific information including: Patient name, address, drug name and strength, quantity prescribed, directions for use, and the name, address and DEA number of the issuing practitioner. 21 CFR 1306.05(a). All prescriptions for controlled substances must be dated as of, and signed on, the day when issued. Paper prescriptions must be manually signed by the issuing practitioner in the same manner that the practitioner would sign a check or other legal document (21 CFR 1306.05(d)); electronic prescriptions for controlled substances must be signed in accordance with DEA regulations (21 CFR 1306.05(e), 21 CFR 1311.140).

The regulations provide that "[a] prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations." 21 CFR 1306.05(f). Accordingly, an authorized agent may prepare a controlled substance prescription only based on the instructions of the prescribing practitioner as to the required elements of a valid prescription and then provide the prescription to the practitioner to review. The authorized agent does not have the authority to make medical determinations. The practitioner must personally sign the prescription, whether manually or electronically. The

prescribing practitioner cannot delegate his or her signature authority.

*Role of Agent Under the CSA*

As discussed above, the CSA does not permit a prescribing practitioner to delegate to an agent or any other person the practitioner's authority to issue a prescription for a controlled substance. A practitioner acting in the usual course of his or her professional practice must determine that there is a legitimate medical purpose for a controlled substance prescription; an agent may not make this determination. Even though the CSA established a closed system in which all persons in the distribution chain are required to be registered and are held accountable for every controlled substance transaction, Congress recognized a role for agents under the Act. The CSA exempts agents of registrants, including practitioners, from the requirement of registration. 21 U.S.C. 822(c)(1). The statute defines an "agent" as "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. \* \* \*." 21 U.S.C. 802(3). Likewise, DEA regulations implementing the CSA specifically permit a practitioner to use an authorized agent to perform certain ministerial acts in connection with communicating prescription information to a pharmacy. The common means to communicate a prescription to a pharmacy include hand delivery, facsimile, phone call, or an electronic transmission. As explained below, the proper role of an agent depends upon the schedule of the controlled substance prescribed, the circumstances of the ultimate user, and the method of communication.

*Communication by Facsimile or Oral Communication of a Valid Prescription for a Schedule III, IV, or V Controlled Substance May be Delegated to an Authorized Agent*

The CSA provides that a pharmacy may dispense Schedule III and IV controlled substances pursuant to a "written or oral prescription." 21 U.S.C. 829(b). DEA regulations further specify that a pharmacist may dispense a Schedule III, IV, or V controlled substance pursuant to "either a paper prescription signed by a practitioner [or] a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, \* \* \*." 21 CFR 1306.21(a). Accordingly, an authorized agent may transmit such a practitioner-signed paper prescription via facsimile to the pharmacy on behalf of the practitioner.

Controlled substances in Schedules III, IV and V may also be dispensed by a pharmacy pursuant to "an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required [for a valid prescription], except for the signature of the practitioner." 21 CFR 1306.21(a). Under DEA regulations, an authorized agent may orally communicate such a prescription to a pharmacist. 21 CFR 1306.03(b). Where the pharmacist has reason to believe that a prescription has been communicated by an agent, the pharmacist, in accordance with his or her responsibility for proper dispensing of controlled substances, may have a duty to inquire into the legitimacy of the prescription. The particular circumstances will dictate the appropriate level of inquiry by the pharmacist. As noted above, the practitioner remains responsible for ensuring that the prescription conforms to the law and regulations, and the practitioner cannot delegate to an agent the authority to make a medical determination of need for a controlled substance prescription.

*Generally, a Valid Schedule II Controlled Substance Prescription May Not be Communicated by Facsimile*

Because Schedule II controlled substances have the highest potential for abuse and the greatest likelihood of dependence among the pharmaceutical controlled substances (those in Schedules II-V), the CSA controls on Schedule II drugs are the most restrictive. The CSA requires that a Schedule II controlled substance be dispensed by a pharmacy only pursuant to a written prescription, except in emergency situations, and prohibits Schedule II prescriptions from being refilled. 21 U.S.C. 829(a). Thus, in most cases, a pharmacist must receive the original, manually signed paper prescription or an electronic prescription prior to dispensing a Schedule II controlled substance. 21 CFR 1306.11(a).

*A Valid Schedule II Controlled Substance Prescription For a Person in a Hospice or Long Term Care Facility (LTCF) May be Communicated by Facsimile and That Communication May be Delegated to an Authorized Agent*

DEA regulations specify two exceptions whereby a Schedule II controlled substance prescription sent by facsimile may serve as the original written prescription. A practitioner or a practitioner's authorized agent may transmit a valid Schedule II controlled

substance prescription to a pharmacy via facsimile for: (1) Patients enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or hospice programs which are licensed by the State (21 CFR 1306.11(g)); and (2) residents of LTCFs (21 CFR 1306.11(f)). The facsimile serves as the original written prescription and must be maintained by the pharmacy as such. An authorized agent of the prescribing practitioner may transmit the practitioner-signed prescription by facsimile on behalf of the practitioner.

*Emergency Oral Communication of a Valid Schedule II Controlled Substance Prescription May Not be Delegated to an Authorized Agent*

The CSA contains an exception that allows a practitioner to issue oral prescriptions for Schedule II controlled substances in an emergency. 21 U.S.C. 829(a). An emergency for this purpose is defined by the Food and Drug Administration in 21 CFR 290.10. DEA regulations limit such an emergency oral prescription to the quantity necessary to treat the patient during the emergency period and require that it be followed up within 7 days by a practitioner-signed, written prescription to the dispensing pharmacy. 21 CFR 1306.11(d). Moreover, oral emergency prescriptions must immediately be reduced to writing by the pharmacist and must contain all the information ordinarily required in a prescription, except for the signature of the prescribing individual practitioner. If the prescribing individual practitioner is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner and/or other good faith efforts to ensure the practitioner's identity. 21 CFR 1306.11(d). Because the more specific requirement that the emergency Schedule II oral authorization must be from a registered individual practitioner (21 CFR 1306.11(d)) supersedes the general rule that an employee or agent of the individual practitioner may communicate prescriptions to a pharmacist (21 CFR 1306.03(b)), the prescribing individual practitioner must personally communicate the emergency oral prescription to the pharmacist. An agent may not call in an oral prescription for a Schedule II controlled substance on behalf of a practitioner even in an emergency circumstance.

*Pharmacist Dispensing a Controlled Substance Prescription Has a Duty To Fill Only Valid Prescriptions*

Regardless of the method of transmission of a controlled substance prescription—by hand delivery, facsimile, phone call or electronically—DEA regulations make it clear that the legal responsibility for issuing a valid prescription that “conform[s] in all essential respects to the law and regulations” rests upon the prescribing practitioner. As noted, however, a pharmacist has a corresponding responsibility for the proper prescribing and dispensing of controlled substances. 21 CFR 1306.04(a). Further, “A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.” 21 CFR 1306.05(f). A pharmacist must carefully review all purported controlled substance prescriptions to ensure that the prescription meets all of the legal requirements for a valid prescription. The pharmacist has a duty to inquire further as to any question surrounding the satisfaction of any or all of the legal requirements for a valid prescription depending upon the particular circumstances, including the requirement that the prescription be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The pharmacist must be satisfied that the prescription is consistent with the CSA and DEA regulations before dispensing a controlled substance to the ultimate user.

*Summary of the Acts That an Agent May Take in Connection With Controlled Substance Prescriptions*

1. An authorized agent of an individual practitioner may prepare a written prescription for the signature of the practitioner, provided that the practitioner, in the usual course of professional practice, has determined that there is a legitimate medical purpose for the prescription and has specified to the agent the required elements of the prescription. 21 CFR 1306.04(a); 1306.05(a), (f).
2. Where a DEA-registered individual practitioner has made a valid oral prescription for a controlled substance in Schedules III–V by conveying all the required prescription information to the practitioner's authorized agent, that agent may telephone the pharmacy and convey that prescription information to the pharmacist. 21 CFR 1306.03(b), 1306.21(a).

3. In those situations in which an individual practitioner has issued a valid written prescription for a controlled substance, and the regulations permit the prescription to be transmitted by facsimile to a pharmacy (as set forth in 21 CFR 1306.11(a), 1306.11(f), 1306.11(g), and 1306.21(a)), the practitioner's agent may transmit the practitioner-signed prescription to the pharmacy by facsimile.

*Who Is an Agent of an Individual Practitioner for the Purpose of Communicating a Prescription for a Controlled Substance*

The CSA defines an “agent” as “an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. \* \* \*” 21 U.S.C. 802(3). Under the CSA, the term “dispense” includes “prescribing.” 21 U.S.C. 802(10). Establishment of an agency relationship, consistent with the CSA, is guided by general precepts of the common law of agency. For the purposes of explaining the law of agency as it relates to the CSA, it is appropriate to refer to and consider as generally applicable the Restatement of Agency (Restatement) which provides:

Agency is the fiduciary relationship that arises when one person (a “principal”) manifests assent to another person (an “agent”) that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act.  
Restatement (Third) of Agency § 1.01 (2006).

The Restatement is useful in evaluating whether, for CSA purposes, a valid agency relationship exists between a prescribing practitioner and another person for the purpose of communicating a prescription for a controlled substance to a pharmacy. The Restatement requires that the principal (in this context, the DEA-registered individual practitioner) “manifests assent” for a certain person to act on his or her behalf. This is consistent with the CSA and its registration-based system of accountability. Where non-DEA registrants communicate a prescription for a controlled substance on behalf of a registrant, it is important that such persons be clearly identified and their activities be subject to evaluation to ensure they do not exceed the bounds of the agency relationship and the legal limits of an agent's role under the CSA. Because the individual practitioner remains responsible for ensuring that all prescriptions issued pursuant to his or her DEA registration comply in all respects with the CSA and DEA regulations, it is important that the practitioner decide who may act as his

or her agent. This is also consistent with the CSA definition that an agent is “an authorized person who acts on behalf of or at the direction of” the prescribing individual practitioner. 21 U.S.C. 802(3).

In addition to requiring that the principal (*i.e.*, individual prescribing practitioner) “manifests assent” to having a particular person act as his or her agent, and that the agent reciprocate by manifesting assent to serve as such, the Restatement also requires that the agent acts “subject to the principal’s control.” In an employment situation, an individual practitioner may establish the duties of his or her employees and is responsible for monitoring their activities. Absent an employer-employee relationship, a practitioner will generally have less control over other persons that he or she may designate as his or her agent(s). Prior to designating an agent, a practitioner may wish to consider the degree of control that the registrant may exercise over the proposed agent, the proposed agent’s licensure, level of training and experience, and other such factors to determine whether the person would be an appropriate agent and to ensure that the agent will not engage in activities that exceed the scope of the agency relationship. Absent affirmative actions by the practitioner and the proposed agent, a valid agency relationship generally will not exist outside an employer-employee relationship.

By requiring that an agency relationship is created when (1) the principal manifests assent that a particular person shall act (i) on his or her behalf and (ii) subject to his or her control, and (2) the agent manifests assent so to act, the Restatement definition of “agency” is consistent with the CSA’s definition of “agent” as “an authorized person who acts on behalf of or at the direction of” the prescribing practitioner. 21 U.S.C. 802(3). An agent may not legally perform duties that must be personally performed by the individual practitioner. The practitioner may assign only those duties which may be carried out by an agent.

DEA notes that in a 2001 notice and solicitation of information on the potential use of automated dispensing systems to prevent the accumulation of surplus controlled substances at LTCFs, DEA briefly discussed the role of nurses in the narrow setting of LTCFs outside of an employer-employee relationship and where no affirmative actions established an agency relationship between the individual practitioner and the LTCF nurse. 66 FR 20833, 20834 (April 25, 2001). This incidental example and other informal discussions

have resulted in the need for this published articulation of what existing law allows and what affirmative actions may be required to establish a valid agency relationship for purposes of an authorized agent to communicate controlled substance prescriptions to pharmacies, particularly in settings where there is no employer-employee relationship. DEA regulations on the role of authorized agents in communicating controlled substance prescriptions to pharmacies generally have not changed.

This policy statement outlines the proper role of agents in those situations where an individual practitioner and an individual agent (including but not limited to an LTCF nurse) have taken affirmative steps to establish a valid agency relationship for those aspects of the CSA that may be appropriately executed by an authorized agent under Federal law. As such, DEA is hereby outlining a suggested mechanism to establish a valid agency relationship as well as explaining the appropriate roles an authorized agent may play regardless of the setting. This statement of policy is intended to provide general guidance on establishment of a valid agency relationship between an individual practitioner and an identified individual. DEA wishes to emphasize that, regardless of the setting, it is the practitioner’s sole decision as to whether or not to designate an agent to act on his or her behalf and subject to his or her control. To be consistent with the purpose of the CSA to implement a “closed system” of distribution and for DEA to enforce this framework, an agency relationship between a registered individual practitioner and an identified agent for the purposes of communicating controlled substance prescriptions must be explicit and transparent. DEA believes its existing regulations are adequate in addressing the role of an authorized agent but will analyze whether additional federal rulemaking or guidance is needed beyond this statement to establish the necessary explicit and transparent nature of an authorized agency relationship, particularly when outside an employer-employee relationship.

*Written Authorization of an Agent Recommended—Sample Agency Agreement*

Due to the legal responsibilities of practitioners and pharmacists under the CSA and the potential harm to the public from inappropriate and unlawful prescribing and dispensing of controlled substances, violations of the law are subject to criminal, civil, and administrative sanctions. DEA believes

it is in the best interests of the practitioner, the agent, and the dispensing pharmacist that the designation of those persons authorized to act on behalf of the practitioner and the scope of any such authorization be reduced to writing.

DEA provides below an example of a written agreement that would properly confer authority to an agent to act on behalf of an individual practitioner with regard to controlled substance prescriptions. Individual practitioners may choose to designate and authorize one or more persons at one or more locations within or outside their practice to act as their agent. Likewise, an individual may act as an authorized agent for multiple individual practitioners depending upon the circumstances. A practitioner may or may not wish to delegate all of these types of authorized communications to a particular agent and may tailor the agreement accordingly. The agreement should be clear that the agent may not further delegate the outlined responsibilities.

*Designating Agent of Practitioner For Communicating Controlled Substance Prescriptions to Pharmacies*

\_\_\_\_\_  
(Name of registered individual practitioner)

\_\_\_\_\_  
(Address as it appears on certificate of registration)

\_\_\_\_\_  
(DEA registration number)

I, \_\_\_\_\_ (name of registrant), the undersigned, who is authorized to dispense (including prescribe) controlled substances in Schedules II, III, IV, and V under the Controlled Substances Act, hereby authorize \_\_\_\_\_ (name of agent), to act as my agent only for the following limited purposes:

1. To prepare, for my signature, written prescriptions for controlled substances in those instances where I have expressly directed the agent to do so and where I have specified to the agent the required elements of the prescription (set forth in 21 CFR 1306.05).
2. To convey to a pharmacist by telephone oral prescriptions for controlled substances in Schedules III, IV, and V in those instances where I have expressly directed the agent to do so and where I have specified to the agent the required elements of the prescription (set forth in 21 CFR 1306.05).
3. To transmit by facsimile to a pharmacy prescriptions for controlled

substances in those instances where I have expressly directed the agent to do so and where I have specified to the agent the required elements of the prescription (set forth in 21 CFR 1306.05) and I have signed the prescription.

This authorization is not subject to further delegation to other persons. Both the undersigned DEA-registered individual practitioner and the undersigned agent understand and agree that the practitioner is solely responsible for making all medical determinations relating to prescriptions for controlled substances communicated by the agent pursuant to this agreement, and for ensuring that all such prescriptions conform in all other essential respects to the law and regulations.

The undersigned agent understands he or she does not have authority to make any medical determinations. The undersigned DEA-registered prescribing practitioner further understands that the prescribing practitioner must personally communicate all Schedule II emergency oral prescriptions to the pharmacist. Both the undersigned practitioner and agent understand that the agent may not call in an emergency oral prescription for a Schedule II controlled substance on behalf of the practitioner.

This agency agreement shall be terminated immediately if and when any of the following occur:

1. The undersigned practitioner no longer possesses the active DEA registration specified in this agreement.
2. The undersigned agent is no longer employed in the manner described in this agreement.
3. The practitioner or the agent revokes this agency agreement by completing the revocation section at the end of this document or by executing a written document that is substantially similar to the revocation section at the end of this document.

(Signature of practitioner)

I, \_\_\_\_\_ (name of agent), hereby affirm that I am the person named herein as agent and that the signature affixed hereto is my signature. I further affirm that I am a \_\_\_\_\_ (title), licensed in the State of \_\_\_\_\_, (where applicable) and (if applicable) am employed by/under contract with \_\_\_\_\_ (name of employer or contracting entity). I agree to abide by all the terms of this agreement and to comply with all applicable laws and regulations relating to controlled substances.

(Signature of agent)

\_\_\_\_\_  
(State license number of agent where applicable)

\_\_\_\_\_  
(Name of employer/contracting entity where applicable)

\_\_\_\_\_  
(Address of employer/contracting entity where applicable)

Witnesses:

1. \_\_\_\_\_
2. \_\_\_\_\_

Signed and dated on the \_\_\_\_\_ day of \_\_\_\_\_ (month) \_\_\_\_\_, (year), at \_\_\_\_\_.

Revocation

The foregoing agency agreement is hereby revoked by the undersigned. The agent is no longer authorized to communicate Schedule II, III, IV and V controlled substance prescriptions to a pharmacy on my behalf. A copy of this revocation has been given to the agent this same day.

\_\_\_\_\_  
(Signature of registered practitioner revoking power)

Witnesses:

1. \_\_\_\_\_
2. \_\_\_\_\_

Signed and dated on the \_\_\_\_\_ day of \_\_\_\_\_ (month) \_\_\_\_\_, (year), at \_\_\_\_\_.

DEA recommends that the original signed agency agreement be kept by the practitioner during the term of the agency relationship and for a reasonable period after termination or revocation. DEA requires that inventory and other records be kept for at least two years (21 U.S.C. 827(b), 21 U.S.C. 828(c), 21 CFR 1304.04). This is simply a suggested time period for retention of agency agreements and is not required by DEA. A signed copy should also be provided to the practitioner's designated agent, the agent's employer (if other than the practitioner), and any pharmacies that regularly receive communications from the agent pursuant to the agreement. Providing a copy to pharmacies likely to receive prescriptions from the agent on the practitioner's behalf may assist those pharmacies with their corresponding responsibility regarding the dispensing of controlled substances. It is important to reiterate that a pharmacist always has a corresponding responsibility to ensure that a controlled substance prescription conforms with the law and regulations, including the requirement that the prescription be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, and a corresponding liability if a prescription is not prepared or

dispensed in a manner consistent with the CSA or DEA regulations. Even where the pharmacist has a copy of an agency agreement, the pharmacist may also have a duty to inquire further depending upon the particular circumstances. Because the agency agreement may be revoked at any time by the practitioner or by the agent, the party terminating the agreement should notify the other party immediately upon termination. The practitioner should notify those pharmacies that were originally made aware of the agency agreement of the termination of that agreement. In most circumstances where an agent changes employment, the agreement should be revoked.

Dated: October 1, 2010.

**Joseph T. Rannazzisi,**

*Deputy Assistant Administrator, Office of Diversion Control.*

[FR Doc. 2010-25136 Filed 10-5-10; 8:45 am]

**BILLING CODE 4410-09-P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### 32 CFR Part 323

[Docket ID DOD-2010-OS-0139]

#### Privacy Act of 1974; Implementation

**AGENCY:** Defense Logistics Agency; DoD.

**ACTION:** Final rule; request for comments.

**SUMMARY:** The Defense Logistics Agency is revising two exemption rules. The exemption rule for S100.10 entitled "Whistleblower Complaint and Investigative Files" is being deleted in its entirety and the exemption rule system identifier for the "Incident Investigation/Police Inquiry Files" system of records is being revised.

**DATES:** The rule will be effective on December 6, 2010, unless comments are received that would result in a contrary determination.

Comments will be accepted on or before December 6, 2010.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Room 3C843, Washington, DC 20301-1160.

*Instructions:* All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy

# **Attachment 15**

# National Practitioner Data Bank

## Healthcare Integrity and Protection Data Bank



Home Customer Service FAQs Site Index Visit DPDB

### ABOUT THE DATA BANKS

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- HIPDB
- What's New
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- Billing and Fees
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### QUERYING & REPORTING

- IQRS Features
- Using the PDS Prototype
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## About Reporting Compliance Status of Government Agencies

### Background

The HIPDB and NPDB statutes require State licensing authorities to submit, generally within 30 days, adverse licensing and certification actions, as well as negative actions and findings, taken against health care entities, providers, suppliers, and practitioners. These reportable actions or findings include both final actions and those taken as a result of formal proceedings.

### Process

HRSA has undertaken two different activities to encourage complete and accurate reporting to the HIPDB and NPDB by Government Agencies.

The first activity focused on identifying Government Agencies (State Agencies and Licensing Boards) responsible for licensing or certifying health care practitioners that have never reported an action to the HIPDB. HRSA developed a list of current Government Agencies that are responsible for reporting data to the HIPDB and NPDB to determine the subset that have never reported any actions to the Data Banks.

The second activity identified potential gaps in data and requested that State Agencies and Licensing Boards respond to the potential gaps. HRSA focused on six professions (nurses, pharmacists, physician assistants, podiatrists, psychologists, and social workers) that are frequently queried by hospitals and other health care entities. We compared publicly available disciplinary licensure actions published on State web sites for certain years with data currently stored in the HIPDB. The data were obtained from the State web sites primarily between February 1st and March 25th, 2010. For the States that we could not find publicly available disciplinary actions on the web site, HRSA requested that the State provide the data so that HRSA could conduct a comparison.

In all situations where our review indicated that a Government agency may not be compliant with the reporting requirements, HRSA contacted the agency with a request to, within 30 days: (1) Supply a written explanation stating the reason that the professions are not subject to the reporting requirements; or (2) Report the actions taken by the Government agency to the HIPDB and provide written notice to HRSA that the actions were reported and that future reporting will continue; or (3) Provide a corrective action plan detailing how the Government Agency will meet the reporting requirements.

The compliance status of Government agencies includes only those States and professions that HRSA has reviewed or is currently reviewing. Physicians and dentists are not generally included on the current listing as they will be the focus of future efforts. In addition, HRSA will be adding Government agencies that report on providers and suppliers, such as hospitals and pharmacies, while continuing the focus on Government agencies that report individuals.

### Compliance Status

For the purposes of this compliance review, a determination of compliance is based upon the information received directly from the State (e.g., information submitted by the State in response to a written request for action, data obtained from State web sites). The [Reporting Compliance List](#) contains five status levels:

### Compliant

A Government agency has provided a written response for the profession(s) to HRSA fulfilling one of the statements below:

1. The Government agency has attested that there are no reportable adverse actions to report to the Data Banks for the professions identified by HRSA; or,
2. A corrective action plan was submitted and completed, which included the reporting to the NPDB/HIPDB of all previous reportable actions (in the case of letters sent regarding failure to report specific actions, all reportable actions that were identified in the letter as missing), and assurance that the Government agency will continue to report adverse actions in the future for the profession.

### Non-Compliant

A State is identified as non-compliant for a profession if:

1. The Government agency has not begun reporting for the profession and there was no written response to HRSA in response to the written request for action; or,
2. The Government agency has not begun reporting for the profession and the written response provided to HRSA was inadequate and/or unresponsive to the request for action; or,
3. The Government agency did not substantially meet deadlines identified in their corrective action plan for submitting adverse actions on the profession.

### Working Toward Compliance

A State is identified as working towards compliance for a profession if, after a written request for action:

1. The Government agency provides an acceptable corrective action plan including a timeline for coming into compliance for the profession; or,
2. The Government agency begins to report adverse actions for the profession and continues to make acceptable progress towards full compliance but has not submitted a corrective action plan and a timeline for coming into compliance; or,
3. The Government agency begins, but has not completed, reporting adverse actions for the profession as described in their corrective action plan.

### Under Review

A letter requesting a response has been sent by HRSA to a Government agency for the specified profession(s) and:

1. The 30 day response deadline has not passed; or,
2. The corrective action plan submitted by the Government agency for the profession is under review by HRSA; or,
3. There are mitigating issues that prevent a determination of compliance status.

### Not Reviewed

HRSA has not completed reviews of all professions in each State. The status of "Not Reviewed" indicates that the profession was not reviewed before the end date of the previous review period.

*Note: Not all States license or certify the same professions. Given these differences, a direct*

*comparison between States is difficult. Also, the name of the Government agency is not listed because the Agency may license or certify more than one profession and may have met the reporting requirements for some, but not all, of the professions (e.g., Dental Board licenses dentists, dental hygienists and denturists).*

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<b>California</b>	Status as of 7/1/2010	Status as of 10/1/2010
Accountant	<a href="#">Under Review</a>	<a href="#">Working Toward Compliance</a>
Acupuncturist	<a href="#">Working Toward Compliance</a>	<a href="#">Compliant</a>
Administrator of Adult Residential Facility	<a href="#">Under Review</a>	<a href="#">Non-Compliant</a>
Administrator of Group Homes	<a href="#">Under Review</a>	<a href="#">Non-Compliant</a>
Administrator of Residential Care Facilities of the Elderly	<a href="#">Under Review</a>	<a href="#">Non-Compliant</a>
Certified Hemodialysis Technician	<a href="#">Compliant</a>	<a href="#">Compliant</a>
Clinical Laboratory Scientist	<a href="#">Under Review</a>	<a href="#">Non-Compliant</a>
Cytotechnologist	<a href="#">Under Review</a>	<a href="#">Non-Compliant</a>
Hearing Aid Dispenser	<a href="#">Working Toward Compliance</a>	<a href="#">Compliant</a>
Home Health Aide(Homemaker)	<a href="#">Compliant</a>	<a href="#">Compliant</a>
Laboratory Director	<a href="#">Under Review</a>	<a href="#">Non-Compliant</a>
Medical Laboratory Technician	<a href="#">Compliant</a>	<a href="#">Compliant</a>
Midwife	<a href="#">Compliant</a>	<a href="#">Compliant</a>
Naturopath	<a href="#">Compliant</a>	<a href="#">Compliant</a>
Nuclear Medicine Technologist	<a href="#">Working Toward Compliance</a>	<a href="#">Under Review</a>
Nursing Home Administrator	<a href="#">Working Toward Compliance</a>	<a href="#">Compliant</a>
Nursing Related Professions (Other Than Midwife)	<a href="#">Working Toward Compliance</a>	<a href="#">Working Toward Compliance</a>
Occupational Therapist	<a href="#">Working Toward Compliance</a>	<a href="#">Compliant</a>
Occupational Therapy Assistant	<a href="#">Working Toward Compliance</a>	<a href="#">Compliant</a>
Optician	<a href="#">Compliant</a>	<a href="#">Compliant</a>
Optometrist	<a href="#">Working Toward Compliance</a>	<a href="#">Compliant</a>
Pharmacist	<a href="#">Not Reviewed</a>	<a href="#">Compliant</a>
Phlebotomist	<a href="#">Under Review</a>	<a href="#">Non-Compliant</a>
Physician Assistant	<a href="#">Not Reviewed</a>	<a href="#">Compliant</a>
Podiatrist	<a href="#">Under Review</a>	<a href="#">Compliant</a>
Psychologist	<a href="#">Not Reviewed</a>	<a href="#">Compliant</a>
Registered Dispensing Optician	<a href="#">Compliant</a>	<a href="#">Compliant</a>
Research Psychoanalyst	<a href="#">Compliant</a>	<a href="#">Compliant</a>
Social Worker	<a href="#">Under Review</a>	<a href="#">Working Toward Compliance</a>
X-Ray Technician	<a href="#">Working Toward Compliance</a>	<a href="#">Under Review</a>
X-Ray Technologist	<a href="#">Working Toward Compliance</a>	<a href="#">Under Review</a>

# **Attachment 16**

# GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

## ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months.						
Measure:	Percentage of cases closed.						
Tasks:	1. Complete all desk investigations within 90 days (for cases closed during quarter).						
		<u>N</u>	< 90 days	< 120 days	< 180 days	Longer	<u>Average Days</u>
	Qtr 1	547	145 26%	45 8%	80 15%	277 51%	276
	Qtr 2						
	Qtr 3						
	Qtr 4						
	2. Complete all field investigations within 120 days (for cases closed during quarter).						
		<u>N</u>	< 120 days	< 180 days	< 270 days	Longer	<u>Average Days</u>
	Qtr 1	363	140 38%	93 26%	75 21%	55 15%	195
	Qtr 2						
	Qtr 3						
	Qtr 4						
	Data is calculated from date received to the date the report was accepted by SI/Manager. Does not include split cases.						

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

<b>Qtr 1</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals	407	298	45	14	50
Rap sheet/CCU - 4301 letters and license denials	169	81	23	38	27
Cite and/or fine letter of admonishment	248	99	63	28	57
Attorney General's Office	87	25	19	13	30
<b>Qtr 2</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals					
Rap sheet/CCU - 4301 letters and license denials					
Cite and/or fine letter of admonishment					
Attorney General's Office					
<b>Qtr 3</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals					
Rap sheet/CCU - 4301 letters and license denials					
Cite and/or fine letter of admonishment					
Attorney General's Office					
<b>Qtr 4</b>	<b>N</b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed investigations, no additional action, license approvals					
Rap sheet/CCU - 4301 letters and license denials					
Cite and/or fine letter of admonishment					
Attorney General's Office					

Data is calculated from date received to date closed or referred to the AG.  
 One case may have multiple respondents. The actual number of citations and letters of admonishment issued are shown on the next page.

Objective 1.2	Manage enforcement activities for achievement of performance expectations.																																									
Measure:	Percentage compliance with program requirements.																																									
Tasks:	<p><b>1. Administer the Pharmacists Recovery Program.</b></p> <table border="1"> <thead> <tr> <th></th> <th>Voluntary Participants</th> <th>Participants Mandated Into Program</th> <th>Noncompliant, Terminated From Program</th> <th>Successfully Completed Program</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>30</td> <td>45</td> <td>1</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program	Qtr 1	30	45	1	0	Qtr 2					Qtr 3					Qtr 4																				
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**5. Obtain immediate public protection sanctions for egregious violations.**

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

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

	30 days	60 days	> 60 days	<u>N</u>
Qtr 1	1	1	7	9
Qtr 2				
Qtr 3				
Qtr 4				

Objective 1.3	Achieve 100 percent closure on all administrative cases within 1 year.																																																							
Measure:	Percentage of administrative cases closed within 1 year.																																																							
Tasks:	1. File pleadings within 90 days of referral.																																																							
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Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/11.																																																							
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																																																							
Tasks:	<p>1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.</p> <table border="1" data-bbox="370 289 1481 506"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Aggregate Inspections This Cycle</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>404</td> <td>4550</td> <td>65%</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</p> <table border="1" data-bbox="370 617 1166 833"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>50</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> </tr> </tbody> </table> <p>3. Initiate investigations based upon violations discovered during routine inspections.</p> <table border="1" data-bbox="370 909 1481 1125"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number of Investigations Opened</th> <th>Percent Opened</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>404</td> <td>7</td> <td>2%</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	404	4550	65%	Qtr 2				Qtr 3				Qtr 4					Number of Inspections	Number Inspected Late	Qtr 1	50	0	Qtr 2			Qtr 3			Qtr 4				Number of Inspections	Number of Investigations Opened	Percent Opened	Qtr 1	404	7	2%	Qtr 2				Qtr 3				Qtr 4			
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Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1487 695"> <p><b>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</b></p> <p><i>Oct. 2009: Executive Officer provides information about California's e-pedigree requirements at a SecurePharma Conference of drug manufacturers and wholesalers in Philadelphia and at a SpecialtyPharma Conference (contract drug manufacturers) in Phoenix.</i></p> <p><i>Dec. 2009: Executive Officer provides information about California's e-pedigree requirements at the Health Care Distributors Association Trace and Track Conference in Washington D.C.</i></p> <p><i>March 2010: Executive Officer provides information about California's e-pedigree requirements via a Webinar hosted by IBS.</i></p> <p><i>April 2010: Board reviews Food and Drug Administration guidance on a unique serialized identifier released March 26.</i></p> </li> <li data-bbox="370 695 1487 919"> <p><b>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.</b></p> <p><i>Sep. 2006: Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.</i></p> <p><i>Oct. 2006: Board adds Consumer friendly materials regarding sales of these drugs to its website.</i></p> </li> <li data-bbox="370 919 1487 1396"> <p><b>3. Monitoring the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.</b></p> <p><i>Nov. 2006: Board submits letter supporting change in Drug Enforcement Administration policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.</i></p> <p><i>Sep. 2008: Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.</i></p> <p><i>Dec. 2009: Executive Officer meets with DEA officials in Washington D.C. to discuss interest in e-prescribing of controlled drugs.</i></p> <p><i>April 2010: Board reviews proposed Drug Enforcement Administration requirements for electronic prescribing of controlled substances.</i></p> <p><i>June 2010: Enforcement Committee received updates on DEA rule change.</i></p> </li> <li data-bbox="370 1396 1487 1696"> <p><b>4. Evaluate establishment of an ethics course as an enforcement option.</b></p> <p><i>Oct. 2008: Board holds regulation hearing on proposed requirements for the ethics class.</i></p> <p><i>Jan. 2009: Board adopts regulation.</i></p> <p><i>Sept. 2009: Regulation takes effect.</i></p> <p><i>3rd Qtr 09-10: Board subcommittee of two board members begins work with staff on suggested specific components and topics for the program, in compliance with board regulations.</i></p> </li> <li data-bbox="370 1696 1487 1948"> <p><b>5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.</b></p> <p><i>Dec. 2009: Executive Officer provides presentation on California's e-pedigree requirements to three national association meetings.</i></p> <p><i>3rd Qtr 09-10: Board initiates rulemaking on a regulation to establish requirements for patient-centered prescription container labels (see report on Legislation and Regulation Committee's Goals, Outcomes, Objectives and Measures).</i></p> </li> </ol>

	<p><b>6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.</b></p> <p><i>Sep. 2007: Provided comments on proposed statutory requirements.</i></p> <p><i>Dec 2007: Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.</i></p> <p><i>Provided comments on proposed e-prescribing initiatives.</i></p> <p><b>Oct. 2008:</b> <i>Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.</i></p> <p><b>Nov. 2008:</b> <i>Board hosts conference on e-prescribing as part of department's professionals</i></p> <p><i>Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.</i></p> <p><b>Jan. 2009:</b> <i>Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.</i></p> <p><b>March 2009:</b> <i>Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.</i></p> <p><b>April 2010:</b> <i>Board reviews Drug Enforcement Agency proposed regulations on e-prescribing of controlled substance.</i></p> <p><b>7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.</b></p> <p><b>Oct. 2008:</b> <i>Requirements for security forms in place..</i></p> <p><b>2nd Qtr 09-10:</b> <i>Board executive staff and several board members attend California Healthcare Foundation's annual summit to implement e-prescribing.</i></p>
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**8. Liaison with other state and federal agencies to achieve consumer protection.**

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

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

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

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

**3rd Qtr 08/09:** *Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.*

**4th Qtr 08/09:** *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.  
Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.  
The federal Drug Enforcement Administration provides training to board staff on new requirements for online pharmacies selling controlled substances.*

**2nd Qtr 09/10:** *Executive staff meet with Department of Health Care Services staff on mutual investigations; DEA staff in Washington D.C. on enforcement issues involving controlled drugs; the U.S. Attorney General's office in Sacramento on two major enforcement matters; and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

**3rd Qtr 09/10:** *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

*Board staff redirected to complete HIPDB reporting.*

**4th Qtr 09/10:** *Board staff continue to report to HIPDB.*

9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public.
- March 2008:** *Second meeting with state agency stakeholders on developing components for model programs that conform with diverse state agency security and safety requirements.*
- June 2008:** *Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take-back programs.*
- Aug. 2008:** *Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.*
- Oct. 2008:** *Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps. Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.*
- Nov. 2008:** *Executive Officer provides written and verbal testimony at California Integrated Waste Management Board hearing on the model guidelines.*
- Dec. 2008:** *Executive Officer participates in public hearing at the California Integrated Waste Management Board on possible changes to the model guidelines adopted by the California Integrated Waste Management Board in November.*
- Feb. 2009:** *California Integrated Waste Management Board amends model guidelines to include provisions advanced by the board.*
- Jan. 2010:** *Board writes article on the guidelines for publication in the next issue of The Script. Board executive staff attend meetings on "take back drugs" at a statewide conference of the California Integrated Waste Management Board. Executive Officer provides presentation on the CIWMB Model Guidelines at a meeting of 20 rural California counties.*
- March 2010:** *Board publishes the guidelines in The Script.*
- April 2010:** *Board inspector will collect information about take back programs in California pharmacies during inspections.*

**10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas.**

**4th Qtr 07/08:** *Board initiates inspections of 40 California hospitals looking for counterfeit heparin and unlicensed sales but discovers recalled heparin still in 40 percent of hospitals inspected. Board notifies the Food and Drug Administration and California Department of Public Health and initiates inspections of 533 hospitals during April-June.*

*Recalled heparin is found in 94 of these facilities. Data reported to board during June Board Meeting.*

**1st Qtr 08/09:** *The Script highlights problems found in heparin inspections. Citations and fines issued to facilities with recalled heparin. Work with hospitals begins to strengthen drug control within facilities.*

**2nd Qtr 08/09:** *Hospitals and Pharmacists-in-Charge fined where recalled heparin was discovered by the board.*

**3rd Qtr 08/09:** *First stakeholder meeting scheduled to discuss drug distribution within hospitals.*

**March 2009:** *First stakeholder meeting convened.*

**June 2009:** *Second stakeholder meeting convened. Development of model guidelines for recalls underway.*

**Sep. 2009:** *Stakeholder meeting convened.*

*Recall guidelines evaluated and additional comments solicited.*

**Jan. 2010:** *Board reviews final version of recommended steps for addressing recalls in hospitals.*

**April 2010:** *Manuscript of addressing recalls in hospitals completed, compiled into finished report and posted on Website.*

*Executive officer works with the Healthcare Distributors Management Association (representing drug wholesalers) to secure notices of recalls more timely to share with board subscriber list.*

*Appeals of citations and fines nearly complete.*

**May 2010:** *Outstanding enforcement/compliance completed.*

11. **Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards.**  
*4th Qtr 08/09: Draft proposals for required components 1-6 developed.*  
*1st Qtr 09/10: Draft proposals for required components 7-13 developed.*  
*3rd Qtr 09/10: Board hears presentation on uniform standards. Staff/counsel identifies changes required to implement standards.*
12. **Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.**  
*4th Qtr 08/09: Provisions for Request for Proposal developed: Request for Proposal released.*  
*2nd Qtr 09/10: Contract awarded.*
13. **Participate in Department of Consumer Affairs Consumer Protection Enforcement Initiative to strengthen board enforcement activities and reduce case investigation completion times for formal discipline.**  
*1st & 2nd Qtr 09/10: Work with Department of Consumer Affairs on identification of Enforcement Best Practices.*  
*Board discusses SB 1441 components for Diversion Programs to strengthen consumer protection enforcement staff attend Enforcement Best Practices work group.*  
*3rd Qtr 09/10: Board senior staff and Board President meet with Department of Consumer Affairs to discuss enforcement program enhancements in SB 1111.*  
*Board staff begin submitting monthly reports detailing workload and improvement efforts to the department.*  
*4th Qtr 09/10: Board hears presentation on CPEI and current status of department and board efforts.*
14. **Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions.**  
*1st Qtr 09/10: Unit created via budget change proposal, 6.5 staff hired, trained, initiate work.*  
*There are 1,287 rapsheet investigations under review.*  
*2nd Qtr 09/10: There are 1,037 rapsheet investigations under review.*  
*3rd Qtr 09/10: There are 652 rapsheet investigations under review.*  
*4th Qtr 09/10: Post implementation review of Criminal Conviction Unit completed.*  
*Enforcement Committee advised of new unit outcomes.*
15. **Complete comprehensive review of investigative and enforcement internal processing to identify process improvements.**  
*1st Qtr 09/10: Board staff implemented on-line assignment of investigations.*  
*Board staff implemented on-line review of draft pleadings.*  
*2nd Qtr 09/10: Board staff began drafting Default Decision and Orders.*  
*4th Qtr 09/10: Board staff began drafting Petition to Revoke Probation Pleadings.*  
*Board staff implemented a pilot program to provide pre-populated investigation reports to the Compliance Team.*
16. **Complete review of pharmacies dispensing prescriptions for Internet web site operators.**
17. **Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB).**

# **Attachment 17**

# Board of Pharmacy Enforcement Statistics Fiscal Year 2010/2011

**Workload Statistics**                      **July-Sept**    **Oct-Dec**    **Jan-Mar**    **Apr-June**    **Total 10/11**

**Complaints/Investigations**

Received	565				565
Closed	754				754
Pending (at the end of quarter)	1151				1151

**Cases Assigned & Pending (by Team)**

Compliance Team	394				394
Drug Diversion/Fraud	98				98
Probation/PRP	85				85
Mediation/Enforcement	74				74
Criminal Conviction	475				475

**Application Investigations**

Received	181				181
Closed					
Approved	85				85
Denied	23				23
Total*	150				150
Pending (at the end of quarter)	448				448

**Letter of Admonishment (LOA) / Citation & Fine**

LOAs Issued	65				65
Citations Issued	307				307
Citations Closed	339				339
Total Fines Collected**	\$191,990.00				\$191,990.00

\* This figure includes withdrawn applications.

\*\* Fines collected (through 8/31/2010) and reports in previous fiscal year.

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2010/2011

**Workload Statistics**                      **July-Sept**    **Oct-Dec**    **Jan-Mar**    **Apr-June**    **Total 10/11**

**Administrative Cases** (by effective date of decision)

Referred to AG's Office*	104				104
Pleadings Filed	82				82
<b>Pending</b>					
Pre-accusation	179				179
Post Accusation	254				254
Total*	508				508
<b>Closed**</b>					
<b>Revocation</b>					
Pharmacist	2				2
Pharmacy	0				0
Other	17				17
<b>Revocation, stayed; suspension/probation</b>					
Pharmacist	5				5
Pharmacy	0				0
Other	0				0
<b>Revocation, stayed; probation</b>					
Pharmacist	2				2
Pharmacy	1				1
Other	1				1
<b>Suspension, stayed; probation</b>					
Pharmacist	0				0
Pharmacy	0				0
Other	0				0
<b>Surrender/Voluntary Surrender</b>					
Pharmacist	2				2
Pharmacy	1				1
Other	12				12
<b>Public Reproval/Reprimand</b>					
Pharmacist	0				0
Pharmacy	0				0
Other	0				0
Cost Recovery Requested	\$108,566.50				\$108,566.50
Cost Recovery Collected	\$38,755.24				\$38,755.24

\* This figure includes Citation Appeals

\*\* This figure includes cases withdrawn

# Board of Pharmacy Enforcement Statistics Fiscal Year 2010/2011

**Workload Statistics**                      **July-Sept**    **Oct-Dec**    **Jan-Mar**    **Apr-June**    **Total 10/11**

**Probation Statistics**

Licenses on Probation

Pharmacist	99				99
Pharmacy	8				8
Other	27				27
Probation Office Conferences	51				51
Probation Site Inspections	36				36
Probationers Referred to AG for non-compliance	1				1

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

**Pharmacists Recovery Program** (as of 9/30/2010)

Program Statistics

In lieu of discipline	1				1
In addition to probation	3				3
Closed, successful	0				0
Closed, non-compliant	1				1
Closed, other	2				2
Total Board mandated Participants	45				45
Total Self-Referred Participants*	30				30
Treatment Contracts Reviewed	73				73

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

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

As of September 30, 2010