# ATTACHMENT O

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

# ENFORCEMENT COMMITTEE MEETING

Holiday Inn Capitol Plaza
300 J Street
Sacramento, CA 95814
June 22, 2005

Present: Stan Goldenberg, R.Ph., Board President and Member
David Fong, Pharm.D., Board Member

Staff: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room, Liaison Counsel, Deputy Attorney General

## Call to Order

Dr. Fong called the meeting to order at 9:35 a.m. He announced that Committee Chair Bill Powers was be unable to attend the meeting due to a previous commitment.

## Importation of Prescription Drugs

Dr. Fong reported that the importation of prescription drugs is an ongoing issue that continues to be on the agendas of the Enforcement Committee and Board of Pharmacy meetings.

Articles were provided regarding the political uncertainty surrounding Canada's Internet pharmacy industry and the differences between foreign prescription drugs and U.S. brand medications.

## Use of Automated Delivery System as Authorized by Business and Professions Code section 4186 in a Clinic Licensed by the Board of Pharmacy

Dr. Louie, Associate Dean at UCSF School of Pharmacy explained that the school is working with the McKesson Foundation to set up a telepharmacy network for urban center indigent clinics.

These clinics are licensed with the Board of Pharmacy pursuant to B & P Code section 4180. The proposal is to place an automated drug delivery system (ADDS) with a video-conferencing system in these clinics. The ADDS will be placed in the clinic with a video-consulting link to UCSF, School of Pharmacy where patients will receive consultative services from a pharmacist/pharmacist intern through the teleconference system. The system is called PickPoint.

Kevin Delaney, President of PickPoint presented an overview of the telepharmacy network that will be placed in the clinics. The telepharmacy is designed for the physician (pharmacist or other person authorized by law to dispense dangerous drugs) to dispense medications from the ADDS to the patients. It is proposed that only those prescription medications dedicated to the community clinics' "focused therapeutics" will be stored in the delivery system. A video-consulting link will be connected to network and routed to the school of pharmacy. Patients will receive pharmaceutical care from the pharmacists and pharmacist interns through the teleconferencing system. A vendor such as McKesson will replenish the delivery system.

Mr. Delaney discussed that the use of PickPoint in these clinics is authorized by Business and Professions Code section 4181 and that Business and Professions Code section 4186 does not govern this type of delivery system because the PickPoint system is only automating the manual prescription drug dispensing system currently allowed in clinics.

Business and Professions Code section 4186 authorizes and defines ADDS in licensed clinics. B & P Code section 4186(b) requires that the drugs be removed from the ADDS only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions, which can be done remotely by a pharmacist in California. Additionally, the law requires that a pharmacist must stock the ADDS and the ADDS must provide for patient consultation with a pharmacist via a telecommunication link that has two-way audio and video.

B & P Code section 4186(h) defines an ADDS as a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. This section also specifies the recordkeeping and accountability requirements for the ADDS.

While the UCSF School of Pharmacy's proposal will provide clinic patients access to the pharmacist and pharmacist intern through a ADDS video-conferencing link, the issue is whether the PickPoint system needs to meet all the requirements of B & P Code section 4186 in order for it to be used in board licensed clinics.

The committee requested clarification from board counsel on the interpretation of pharmacy law related to the use of the PickPoint system in clinics for consideration at the July board meeting.

**Clarification of Pharmacy Law Related to Intern Pharmacists, Orally and Electronically Transmitted Prescriptions and Filling Non-Security Prescription Forms**

Executive Officer Patricia Harris explained that the board requested from its counsel clarification of certain statutes and regulations pertaining to two general areas of inquiry: (1) Whether licensed intern pharmacists may perform certain tasks, including "advanced" techniques such as emergency contraception protocols under Business and Professions Code section 4052, skin puncture under Business and Professions Code section 4052.1, or final checks on prescriptions;

and (2) Whether and how California pharmacists may accept prescriptions not written on security prescription forms, and how these prescriptions fit with the treatment required of orally or electronically transmitted prescriptions.
In responding to this request, counsel advised the board that as always it should not issue any "regulation," guideline, criterion, or rule of general application, giving the agency's interpretation or application of its laws and/or procedures, or the like, except where the formal processes of the Administrative Procedure Act are followed. To avoid an underground regulation, counsel reminded the board that it should refrain from offering or suggesting a binding interpretation of law, or supplementing the existing law.

**Performance of "Pharmacist" Tasks by Intern Pharmacists**

The first inquiry is about the scope of practice authorized for intern pharmacists, and the propriety of their performance of certain specific tasks, including initiation of emergency contraception (EC) therapies, skin punctures, and/or final checks on prescriptions. On the one hand, there are concerns that certain "advanced" or "responsible" tasks are not appropriate for intern pharmacists who are not yet fully trained as pharmacists, and/or are not yet established as professionals in the pharmacy field. On the other hand, the board has heard from others that it is crucial that intern pharmacists get experience in all techniques and tasks they will later perform unsupervised, while they are still training, and that intern pharmacists should become accustomed to being responsible for pharmacy conduct.

The statute(s) pertaining to intern pharmacists, both presently and historically, appear to have adopted this second approach, placing no limits on the tasks to be performed by pharmacist interns, and assuming they will act entirely as pharmacists while they are in supervised training. The present version of Business and Professions Code section 4114 reads as follows:

**§ 4114. Intern pharmacists**

(a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the supervision of a pharmacist whose license is in good standing with the board.
(b) A pharmacist may not supervise more than two intern pharmacists at any one time.

This language states, without limitation, that intern pharmacists "may perform all functions of a pharmacist." Accordingly, anything that a pharmacist may do, an intern pharmacist may do, so long as the pharmacist by whom the intern is supervised agrees/permits it (as these functions may only be performed by intern pharmacists "at the discretion of and under the supervision of" the supervising pharmacist), and so long as the supervising pharmacist is licensed in good standing.

This analysis will not change based on the language expected to be amended via SB 1111. SB 1111 will merely change "supervision of a pharmacist" to "direct supervision and control of a pharmacist," specifying that intern pharmacists may only perform functions of a pharmacist when their supervising pharmacist is on the premises and fully aware of the functions performed.

This analysis is also consistent with the history of section 4114. The current version of the statute was enacted in 2004. Before 2004, and since its initial enactment in 1965, Business and Professions Code section 4097, which became section 4114 in the 1996-97 reorganization of the Pharmacy Law, was even more explicit about the authorization of full intern practice:

**§ 4097. Performance of duties by intern pharmacists; regulations; supervision**
An intern pharmacist may perform such activities pertaining to the practice of pharmacy as the board may determine by regulation. Whenever in this chapter the performance of an act is restricted to a registered pharmacist, such act may be performed by an intern pharmacist under the supervision of a registered pharmacist.

An intern pharmacist may perform such activities pertaining to the practice of pharmacy as the board may determine provided that at the time of performing such acts he was under the immediate, direct and personal supervision of a registered pharmacist, and provided further, that such registered pharmacist shall not supervise more than one intern pharmacist at any one time.

Thus, former section 4097, and section 4114 prior to its simplification in 2004, stated in no uncertain terms that any act "restricted to a registered pharmacist" could "be performed by an intern pharmacist under the supervision of a registered pharmacist." This intention to authorize pharmacy interns to perform the full scope of pharmacy practice (so long as they are supervised by a licensed pharmacist, the supervising pharmacist consents, and the supervising pharmacist is licensed in good standing with the Board) continues in the present version of section 4114, which states that an intern pharmacist "may perform all functions of a pharmacist . . ."

In summary, counsel concluded that Business and Professions Code section 4114 places no limitation on the scope of intern pharmacist practice, other than that: (i) any task must be done under the supervision (soon to be "direct supervision and control") of a licensed pharmacist; (ii) the supervising pharmacist must consent/agree to the performance of any task by the intern pharmacist; and (iii) the supervising pharmacist must be licensed and in good standing with the Board. Section 4114 no longer allows the Board to limit intern pharmacists' scope of practice by Board regulation. Nor, in any event, are there any regulations attempting to do so. (See, e.g., Cal. Code Regs., tit. 16, §§ 1727, 1728).

Accordingly, properly supervised intern pharmacists may, with the consent/supervision of a supervising pharmacist, perform any function authorized for licensed pharmacists. Included in the authorized functions for both pharmacists and intern pharmacists, therefore, are EC therapies (Bus. & Prof. Code, § 4052(a)(8)), skin punctures (Bus. & Prof. Code, § 4052.1), and final check on prescriptions (Bus. & Prof. Code, §§ 4051, 4115; Cal. Code Regs., tit. 16, § 1793 et seq.)

Both the intern pharmacist and his/her supervising pharmacist must, however, meet any necessary prerequisites to performance of any particular function before that function is properly performed by the intern pharmacist. For instance, with regard to provision of EC drug therapy, pursuant to Business and Professions Code section 4052, subdivision (a)(8), prior to performing any procedure authorized under this paragraph, *both* the intern pharmacist (to ensure appropriate provision of services) *and* the supervising pharmacist (to ensure appropriate supervision thereof) must first (i) have participated in instituting and implementing standardized procedures/protocols meeting subdivision (a)(8)(A)(i) and/or (a)(8)(A)(ii), *and* (ii) have received the training required by subdivision (a)(8)(B). Obviously, intern pharmacists cannot receive CE credit for the training, but they must nonetheless have participated in an approved course of training on EC therapy.

Orally and Electronically Transmitted Prescriptions

Acceptance/Filling of Non-Security Prescription Form Prescriptions

The second area of inquiry pertains to what effect(s) ought to be given by pharmacists or pharmacies to written prescriptions not written on the security prescription forms required (as to controlled substances) by Health and Safety Code section 11150 et seq. (particularly 11162.1 and 11164). The board posed a number of specific questions/hypotheticals, including:

> (1) If the Board directs pharmacists to treat Schedule III-V prescriptions not written on the security prescription forms as "oral" prescriptions (under, *inter alia*, Cal. Code Regs., tit. 16, § 1717(c)), is the pharmacist required to rewrite the prescription?
> (2) What if the pharmacist takes the oral order over the telephone and directly enters it into the computer, what is then required of the pharmacist?
> (3) What about prescriptions that are sent electronically from the prescriber's computer to the pharmacy's computer, what is required by Business and Professions Code section 4070, Health and Safety Code section 11164(b)(1) (and/or other statutes and regulations)?
> (4) With the advent of new technologies, does 16 C.C.R. § 1717(c) need to be rewritten?

Counsel explained that as a general matter, the law (at least pertaining to controlled substances) presently permits prescriptions to be transmitted by prescribers in only three ways (excepting chart orders, which are treated differently - Health & Safety Code, §§ 11159, 11159.1): (1) in written form, exclusively on security prescription forms; and, for Schedule III-V drugs plus Schedule II drugs for patients in licensed health care facilities, (2) orally or (3) by electronic transmission. (Health & Safety Code, §§ 11158, 11164, 11167.5). Present law does not permit prescriptions for controlled substances to be transmitted in any written form other than on a section 11162.1 security prescription form.

Present law further specifies that where a controlled substance prescription is transmitted orally or electronically, the pharmacist shall, *prior to filling the prescription*, produce a hard copy of the prescription, signed and dated by the pharmacist(s) (or other authorized person(s)) filling the prescription, containing the date and time of transmission, as well as specified information on the patient, prescriber, and pharmacist. (Health & Safety Code, §§ 11164(b)(1), 11167, 11167.5).

In addition, pharmacy statutes and regulations *further* specify or confirm that all oral and electronic prescription transmissions must be reduced to writing and properly identified before they are filled. (Bus. & Prof. Code, § 4070; Cal. Code Regs., tit. 16, § 1717(c)). Business and Professions Code section 4070 and 16 C.C.R. § 1717(c) each restate the general obligation of a pharmacy/pharmacist to reduce orally- and electronically-received prescriptions to writing prior to compounding, filling, dispensing, or furnishing. Section 4070 goes on to exempt pharmacies from the need to create hard copies of electronically transmitted prescriptions so long as all the information required by Business and Professions Code section 4040, plus the prescriber's name or identifier, can be produced in hard copy form for three years from the last date of furnishing. However, this exemption, by its terms, applies only to non-controlled substance (dangerous drug or device) prescriptions, unless a hospital or pharmacy has received specific permission/waiver under Health and Safety Code section 11164.5 to retain *electronic* records of such prescriptions. In other words, section 4070 (and 16 C.C.R. § 1717(c)) have no general application to treatment of orally- or electronically-transmitted prescriptions for Schedule II-V controlled substances.

Thus, the general state of the law is as follows: (1) a controlled substance written prescription is validly filled only if it is written on a security prescription form; (2) an orally-transmitted prescription for any drug, whether a controlled substance or a dangerous drug, must be reduced to a writing meeting the requirements of Business and Professions Code section 4070 and/or 16 C.C.R. § 1717(c) [for dangerous drugs], and/or Health and Safety Code section 11164.1, 11167, and/or 11167.5 [for all Schedule II-V controlled substances] *prior to* being compounded, filled, dispenses, or furnished; (3) an electronically-transmitted prescription for a Schedule II-V controlled substances, unless a hospital or pharmacy has been granted permission under Health and Safety Code section 11164.5 to retain only electronic records thereof, also must be reduced to a hard copy meeting all of these same requirements; and (4) an electronically-transmitted prescription for a non-Schedule II to V, non-controlled substance, can be filled without reducing the prescription to writing so long as the pharmacy is able to meet the requirements of Business and Professions Code section 4070.

Responding to the specific questions/hypotheticals posed, counsel provided the following applications of the above-stated general principles and understandings to those issues:

(1) For a pharmacist faced with a written prescription not made on a security prescription form, the board has advised that the best course for the pharmacist is to treat that prescription as if it had been orally transmitted. In doing so, however, a pharmacist must actually *transform* the writing into an oral prescription. In other words, the pharmacist *cannot rely* on the written document as assurance of the validity or accuracy of the prescription, and has to contact the authorized prescriber and orally verify and record all of the information that is required by Business and Professions Code section 4070 (dangerous drugs), Health and Safety Code section 11164(b)(1) (Schedule III-V drugs), or Health and Safety Code section 11167/11167.5 (Schedule II drugs in applicable circumstances).

In other words, a written prescription on an "old" triplicate form or any other non-secured prescription form is essentially irrelevant to the validity or accuracy of the prescription. The only purpose it serves is that there is no need for the pharmacist to entirely "recreate" a *new* hard copy of the prescription. Instead, the pharmacist may use the non-security form prescription to record the necessary information, and/or attach documents to that form containing that information. In the strictest sense, the pharmacist is not required to "rewrite" the prescription, but he or she must be sure that all of the pertinent information was received/verified orally, sign and date it, etc.

(2) As to the second question, pertaining to direct entry of orally-received prescriptions into a pharmacy computer, it does not appear that this procedure would exempt the pharmacist from the requirement(s) of hard copy production, personal signature and dating, and recording of all of the required information. Direct entry of orally-transmitted information is not "electronic transmission" exempting the pharmacy from keeping hard copies per Business and Professions Code section 4070 (dangerous drugs) or Health and Safety Code section 11164.5 (controlled substances). In other words, direct entry does not eliminate any of the hard copy requirements.

(3) The third question, pertaining to prescriptions sent electronically from a prescriber or hospital computer to a pharmacy computer, has been answered already by the foregoing general discussion. As a general rule, a hard copy of these prescriptions must be printed out, the required signatures affixed, the required information collected, and the hard copies retained. A hard copy of electronically-transmitted dangerous drug/device prescriptions need not be produced/retained

when the conditions in Business and Professions section 4070 are all met, and a hard copy of an electronically-transmitted controlled substance prescription need not be produced/retained when permission is given and all of the conditions in Health and Safety Code section 11164.5 are met.

(4) Finally, counsel responded to the board's question as to whether it should consider revisions to California Code of Regulations, title 16, section 1717, subdivision (c), to account for technological updates. Because section 1717(c) only covers oral transmissions, it has not yet really been affected by the increasing availability of electronic prescription transmission. However, if the board wanted to also specify treatment of electronically-transmitted prescriptions, either in affirmance of section 4070, or in addition thereto, it might want to include this treatment in section 1717. This might give the board some flexibility to respond to upcoming changes in these technologies.

The Enforcement Committee requested that the pharmacy law clarifications be placed in a question and answer format for the next newsletter.

**Request to Repeal 16 CCR § 1717.2 – Notice of Electronic Prescription Files**

On December 10, 2004 the Board received an email from Steve Gray, Kaiser Permanente, inquiring on the status of repealing California Code of Regulations (CCR) section 1717.2, Notice of Electronic Prescription Files. In his email Mr. Gray outlined the chronology of the board's efforts to repeal 1717.2; board discussion ran from January 2002 through September 2003 with the board taking no action to repeal the section. A review of the board's file on 1717.2 found that there is no written record as to why the board stopped its efforts to repeal 1717.2.

Paul Riches, former board Chief of Legislation and Regulation, recently recalled that the board did not pursue repealing 1717.2, because of concerns that repealing the section might conflict with provisions in the Confidentiality of Medical Information Act. Many laws governing the use of patient information require a patient to give their consent to having their medical records shared with additional parties. CCR 1717.2 is unique in that a patient's information is shared unless a patient specifically request otherwise. If, at some point, the board chooses to repeal 1717.2 it might be perceived as a move to limit patients' ability to control their medical record information. As such, its repeal might be met with significant opposition from privacy protection advocates.

Dr. Gray spoke before the Enforcement Committee to advocate for the repeal of 1717.2. He argued that the sharing of a patient's prescription information is paramount to good patient care in providing the pharmacy with all the patient's prescription information. He also explained that in some instances, patients who are abusing controlled substances are shielded from detection when they choose not to have their prescription information shared. It was also his position that federal privacy laws [Health Insurance Portability and Accountability Act (HIPAA)] allows for the sharing of patient information and this notice is just duplication of the federal law. It was felt that the regulation was out-of-date and state and federal law protects a patient's privacy and this notice is not longer necessary.

The Enforcement Committee requested counsel review the requirements of HIPAA for further discussion of this request at the July board meeting.

Request from the California Pharmacists Association to Require a "Pharmacy Service Plan" When a Waiver is Granted Pursuant to 16 CCR § 1717(e) to Use a Self-Service Drug Delivery System for Refill Medications

The California Pharmacists Association (CPhA) is requesting that the Board of Pharmacy require a pharmacy that is granted a waiver to use a self-service drug delivery system for refill medications to have a "pharmacy services plan" as a condition of granting the waiver.

CPhA is prosing that the pharmacy would be required to have a pharmacy services plan that would include a clear description of how the requested waiver would facilitate the provision of pharmacist care and improve patient care in the pharmacy. It would also include a description of how the pharmacy would monitor and measure the attainment of the plan's goal. The plan could also include a description of the anticipated impact on business operations, hours of operation and staff. It is recommended that compliance with the plan would be monitored by periodic visits by board inspectors. Failure to comply with the pharmacy services plan would be basis for withdrawal of the waiver, or other action by the board.

The committee moved the discussion to the board meeting in July and requested that CPhA provide in its proposal the requirements for a pharmacy service plan in a bullet format that includes a template for such a plan.

Legal Requirements and Process for a Petition for Reconsideration

Executive Officer Patricia Harris reported that when the board adopts a proposed decision of an administrative law judge (ALJ), the respondent (licensee) can appeal or protest all or part of the decision by filing a request (petition) for reconsideration. Oftentimes, the licensee is contesting part or the entire penalty and is requesting a reduction or modification of the disciplinary action. Petitions are usually in a letter format and should clearly state the reasons or grounds for reconsideration.

The board itself may also order reconsideration of a decision on its own motion. This might be done on the request of staff or the Attorney General's Office for the purpose of correction or clarification of the decision.

The Administrative Procedures Act (APA) grants the board authority under Government Code section 11521 to order or grant the reconsideration of a decision. The power to order reconsideration expires on or after the effective date of the decision. Petitions for reconsideration should be submitted well before the decision's effective date to allow the board sufficient time to consider the request. If not submitted timely, the effective date may be stayed in order for the board to decide whether to reconsider its decision. If the board takes no action within the time allowed for ordering reconsideration, the petition is deemed denied.

The APA does not specify the grounds on which an agency may grant or deny a stay of execution and the board's discretion in denying or granting a stay is broad. The board does not have to provide reasons for its action or inaction.

The respondent does not have the constitutional right to reconsideration and the board is not required to act on a petition. Seeking reconsideration is not a prerequisite to judicial review and not acting on a petition does not deny the respondent due process. The respondent still may file for judicial review under Code of Civil Procedure section 1904.5 within 30 days after the effective date of the decision.

Ms. Harris explained that Section 11519 of the APA states that a decision shall become effective 30 days after it is delivered or mailed to the licensee unless; the agency specifically orders that the decision shall become effective sooner than 30 days after service of the decision, the agency itself orders the case to be reconsidered, or a stay of the effective date is ordered. Historically, the board has made the effective date of an adopted decision of the ALJ 30 days after its service.

The board's current policy for handling petitions for reconsideration of a board- adopted decision by an ALJ is as follows:

- Petitions received after the time allowed for reconsideration (on or after the decision's effective date): The petitioner is notified in writing that the board's authority to order reconsideration has elapsed and their option to file for judicial review.

- Petitions received not timely (within a few days of the effective date): The Board of Pharmacy has delegated to the board president the authority to either stay the effective date of the disciplinary order to allow the board to decide whether they will agree to reconsider; or to not take action and consider the petition denied. The board president considers whether there are sufficient reasons provided by the petitioner to grant a request to issue a stay, or to deny the request. If the president decides to issue a stay of the effective date, a stay order of not more than 10 days is issued to allow the board time to decide whether to reconsider the decision. The petition will then be sent to the board for mail vote.

- Petitions received timely (within a sufficient time frame to have the board consider without issuing a stay order): Staff prepares the petition for board review by mail vote. Again, at this stage, the board is only making a decision on whether to reconsider its decision. If the board agrees to reconsideration, a stay order is issued allowing the board sufficient time to reconsider the decision.

Although a licensee who agrees to a stipulated settlement also agrees to waive reconsideration rights, the board has applied its reconsideration policy to those disciplinary decisions adopted by stipulation.

The boards' decision whether to consider a petition is done by mail vote. Because of the short time frame in which to make a decision, this is an expedited process and requires immediate

mailing to the board and close monitoring of the mail votes, oftentimes requiring daily contact with board members.

During a mail vote, based on the information provided in the petition, the board is making a decision on whether to consider a petition. The board is not in the initial vote, deciding on the actual merits of the case or concluding the previously adopted decision should be set aside; it is merely, by its vote to grant reconsideration, concluding that there is adequate legal, factual, and/or policy basis for reviewing the factual findings, legal conclusions and/or disciplinary order.

If reconsideration is granted, the effective date of the penalty will be stayed to allow the board time to consider the issues raised in the petition. The board may reconsider by: (1) receiving written argument from the petitioner and the Attorney General's Office; (2) reviewing pertinent parts of the record or by taking additional evidence, or both, and at its option considering additional argument; or (3) assigning the matter back to the administrative law judge. The board considers the petition and additional written argument during closed session at the next regularly scheduled board meeting or, depending on the complexity of the request, by mail vote.

In the last three years, the board has received 9 petitions for reconsideration. Five of those petitions were sent to the board for mail vote, three were denied by the board president, and one was received on the effective date of the decision, thus not timely and denied. All of the petitions were subsequently denied. Three of those have filed for judicial review and are still pending in the courts. One licensee did not request reconsideration, but requested a stay of the decision pending judicial review of the case. That stay request was denied and the writ review is still with the courts.

Due to the significant resources that were involved in the initial hearing process and are required to process petitions for reconsideration of those decisions and penalties already adopted by the board, and the immediate turn-around time required, the Enforcement Committee was requested to review the board's policy on considering petitions for reconsideration and granting stay orders. The following options were provided for consideration:

1. Effective Date: Disciplinary decisions – either through stipulation or adopted proposed decisions – become effective 15 days after delivery and service to respondent, unless a different date, to be not more than 30 days after delivery, is specifically agreed upon.

2. Petitions for Reconsideration Submitted by Respondent: Do not take action on petitions submitted by respondents – whether timely or untimely, whether as a result of a stipulated settlement or an adopted proposed decision. The board members delegate to the board president the authority not to take action on these petitions and that notice be sent to the licensee that action will not be taken by the board on his/her right to judicial review.

3. Board Reconsideration: Where reconsideration is requested by board staff or the Attorney General's Office, the board members delegate to the board president the authority to grant reconsideration and stay the effective date of the

order to allow the board sufficient time to consider the issues raised in the reconsideration order.

The committee discussed the options. It was noted that when petitions for reconsideration are submitted, the board should evaluate whether or not the petitioner has provided new facts as a basis for reconsidering a decision, or whether new laws have been enacted that may impact the decision. When petitions are provided that argues new facts, the deputy attorney general who represented the board reviews the petition to determine if indeed new facts are being presented. However, the petitions are usually requesting reconsideration of the discipline.

The enforcement committee recommended that the Board of Pharmacy keep its current policy regarding petitions for reconsideration.

**Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Controlled Substance Prescriptions to Become Effective January 1, 2005**

Over the past year and a half, the Board of Pharmacy has been implementing the changes to prescribing and dispensing laws for controlled substances that resulted from SB 151 (Chapter 406, Statutes of 2003). The board has been working hard at educating pharmacists and prescribers on the new requirements and coordinating its efforts with the Bureau of Narcotic Enforcement, the Medical Board of California, other prescribing boards, and professional associations. Since January 2004, the board has provided more than 50 presentations on SB 151. Some of the presentations were provided by teleconference to reach large numbers of individual prescribers and pharmacists. In addition, the board has included numerous articles in *The Script* newsletters, and a large number of articles and frequently asked questions and answers are provided on the board's website.

Beginning January 1, 2005, written prescriptions for all controlled substances must be on tamper-resistant security prescription forms printed by a board-approved security printing company. The tamper-resistant security prescription forms must contain specific elements and security features. There are no restrictions on format, color, or size; therefore, pharmacists need to be aware of the required elements.

If a pharmacist has questions concerning the validity of the prescription, the board is advising that the prescription should be treated like any other questionable prescription – call the prescriber to verify the prescription. If the prescription form does not contain the proper features, it may indicate that a board-approved printing company did not print it. Such prescriptions should be reported to the Bureau of Narcotic Enforcement (BNE) by calling (916) 319-9062 (new) or via fax at (916) 319-9448 (new).

Pharmacists should also report to BNE, prescribers that are not complying with the new prescription form laws. The BNE will notify the applicable prescriber board and a letter will be sent to the prescriber instructing him or her to comply immediately.

Currently, the board has approved 70 security-printing companies to produce the tamper-resistant security prescription forms for authorized prescribers. These approved printers have more than a thousand distributors marketing the new prescription forms to prescribers and pharmacists.

Ms Harris explained that in its April 2005*Action Report* publication, Medical Board of California (MBC) caution physicians regarding DEA's interim policy statement on prescribing Schedule II controlled substances. The interim policy statement prohibits physicians from issuing multiple prescriptions for Schedule II controlled substances on the same day to the same patient with instructions for the pharmacy to fill some of the prescription on a specific date in the future.

MBC stated in its newsletter that unless DEA changes its position, physicians must see their patients each a prescription for a Schedule II drug is written. In its next newsletter, MBC will be providing the following statement to provide guidance and clarity to physicians who prescribe Schedule II controlled substances their patients:

> *When prescribing Schedule II controlled substances to patients, the length of time and Quantity of each Schedule II prescription should be based on the needs of each patient and must be within the standards of responsible prescribing.*

It was noted that Medical Board's position regarding the DEA interim policy statement prohibiting physicians from issuing multiple prescriptions for Schedule II controlled substances on the same day to the same patient with instructions for the pharmacy to fill some of the prescriptions on a specific date in the future will be added to the board's web site and in the next newsletter. It also requested that the board include an article on electronic signatures as well.

**Implementation of SB 1307 (Chapter 857, Statutes of 2004) Relating to Wholesalers**

Last year, the Board of Pharmacy sponsored SB 1307 (Figueroa). Governor Schwarzenegger signed the bill, which became effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee is monitoring the implementation of this legislation. One area of close oversight is the pedigree requirement. The bill requires an electronic pedigree by January 1, 2006 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States.

It is anticipated that Radio Frequency Identification technology (RFID) will the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

SupplyScape presented its electronic pedigree software program that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs.

Acerity Corporation presented its security software program, which is an electronic authentication process. They presented their system at the April board meeting as well. The system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

It is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement.

The committee was also provided with background articles on counterfeit drugs and efforts to combat the problem.

**Adjournment**

Chair Fong adjourned the meeting at 2:00 p.m.

# ATTACHMENT P

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, Governor

# Enforcement Team Meeting
# March 9, 2005

## 3:30 p.m. – 5:30 p.m.

**Present:** President and Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors
Enforcement Staff

**Announcements/Introductions**
The meeting began at 3:30 p.m.

**Quality Improvement Efforts**
Each supervising inspector reported on his/her team's activity for the quarter. Supervising Inspector Robert Ratcliff reported on the status of complaints/investigations. He directed that those cases over one year old be targeted for completion first. It was noted that a routine inspection program for wholesalers was being implemented A wholesale self-assessment form was being developed.

Supervising Inspector Ming reported that in 2001, the board reinstituted its routine inspection program with the goal to inspect every pharmacy every three years. At the start of this goal there were 5,537 licensed pharmacies. The board met this goal within 4 years completing 99% of the inspections with 35 of the initially licensed pharmacies left to perform. Since July 2001, 2,283 new pharmacies were added for a total 7,820 pharmacies that required inspection. The board has completed 7,450 inspections or 95% of its goal with 370 pharmacies left to be inspected.

**Enforcement Committee Discussions**
The Enforcement Team discussed the agenda items from the Enforcement Committee gathering.

**Adjournment**
The meeting was adjourned the meeting at 5:30 p.m.

# ATTACHMENT Q

# ADMINISTRATIVE ACTIONS

# Board of Pharmacy Enforcement Statistics
# Fiscal Year 2004/2005

| Workload Statistics | July-Sept | Oct-Dec | Jan-Mar | Apr-June | Total 04/05 |
|---|---|---|---|---|---|
| **Complaints/Investigations** | | | | | |
| Initiated | 366 | 356 | 318 | 440 | 1480 |
| Closed | 584 | 532 | 402 | 467 | 1985 |
| Pending (at the end of quarter) | 629 | 537 | 540 | 655 | 655 |
| **Cases Assigned & Pending** (by Team) | | | | | |
| Compliance Team | 59 | 65 | 62 | 87 | 87 |
| Drug Diversion/Fraud | 57 | 72 | 74 | 89 | 89 |
| Mediation Team | 189 | 93 | 88 | 108 | 108 |
| Probation/PRP | 45 | 42 | 23 | 40 | 40 |
| Enforcement | 4 | 117 | 52 | 9 | 9 |
| **Application Investigations** | | | | | |
| Initiated | 41 | 33 | 38 | 17 | 129 |
| Closed | | | | | |
| Approved | 13 | 22 | 42 | 25 | 102 |
| Denied | 2 | 6 | 4 | 3 | 15 |
| Total* | 27 | 35 | 52 | 35 | 149 |
| Pending (at the end of quarter) | 54 | 65 | 57 | 39 | 39 |
| **Citation & Fine** | | | | | |
| Issued | 197 | 220 | 138 | 199 | 754 |
| Citations Closed | 336 | 282 | 227 | 159 | 1004 |
| Total Fines Collected | $113,136.00 | $119,406.00 | $136,476.00 | $59,886.00 | $428,904.00 |

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

# Board of Pharmacy Enforcement Statistics
# Fiscal Year 2004/2005

| Workload Statistics | July-Sept | Oct-Dec | Jan-Mar | Apr-June | Total 04/05 |
|---|---|---|---|---|---|
| **Administrative Cases** (by effective date of decision) | | | | | |
| Referred to AG's Office* | 31 | 41 | 41 | 40 | 113 |
| Pleadings Filed | 22 | 27 | 24 | 22 | 73 |
| Pending | | | | | |
| Pre-accusation | 68 | 63 | 60 | 59 | 59 |
| Post Accusation | 79 | 82 | 81 | 77 | 77 |
| Total | 155 | 165 | 170 | 173 | 173 |
| Closed** | 19 | 28 | 33 | 31 | 80 |
| Revocation | | | | | |
| Pharmacist | 2 | 1 | 2 | 6 | 11 |
| Pharmacy | | 1 | 2 | 1 | 4 |
| Other | 2 | 10 | 8 | 9 | 29 |
| Revocation,stayed; suspension/probation | | | | | |
| Pharmacist | 1 | | 4 | 5 | 10 |
| Pharmacy | | | | | 0 |
| Other | | 1 | | | 1 |
| Revocation,stayed; probation | | | | | |
| Pharmacist | 5 | 4 | 5 | 2 | 16 |
| Pharmacy | | 2 | 1 | | 3 |
| Other | | | 1 | | 1 |
| Suspension, stayed; probation | | | | | |
| Pharmacist | 1 | | | | 1 |
| Pharmacy | | | | | 0 |
| Other | | | | | 0 |
| Surrender/Voluntary Surrender | | | | | |
| Pharmacist | 1 | 3 | 1 | | 5 |
| Pharmacy | | 1 | | | 1 |
| Other | 4 | 1 | 6 | 3 | 14 |
| Public Reproval/Reprimand | | | | | |
| Pharmacist | 1 | 1 | | | 2 |
| Pharmacy | | | | | 0 |
| Other | | | | | 0 |
| Cost Recovery Requested | $49,126.50 | $75,991.00 | $138,531.00 | $129,633.50 | $393,282.00 |
| Cost Recovery Collected | $45,201.47 | $55,390.86 | $31,804.61 | $37,025.56 | $169,422.50 |

* This figure includes Citation Appeals

** This figure includes cases withdrawn

# Board of Pharmacy Enforcement Statistics
# Fiscal Year 2004/2005

| Workload Statistics | July-Sept | Oct-Dec | Jan-Mar | Apr-June | Total 04/05 |
|---|---|---|---|---|---|
| **Probation Statistics** | | | | | |
| Licenses on Probation | | | | | |
| Pharmacist | 105 | 106 | 108 | 103 | 103 |
| Pharmacy | 20 | 19 | 15 | 12 | 12 |
| Other | 23 | 23 | 24 | 23 | 23 |
| Probation Office Conferences | 7 | 8 | 13 | 5 | 5 |
| Probation Site Inspections | 23 | 41 | 46 | 43 | 153 |
| Probationers Referred to AG for non-compliance | 0 | 1 | 1 | 1 | 3 |

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 03/31/05)

| Program Statistics | | | | | |
|---|---|---|---|---|---|
| In lieu of discipline | 0 | 1 | 0 | 1 | 2 |
| In addition to probation | 3 | 3 | 6 | 4 | 16 |
| Closed, successful | 0 | 3 | 7 | 3 | 13 |
| Closed, non-compliant | 3 | 4 | 3 | 2 | 12 |
| Closed, other | 1 | 0 | 0 | 4 | 5 |
| Total Board mandated Participants | 42 | 69 | 45 | 46 | 46 |
| Total Self-Referred Participants* | 30 | 4 | 18 | 16 | 16 |
| Treatment Contracts Reviewed | 38 | 35 | 45 | 46 | 164 |

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

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

As of June 30, 2005.

# Board of Pharmacy Enforcement Statistics

| Workload Statistics | 2002/2003 | 2003/2004 | 2004/2005 |
|---|---|---|---|
| **Complaints/Investigations** | | | |
| Initiated | 1505 | 1491 | 1480 |
| Closed | 1213 | 276 | 1985 |
| Pending (at the end of quarter) | 948 | 683 | 655 |
| **Cases Assigned & Pending** (by Team) | | | |
| Compliance Team | 287 | 49 | 87 |
| Drug Diversion/Fraud | 154 | 61 | 89 |
| Mediation Team | 178 | 125 | 108 |
| Probation/PRP | 116 | 40 | 40 |
| Enforcement | 169 | 61 | 9 |
| **Application Investigations** | | | |
| Initiated | 404 | 140 | 129 |
| Closed | | | |
| Approved | 325 | 197 | 102 |
| Denied | 14 | 10 | 15 |
| Total* | 381 | 233 | 149 |
| Pending (at the end of quarter) | 152 | 35 | 39 |
| **Citation & Fine** | | | |
| Issued | 705 | 1589 | 754 |
| Citations Closed | 445 | 1130 | 1004 |
| Total Fines Collected | $399,775.00 | $880,232.00 | $428,904.00 |

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

# Board of Pharmacy Enforcement Statistics

| Workload Statistics | 2002/2003 | 2003/2004 | 2004/2005 |
|---|---|---|---|
| **Administrative Cases** (by effective date of decision) | | | |
| Referred to AG's Office* | 143 | 136 | 113 |
| Pleadings Filed | 81 | 106 | 73 |
| Pending | | | |
| Pre-accusation | 69 | 60 | 59 |
| Post Accusation | 58 | 75 | 77 |
| Total | 130 | 140 | 173 |
| Closed** | 145 | 34 | 80 |
| Revocation | | | |
| Pharmacist | 12 | 20 | 11 |
| Pharmacy | 7 | 5 | 4 |
| Other | 21 | 20 | 29 |
| Revocation,stayed; suspension/probation | | | |
| Pharmacist | 16 | 4 | 10 |
| Pharmacy | 3 | 0 | 0 |
| Other | 1 | 0 | 1 |
| Revocation,stayed; probation | | | |
| Pharmacist | 16 | 13 | 16 |
| Pharmacy | 4 | 2 | 3 |
| Other | 2 | 4 | 1 |
| Suspension, stayed; probation | | | |
| Pharmacist | 1 | 0 | 1 |
| Pharmacy | 2 | 0 | 0 |
| Other | 0 | 0 | 0 |
| Surrender/Voluntary Surrender | | | |
| Pharmacist | 11 | 9 | 5 |
| Pharmacy | 2 | 4 | 1 |
| Other | 12 | 8 | 14 |
| Public Reproval/Reprimand | | | |
| Pharmacist | 10 | 5 | 2 |
| Pharmacy | 2 | 1 | 0 |
| Other | 0 | | 0 |
| Cost Recovery Requested | $381,764.70 | $263,161.75 | $393,282.00 |
| Cost Recovery Collected | $194,567.74 | $171,694.32 | $169,422.50 |

* This figure includes Citation Appeals

** This figure includes cases withdrawn

# Board of Pharmacy Enforcement Statistics

## Workload Statistics

### Probation Statistics

| | 2002/2003 | 2003/2004 | 2004/2005 |
|---|---|---|---|
| Licenses on Probation | | | |
| Pharmacist | 132 | 113 | 103 |
| Pharmacy | 28 | 22 | 12 |
| Other | 21 | 22 | 23 |
| Probation Office Conferences | 66 | 7 | 5 |
| Probation Site Inspections | 228 | 42 | 153 |
| Probationers Referred to AG for non-compliance | 7 | 8 | 3 |

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

### Pharmacists Recovery Program

| | | | |
|---|---|---|---|
| Program Statistics | | | |
| In lieu of discipline | 1 | 3 | 2 |
| In addition to probation | 10 | 9 | 16 |
| Closed, successful | 9 | 7 | 13 |
| Closed, non-compliant | 14 | 7 | 12 |
| Closed, other | 2 | 4 | 5 |
| Total Board mandated Participants | 50 | 54 | 46 |
| Total Self-Referred Participants* | 15 | 15 | 16 |
| Treatment Contracts Reviewed | 138 | 178 | 164 |

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

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

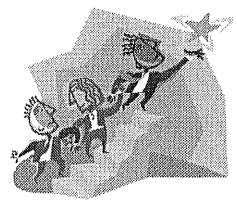
# INSPECTIONS

**State of California** **Department of Consumer Affairs**

# Memorandum

**To:** Patricia Harris, Executive Officer **Date:** July 8, 2005

**From:** Sue Durst, Associate Enforcement Analyst
Board of Pharmacy



**Subject:** **Inspection Program Reaches Strategic Goal**

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On July 1, 2001, the board implemented its Inspection Program toward reaching its strategic goal of inspecting all licensed premises at least once every three to four years. At program implementation, there were approximately **5,530** licensed premises to inspect. Staff is very pleased to report that as of July 1, 2005, a total of **5,524** of those sites or **99.89 percent** have been inspected at least once during this 4-year inspection cycle. Inspectors have already visited 2 of the remaining 6 locations but both sites were closed. Staff anticipates completing all 6 remaining sites by July 20, 2005 and reaching the board's strategic goal.

**Inspection Program 4-Year Inspection Cycle ( July 1, 2001 thru June 30, 2005) ****

| | |
|---|---|
| Number of Licensed Premises as of July 1, 2001 | 5,530 |
| Number of Sites Inspected as of July 1, 2005 | 5,524 |
| Number of Sites Remaining | 6* |

* Two sites already visited once but sites were closed. Anticipate completion of all 6 by July 20, 2005.
** Those sites that were licensed prior to July 1, 2001 Inspection Program implementation that were still active as of July 1, 2005.

The board licensed an additional **2,317** new sites since program implementation; as of July 1, 2005, the board has also inspected **1,958** of these new locations or **95.35 percent**, during the same 4-year inspection cycle.

**Inspection Program 4-Year Inspection Cycle ( July 1, 2001 thru June 30, 2005) Including New Licenses Since Program Implementation ****

| | |
|---|---|
| Total Number of Licensed Premises | 7,847 |
| Total Number of Sites Inspected as of July 1, 2005 | 7,482 |
| Total Number of Sites Remaining | 365 |

*data as of July 1, 2005. These numbers change as licenses are canceled or new licenses added.
** These data reflect the total number of active licensed premises regardless of when the site license was issued.

A grand total of **11,000** [1] inspections were completed during this 4-year inspection cycle (July 1, 2001 to June 30, 2005.) A truly outstanding effort by all board inspectors.

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[1] These data include all inspections completed, including but not limited to, reinspections, routine inspections, complaint inspections, probation/PRP inspections, unlicensed sites, licensed sterile compounding inspections and reinspections, and licenses that have been inspected but have since become inactive or canceled status, etc.

**Other Inspection Program Data**
During this 4-year inspection cycle, inspectors opened 390 [2] complaint investigations (CIs) as a result of a routine inspection (or 5.2 percent of all inspections completed). The following are the top five corrections ordered during a routine inspection:

CCR 1715 Self Assessment
CCR 1711 Quality Assurance Program
CCR 1714 Operational Standards and Security
CCR 1793.7 Requirements for Pharmacies Employing Pharmacy Technicians
B & PC 4342 Sales of Preparations or Drugs Lacking Quality or Strength

**Wholesale Inspection Program Implemented on March 1, 2005**
The Diversion Team implemented its Wholesale Inspection Program on March 1, 2005, with the goal of inspecting all wholesale and veterinary retail licensees at least once every 3 years and educating wholesalers on the new statutes and regulations. The following are highlights of the program as of July 1, 2005:

| | |
|---|---|
| Total Wholesalers | 488 |
| Total Veterinary Food Animal Drug Retail | 19 |
| | 507 |

| | |
|---|---|
| Total inspections completed as of July 1, 2005 | 166 |
| Total CIs opened as a result of inspection | 38 or 22.9% |
| Total inspections resulting in cease & desist | 8 or 4.8% |

***Top Written Notifications For Wholesalers and Veterinary Food Animal Drug Retailers***
- B & PC 4053/1781 – No exemptee employed
- B & PC 4081 – Records violation
- CCR 1780 – Standards
- CCR 1708.2 – Failure to file a discontinuation of business
- B & PC 4160(d) – Owner failure to notify of change of exemptee in-charge
- B & PC 4101(b) - Exemptee- in-charge failure to notify of board of termination of employment
- CCR 1781 - No exemptee present while conducting business

[2] Data for CIs opened as a result of an inspection may not be complete due to the nature of the tracking system. In May 2005, the board implemented a secondary system to assist in capturing these data.

# COMPLAINT/ INVESTIGATIONS

# CITATION AND FINES

# Citation and Fine Statistics
## July 1, 2004 – June 1, 2005

**738 citations have been issued this fiscal year**

Total dollar amount of fines issued $365,525.00

Total dollar amount of fines collected $ 178,425.00*

*This amount only reflects payment of the citations issued this fiscal year.

The average number of days from date case is opened until a citation is issued is 177

The average number of days from the date a citation is issued to the date a citation is closed is 63

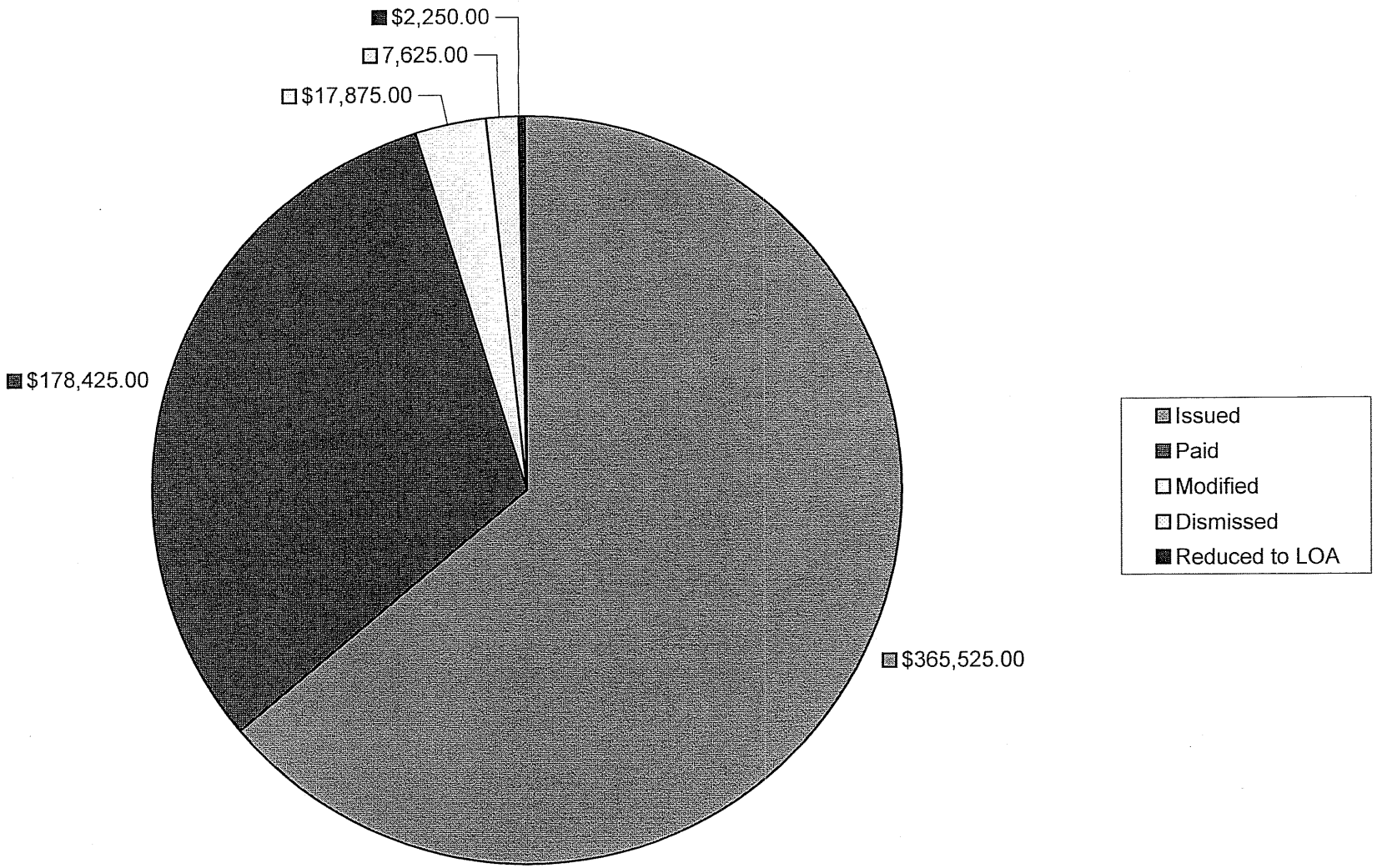
## Citation Breakdown by license type

| Total issued | RPH with fine | RPH no fine | PHY with fine | PHY no fine | PIC with fine | PIC no fine | TCH with fine | TCH no fine |
|---|---|---|---|---|---|---|---|---|
| 738 | 128 | 8 | 164 | 142 | 100 | 68 | 29 | 1 |

## Miscellaneous Citation Breakdown by license type

| Wholesalers | Exemptee's in charge | Clinics | Hypo permits | Hospital pharmacy | Unlicensed Premises | Unlicensed person |
|---|---|---|---|---|---|---|
| 26 | 12 | 8 | 1 | 25 | 19 | 7 |

Citation totals for fiscal year 04 - 05



# Top Ten Violations for the fourth quarter of 2004/2005 by license type

| Pharmacists | % | Pharmacies | % | Pharmacists in charge | % |
|---|---|---|---|---|---|
| 716 - Variation from prescription | 48% | 1716 - Variation from prescription | 35% | 1714(d) - Operational standards and security; pharmacist responsible for pharmacy security | 28% |
| 716/1761 - Variation from Rx / Erroneous Rx | 16% | 1714(b) - Operational standards and security; pharmacy responsible for pharmacy security | 26% | 4125/1711 - Quality assurance program | 12% |
| 714(d) - Operational standards and ecurity; pharmacist responsible for harmacy security | 6% | 1715.6 – Reporting drug loss | 12% | 1716/1761 - Variation from prescription/Erroneous or uncertain prescriptions | 7% |
| 717(b)(4)/4076(a)(4) Preprinted multiple heck off Rx blanks/ container equirements for labeling - Name of the rescriber | 4% | 1716/1761 - Variation from Rx / Erroneous Rx | 12% | 4051/11207/4036 - Conduct limited to a pharmacist; conduct authorized by pharmacist/Only pharmacist or Intern authorized to fill prescription/Pharmacist | 6% |
| 059 – Furnishing dangerous drugs or evices prohibited without prescription | 3% | 4125/1711 - Quality assurance program | 6% | 4127.1 – License to compound injectable sterile drug products required | 6% |
| 125/1711 - Quality assurance program | 2% | 4115(e)-Pharmacy Technician license required | 4% | 4115(e) -4115(e)-Pharmacy Technician license required | 6% |
| 715 - Self-assessment of a pharmacy by the harmacist in charge | 2% | 4127.1(a) - License to compound injectable sterile drug products required | 2% | 4059 – Furnishing dangerous drugs or devices prohibited without prescription | 4% |
| 716/4076(a)(4) - Variation from rescription/ container requirements for abeling - Name of the prescriber | 2% | 4116/1714(d) - Security of Dangerous Drugs and Devices in Pharmacy: Pharmacy responsibility for individuals on premises; | 2% | 1715 - Self-assessment of a pharmacy by the pharmacist in charge | 4% |
| 707.2 – Duty to consult | 2% | 1708.2 – Discontinuance of business | 2% | 4114 – Intern pharmacist: activities permitted | 2% |
| 116/1714(d) - Security of Dangerous Drugs nd Devices in Pharmacy: Pharmacist esponsibility for individuals on premises; Regulations/Operational standards and ecurity | 2% | 1714(c) - Operational standards and security; the pharmacy must be maintained in a sanitary condition | 1% | 1305.11(a) - Unaccepted & defective order forms; No order form shall be filled if it is not complete, legible, or properly prepared, executed, or endorsed; or shows any alteration, erasure, or change of any description | 2% |

# Contested Citations
# Office Conference
# 2004 - 2005

## There were 20 office conferences held during this fiscal year

| Number of requests | 409 |
|---|---|

| Number scheduled | 409 |
|---|---|

| Number appeared | 350 |
|---|---|

| Number Postponed | 80* |
|---|---|

***Please note these are added back into the number of requests and scheduled case totals above.**

| Total number of requests withdrawn | 29 |
|---|---|
| Failed to appear | 8 |

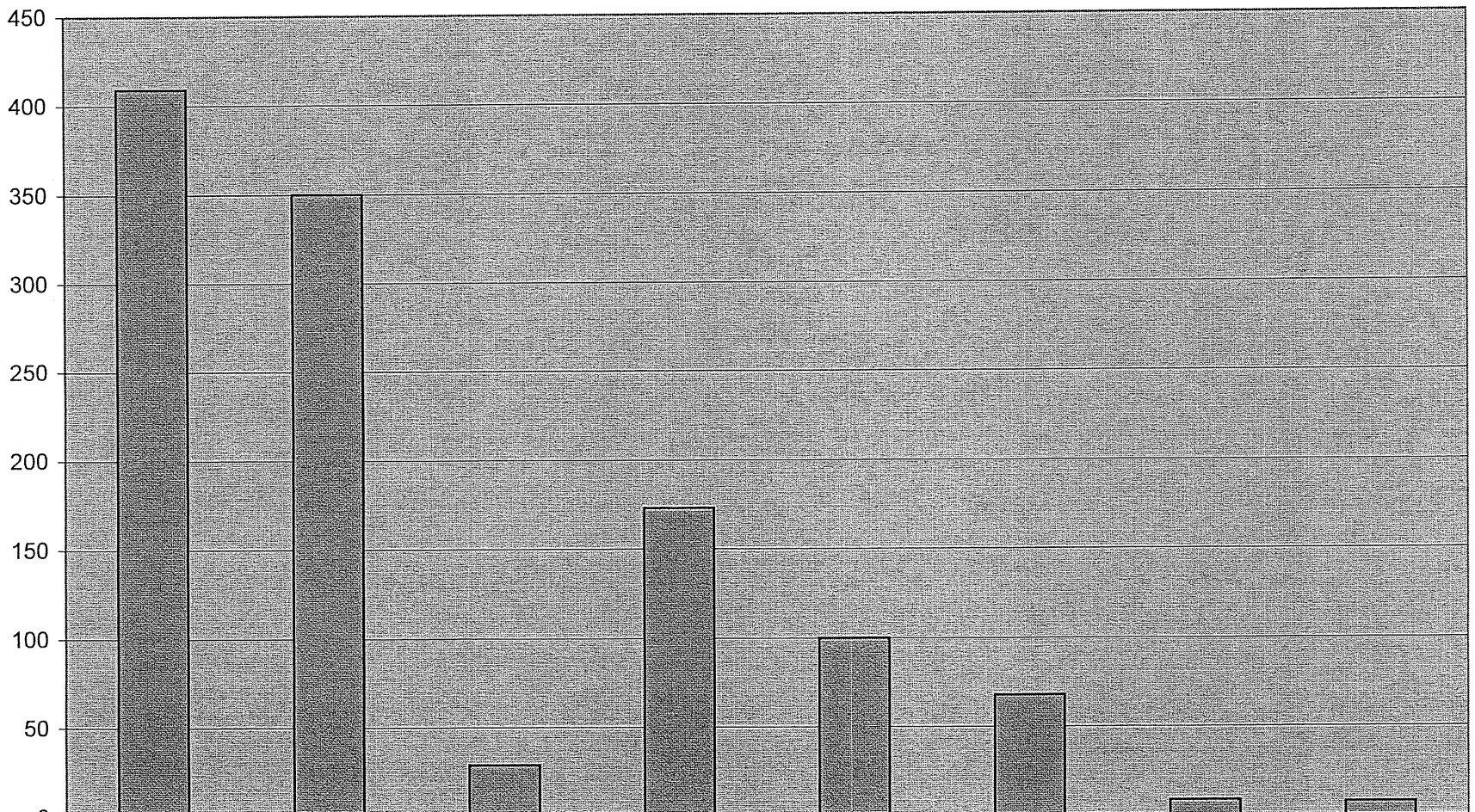
## Office Conference results

| Total number of citations affirmed | 173* |
|---|---|

**(*16 cases have yet to be decided at this time)**

| Decision | Total citations | Total dollar amount reduced |
|---|---|---|
| Dismissed | 100 | $17,875.00 |
| Modified | 68 | $7,625.00 |
| Reduced to letter of admonishment | 9 | $2,125.00 |

## Office Conference Statistics for fiscal year 04-05




| | Requested | Appeared | Withdrawn | Affirmed | Dismissed | Modified | Reduced to LOA | Failed to appear |
|---|---|---|---|---|---|---|---|---|
| Series1 | 409 | 350 | 29 | 173 | 100 | 68 | 9 | 8 |

# Fines Assessed
# Statistic Comparison

| Statistic Category | 02/03 | 03/04 | 04/05 |
|---|---|---|---|
| Total number of citations issued | 908 | 1410 | 689 |
| Average days from case open to citation | 228 | 142 | 177 |
| Total amount of fines assessed | $407,775.00 | $939,259.00 | $365,525.00 |
| Total amount of fines collected to date | $361,975.00 | $852,707.00 | $405,579.00 |
| Number of office conferences requested | 124 | 399 | 409 |
| Total number of conferences held | 20 | 21 | 20 |
| Total number of appearances | 97 | 197 | 350 |
| Number of citations dismissed | 20 | 82 | 100 |
| Number of citations modified | 17 | 72 | 68 |
| Number of citations affirmed | 60 | 43 | 173 |

# CUSTOMER SATISFACTION SURVEY

State of California

Department of Consumer Affairs

# Memorandum

**To:** Patricia Harris

July 11, 2005

**From:** Cassandra Kearney

**Subject:** **Customer Satisfaction Survey**
**Fiscal Report (2004 - 2005)**

The Client Inquiry & Analysis Team (Complaint Unit) mailed out 325 *Customer Satisfaction Survey* postcards from July 1, 2004, through June 30, 2005. The Board received 66 postcards back from consumers; a return rate of 27%.

The *Customer Satisfaction Survey* postcard consisted of four questions with a rating scale of one to five for each question, five being the highest score.

1. Were you satisfied with the way your complaint was handled? *(Average score for the year 3.5)*

2. Were your questions or concerns regarding your complaint or the complaint process answered to your satisfaction? *(Average score for the year 3.4)*

3. Were you satisfied with the outcome of your complaint? *(Average score for the year 3.2)*

4. Were you satisfied with the staff's assistance to you? *(Average score for the year 3.4)*

The overall average score for fiscal year 2004-2005 was 3.4. Information taken from submitted quarterly reports throughout 2004-2005.

# ATTACHMENT R

# Enforcement Committee

**2004-2005**

Fourth Quarter Report

April 1, 2005 thru June 30, 2005

**Goal 1:** **Exercise oversight on all pharmacy activities**

**Outcome:** **Improve consumer protection**

**Objective 1.1:** **To achieve 100 percent closure on all cases within 6 months by June 30, 2005.**

**Measures:** Percentage of cases closed or referred within 6 months.

**Tasks:**

1. **Mediate all consumer complaints within 90 days**

**Quarter 1: based on 228 mediations/investigations sent to Supervising Inspectors for review.**
**Quarter 2: based on 156 sent for review**
**Quarter 3: based on 126 sent for review**
**Quarter 4: based on 114 sent for review**

| Time Frame | Number | | | | Percentage | | | |
|---|---|---|---|---|---|---|---|---|
| **Number of Days** | ***Q1*** | ***Q2*** | ***Q3*** | ***Q4*** | ***Q1*** | ***Q2*** | ***Q3*** | ***Q4*** |
| 0 to 90 | 34 | 12 | 34 | 21 | 68% | 8% | 27% | 18% |
| 91 to 180 | 13 | 26 | 12 | 19 | 26 | 17 | 10 | 17 |
| 181 to 365 | 2 | 1 | 2 | 2 | 4 | 1 | 2 | 2 |
| 366 to 730 | 1 | 0 | 1 | 0 | 2 | 0 | 0 | 0 |

2. **Investigation all other cases within 120 days.**

**Review total stats same as above**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 0 to 90 | 64 | 25 | 39 | 34 | 36% | 16% | 31% | 30% |
| 91 to 180 | 73 | 51 | 26 | 28 | 41 | 33 | 21 | 25 |
| 181 to 365 | 32 | 36 | 10 | 10 | 18 | 23 | 8 | 9 |
| 366 to 730 | 1 | 5 | 0 | 0 | 2 | 3 | 0 | 0 |

3. **Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.**

**Quarter 1: Based on 575 closed mediations/investigations**
**Quarter 2: Based on 495 closed mediations/investigations**
**Quarter 3: Based on 446 closed mediations/investigations**
**Quarter 4: Based on 477 closed mediations/investigations**

| **# of Days** | ***Q1*** | ***%*** | ***Q2*** | ***%*** | ***Q3*** | ***%*** | ***Q4*** | ***%*** |
|---|---|---|---|---|---|---|---|---|
| 0 to 90 | 177 | 31 | 149 | 30 | 150 | 32 | 182 | 38 |
| 91 to 180 | 182 | 32 | 185 | 37 | 149 | 31 | 163 | 34 |
| 181 to 365 | 148 | 26 | 109 | 22 | 122 | 22 | 82 | 17 |
| 366 to 730 | 61 | 11 | 49 | 10 | 20 | 4 | 16 | 3 |
| 731 + | 7 | 1 | 3 | 1 | 5 | 1 | 10 | 2 |

4. **Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any boar-licensed facility when the operations of the facility poses an immediate threat to the public.**

   **Quarters 1 thru 4:** Nothing to report.

5. **Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports).**

**CURES**

**First Quarter:**

The Board has requested the addition of several critical date fields to the CURES system to ensure meaningful and accurate reports: 1) the date CURES was last updated by DOJ; 2) the date data was received at AAI from the pharmacy; and 3) the date data was transmitted from AAI to BNE. The date CURES was last updated is now available. Do to limitations in the current programming and since we are currently in the process of moving to a web based system, BNE has placed the other two date requests on hold until early 2005. No changes this quarter.

**Second Quarter:** Screened transmitted CURES data for pharmacies for data non-compliance issues.

**Third Quarter**

- Staff uploads monthly CURES data files to the inspection program so that inspectors know how many prescriptions were filled, by drug, during the previous 3-month period before going in to do any pharmacy's inspection. Staff reviews data for accuracy and resolves data entry for issues. Staff runs ad hoc reports for additional information on a particular compound pharmacy at the request of the inspector if needed.
- Staff researched CURES records that contained missing or incorrect pharmacy license numbers. The review resulted in bringing approximately 15 pharmacies into compliance.
- BNE implemented the new CURES web-based system mid-February 2005. The CURES enforcement analyst can run ad hoc queries to generate custom reports and schedule standard reports to run automatically all through a web browser. New Cognos Powerplay software appears to provide drag and drop functionality. BNE built a special error data cubes that staff can use to build ad hoc reports to assist in identifying pharmacies transmitting less than 97% accuracy for particular fields of data. For example, a pharmacy entering an
- invalid date of birth or NDC code. BNE has been very responsive when staff call for assistance; however, it will take some time for staff to rebuild many useful reports lost in the migration to the new database.

**Fourth Quarter**

- Staff provided BNE with a list of issues with the new web-based CURES Program. Issues range from the inability to save and print reports, very

slow connectivity, lack of ability to validate data due to lack of documentation provided with standard reports, lack of standard reports requested in the board's business requirements, loss of functionality allowed in the old database using Cognos software, lack of training and more. BNE is working on the issues now and will provide an update at the next Users Group Meeting.

- **5,208 pharmacies reported to CURES 3rd quarter.**
- **5,072 pharmacies reported to CURES 4th quarter.**

CURES reports provided to supervising inspectors and/or inspectors to aid in an investigation or inspection:

- Quarter 1: 23
- Quarter 2: 13
- Quarter 3: 6
- **Quarter 4: 11**

CURES data used in complaint investigations:

- Quarter 1: 26
- Quarter 2: 0
- Quarter 3: 2
- **Quarter 4: 3**

CURES compliance issues found in inspections:

- Quarter 1: 14
- Quarter 2: 8
- Quarter 3: 21
- **Quarter 4: 20**

1782 Wholesaler Data Base: No changes first, second, third or fourth quarter. Board has not been using 1782 reports for the last 3 to 4 years.

DEA 106 Theft/Loss :

- First Quarter: Approx. 39 investigations opened from DEA Loss reports.
- Second Quarter: Approx. 54 investigations
- Third Quarter: Approx. 37 investigations

**Second Quarter:** Created the ability for the analyst to scan the DEA 106 form into a PDF file that is then accessible via an Access database tool.

6. **Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.**

- The CURES Users Group is scheduled to meet the 2nd Wednesday of every month to work on pharmacy noncompliance and data issues as well as to improve database functionality. Additionally, the boards and DOJ have used these meetings to discuss issues and share information related to the implementation of SB 151. Meetings were held on July 20th, September 21st, October 26th and November 30th. The August and December meetings were cancelled. Third quarter meetings are scheduled for January 11th, February 9th and March

16th. Fourth Quarter Meetings are scheduled for May 11 and June 8. The April meeting was canceled due to a conflict with SB734 hearings.

- First Quarter: Board met with BNE to discuss the board's needs for standard reports to be included on the new web-based CURES database scheduled for implementation by the end of this year. The board provided BNE with various samples of board-developed reports currently in use. In addition, staff highlighted numerous issues with BNE-developed standard reports available on the current system. Staff is currently working on updating business requirements and completing formal report development specification documents.

- Second Quarter: Board staff met with BNE to discuss the board's needs for standard reports to be included on the new web-based CURES database. Implementation of the new web-based CURES system is planned for early 2005.

- Third Quarter: The CURES Users Group met the January 11th, February 9th and 10th, and March 9th this quarter. The April meeting is canceled due to a conflict with SB 734 hearings. The User Group meetings focused on SB 151 implementation issues and coordinating FAQ's on the prescribing boards' websites, as well the migration to the new web-based CURES system. BNE presented a PowerPoint presentation and training session to the User Group at its February meeting to introduce the new web-based CURES system.

- Fourth Quarter: The CURES Users Group met on May 11 and June 8. Due to many issues that arose from the migration to the new web-based CURES, meetings have been focused on identifying, discussing, and documenting these issues. BNE is working to rectify as many issues as possible.
- Each quarter: An inspector and a supervising inspector continue to participate on the monthly diversion task force meetings regarding the importation of dangerous drugs, repackaging and distribution in the U.S.; monthly Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego.

7. **Secure sufficient staffing for a complaint mediation team and to support a 1-800 number for the public.**
   - Nothing to report first, second, third, or fourth qtr.

8. **Improve public service of the Consumer Inquiry and Complaint Unit.**

First Quarter:
- Board complaint staff provided information and brochures at the Asian Community Fair on July 15 in Sacramento and at the San Diego Better Business Bureau's Consumer Expo on August 7, 2004.
- Board staff provided consumer information at an adult day care program in Carmichael on September 28.
- In September the board staffed a booth at the Yreka Health Fair where about 450 people attended the event.
- The board staffed a booth at the Sixth Annual Los Angeles

County Health Fair and Senior Exposition on October 7. Nearly 1,000 people attended

- Board has 21 consumer brochures available, including Health Notes.
- Board staff provided information about the board and discount programs for drugs at the Triple "R"
- Adult Day Program in Sacramento on September 28.

Second Quarter:

- October 16th – board staffed a booth at UCD Healthy Aging Event in Sacramento.
- November 16th – board staffed booth at Senior Health Fair in Paso Robles.

Third Quarter:

- March 12, 2005: board staffed a UCD Healthy Aging Fair in Sacramento – "Focus on African American Health."
- 5 health fair events are scheduled for April, May.
- In conjunction with UCSF, board developed and published three new consumer informational flyers addressing the issue of medications that have been recalled, generic medication and cutting drug costs. Board now has a total of 24 consumer brochures, including Health Notes available.

Fourth Quarter

- April 30, 2005: board staffed San Diego Health Fair
- May 7, 2005: staff attended Sacramento Safetyville Fair
- May 19, 2005: outreach table at Sacramento County Health Fair
- May 21, 2005: staffed outreach table at Elk Grove Senior Health Fair

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

**Investigative Activities:**

First Quarter:

- A request to provide the board the capability to download its entire CAS enforcement database into and Access database has been submitted to the department's Office of Information Systems. This modification will enhance the board's reporting capabilities. If approved by OIS January 2005 is targeted for implementation.
- Developed new and improved reports for the automated audit program. This program is used to capture data from prescriptions.
- Security Printer database revisions and improvements this quarter include:
  - Various functionality revisions to ease data entry.
  - Staff developed a new status report and statistical summary,
  - which is set to automatically email an updated version to management weekly.
  - Staff developed a worksheet style report that can be printed and included inside the file cover for easy reference within the file.

Second Quarter:

- CAS download capability request on hold as the department is

evaluating tools to implement ad hoc reporting for Teale enforcement reports.

- Improved the audit program to include a set-up feature multiple pharmacy capability and database replication.
- Provided Blackberry devices to inspector staff.

Third Quarter:

- Department OIS has been evaluating tools to implement ad hoc reporting for Teale CAS enforcement reports. OIS is in the process of selecting a vendor.

Fourth Quarter:

- Evaluation of potential vendors for Teale ad hoc reporting capabilities has begun. Staff has attended one demonstration and more vendor demonstrations are scheduled. Implementation may occur in early 2006.
- Added 2 additional data fields used to destruction inventory purposes.
- Developed new Inventory for Destruction Report to provide to contract vendors to base their costs.
- Revised Evidence Pull List Reports to speed identifying and processing evidence for destruction.
- Developed an Evidence List, by Inspector Report that lists all currently held evidence, whether or not it has been checked out, its current location etc., for each inspector to review. The inspector will sign off that they have reviewed their evidence, identified evidence to destroy, and identified special evidence holds. This new report will ensure evidence is not destroyed without the inspector's approval.

**Inspection Activities** – Automated inspection assignment status reports are sent to supervising inspectors weekly. Revisions and additions made to the automated inspection database include:

First Quarter:

- Modified import specification of Teale data into Access.
- Improved reports in assignment program.
- Improved functionality of Inspector Data program. Now prints nonlicensed staff titles and totals the number of staff employed and present. Inspection report prints license as well as LSC 12345/PHY 67890 when inspecting a LSC site.
- Improvements to be installed by the end of October.
- Added LSC license category to Inspector Activity to more accurately track inspector.
- Data Scrub Program - Each month staff extracts license data in various forms from one large chuck of data to meet the needs of several different internal and external requestors. Board staff finished the development of a data scrub program to automate this function.

Second Quarter:

- Various improvements to the inspection program's functionality were implemented and deployed electronically to all inspectors. Inspectors were able to install the new enhancements with a click of a button to their laptops.
- Uploaded quarterly CURES data to inspection program so that

inspectors can quickly identify whether or not a pharmacy is transmitting CURES data before going in for an inspection. Staff is currently working with DOJ to rectify a data loss issue for pharmacies that have no data during one or more of the 3 months queried. Currently, if a pharmacy has no data for one or two of the three months data queried the pharmacy currently shows they are not transmitting at all. Staff hopes to have the issue rectified early 2005.

- Improved inspector data functionality allows an inspector to select corrections issued on a written notice and also added a print preview on written notices.
- Improved inspection Word file program to automatically update each time the file is accessed by staff to speed download time for inspectors.
- Data Scrub program - staff identified and fixed some minor issues with the program.

Third Quarter:

- Modified Assignment Program report to more accurately reflect submitted data. Single report shows submitted data from the Word database (Word file), Inspection Data (BOP Tank) and Assignment History Tank.
- Added text highlighting to the assignment program to more easily identify and assign inspections that must be completed by June 30, 2005 to make strategic goal of inspecting all sites every 3-4 years. Similar highlighting added to inspector's laptops.
- Modified Inspector Data to automatically give pop-up warning if pharmacy does not have CURES data.
- Modified CURES Scrub Program to allow for importation of data files from a variable location and modified to be able to import up to 15 spreadsheets.
- Modified Evidence program – changes to Inventory Screen - remove duplicates and to show all entries - added comment field and normalized data to eliminate blank data fields - imported TEALE closure codes. Evidence Database – Staff added a destruction box number to the date inventory input worksheet to track the location of evidence that has been pulled and is waiting for destruction. Additionally, staff developed evidence pull list reports by region to aid in the evidence inventory and destruction process.
- Added index to Pharmacy Law PDF file
- Imported January Script into a PDF file with all Scripts for inspectors and staff.
- Modified Inspector Data to tabulate staff statistics, to automatically enter outcomes, enabled all reports to print preview, to automatically generate Word Image file, and changed program flow for more efficient data entry.
- Installed all modifications to Inspector Program on Inspector laptops March 2005
- Security Printer Database – Staff added a new summary worksheet that documents every step of the review process for each application received to in the file when complete.
- Security printer application status reports are emailed monthly to the enforcement manager and executive officer.
- **65** security printers are currently approved to produce controlled

substance prescription forms. **7** of the approved printers utilize the services of **several hundred** distributors that market their prescription products to prescribers.

Fourth Quarter:

- Staff planned, attended meetings, and began developing a new Access database to manage the Probation/PRP program activities.
- Staff developed an Access program for supervisors so that they can view each inspector's assignments and dates of last data transmissions on a real-time basis.
- Staff assisted in the upgrade to the new Digital Dial-up Server to improve remote connectivity. Staff provided instructions to inspectors on how to switch over and use the new server.
- Staff tested, upgraded software, and assisted in the inspector training for the new Garmim GPS units used for mapping travel between inspection locations. These new hand-held GPS voice units replace the old cumbersome paper maps and literally tells the inspector turn by turn directions while driving.
- Various changes to the security printer database were made to improve ease of data entry.
- 70 security printers are currently approved to produce controlled substance prescription forms. 9 of the approved printers utilize the services of several hundred distributors that market their prescription products to prescribers.

**Objective 1.2**

**To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.**

**Measure:**

**Percentage closure on administrative cases within one year.**

**Tasks:**

**1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.**

- April 1st DAG costs increased from $112-$120 per hour to $132 per hour and Legal Assistants hourly costs increased from $53 to $91. Before this increase in fees, the board projected a deficit of $35,000. For 2003/04 the board will have to absorb the increased costs. For 2004/05 the board redirected $70,000 to the AG budget line item rather than pursuing an augment by a BCP.
- July 1 DAG costs increase to $139 per hour. Board receives supplemental funding of $216 thousand to purchase the same level of AG services at a higher hourly rate.

**2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs.**

- Case management and review of pending cases is a continuous process.

| | Q1 | Q2 | Q3 | Q4 |
|---|---|---|---|---|
| Status memos sent to AG | 26 | 19 | 15 | 11 |
| Disciplinary Cases Closed: | | | | |
| 0-365 days | 8 | 8 | 10 | 6 |

| | | | | |
|---|---|---|---|---|
| 366 + days | 13 | 17 | 22 | 25 |
| Accusations reviewed | 27 | 28 | 33 | 31 |
| Accusations needing revision | 10 | 7 | 6 | 5 |
| Accusations filed | 22 | 27 | 24 | 22 |
| Stips/proposed decisions reviewed | 18 | 20 | 26 | 34 |
| Cases reviewed for costs | 12 | 12 | 19 | 9 |

3. **Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.**

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

First Quarter

- Administrative Case Management Database Program -
  - ✓ Changed calculations to reflect change in Legal Analyst and Deputy Attorney General Costs (changes effective April 2004 and July 2004).
  - ✓ Added a report to view cases that had status checks completed during a certain time frame.
  - ✓ Added a report to view Administrative Law Judge costs per case.
  - ✓ Linked the database with the Activity Tracker database. Added reports and more fields to the cost form for easier access and viewing of inspector costs for each case.

Second Quarter: No changes

Third Quarter:

- Administrative Case Management Database Program
  - ✓ Reviewed existing automated reports.
  - ✓ Revised and developed new reports for Enforcement Manager.

Fourth Quarter:

- Administrative Case Management Database Program
  - ✓ Changed calculations to reflect change in Legal Analyst and Deputy Attorney General costs effective 7/2005.
  - ✓ Linked the database with the existing mail vote database for ease of creating and maintaining mail vote information.
  - ✓ Linked the database with the existing Administrative Case Records Retention database for ease of locating stored records.

5. **Review and update disciplinary guidelines**
   - No changes first and second quarter.
   - Third quarter: Guidelines targeted for review and submission at June Enforcement Committee meeting.
   - Fourth quarter: Review and revision started. Guidelines to be reviewed at September Enforcement Committee Meeting.

| | |
|---|---|
| **Objective 1.3:** | **Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004.** |
| **Measure:** | **Percentage of licensed facilities inspected once every 3 years** |

**Tasks:**

1. **Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.**
   - *For all quarters, see response to Objective 1.1, Task #9*

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

Inspection Statistics Background:

Total number of locations identified to inspect from those licensed at the time of the inspection program's July 1, 2001 inception date (does not include sites licensed after 7/1/01) to meet the board's goal of inspecting all sites every 3 to 4 years was approximately **5,530;**
total number of inspections completed **5,524,**
total number of inspections to be completed by July 2005 are **6**.
However, the remaining 6 will be completed by July 20, 2005, reaching the board's strategic goal of 100% sites inspected at least once every 4 years.
(**Percent of all site inspections completed 100%)**

Total number of locations identified to inspect (including sites licensed before and after 7/1/2001) was approximately **7,847**;
total number of inspections completed **7,482**;
total number of inspections to be completed are **365**.

(**Percent of all site inspections completed 95.35%)**

*inspection data as of 7/1/05

| **Number** | **Q1** | **Q2** | **Q3** | **Q4** |
|---|---|---|---|---|
| Inspections Completed | *657* | *593* | *824* | **779** |
| **Type** | | | | |
| Sterile Compounding | *44* | *38* | *42* | ***47*** |
| Status 3 | 3 | 6 | 6 | **4** |
| Routine resulting in complaint investigation. | 9 | 9 | 9 | **39** |

Third Quarter - Implemented Wholesaler Inspection Program beginning March 1, 2005. A total of 490 sites identified for inspection by the Diversion Team.
Fourth Quarter – A total of 507 wholesale and veterinary food animal drug retailer sites identified to inspect.

| | | | **Q3** | **Q4** |
|---|---|---|---|---|
| Wholesaler Inspections Completed | | | 44 | **166** |

3. **Seek legislation to mandate that periodic inspections be done on all board-licensed facilities**

| Objective 1.4<br><br>Measure: | **Develop 4 communications in addition to the inspections program to educate board licensees by June 30, 2005.**<br><br>**Number of communication venues (excluding inspection program)** |
|---|---|
| Task | 1. **Develop the board's website as the primary board-to-licensee source of information.**<br><br>▪ Public disclosure of disciplinary history on licensees is online.<br><br>**First Quarter Web Additions/Revisions**<br>▪ Regulations updates.<br>▪ Added the option to join the Boards e-mail notification list.<br>▪ Posted Memo to Pharmacists on dispensing CII drugs without security or triplicate forms.<br>▪ Posted an audio recording of a presentation on SB 151<br>▪ Listed frequently asked questions on SB 151.<br>▪ Posted Board and Committee Meeting information - agenda, materials and minutes.<br>▪ Revised 2004 Pharmacy Law book.<br>▪ Revised Key Facts about Emergency Contraception.<br>▪ Added Regrade Procedures for Pharmacist Examination.<br>▪ Added additional Security Printers and their distributors (total 25)<br><br>**Second Quarter Web Additions/Revisions**<br>▪ Website redesigned and changed over to the Governor's template<br>▪ Sent out subscriber alert notifications to the board's e-mail notification list.<br>▪ Posted board meeting dates for 2005<br>▪ Posted Board and committee information – agenda, materials & minutes<br>▪ Added an option to take the Board's surveyed.<br>▪ Added non-resident wholesaler forms<br>▪ Updated Security Printer Information<br>▪ Added newly approved Security Printers<br>▪ Regulation updates<br><br>**Third Quarter Web Additions/Revisions**<br>▪ Revised security printer guidelines, and reorganized and revised security printer FAQs.<br>▪ Added new SB151 FAQ's. SB151 Prescribing and Dispensing web page scheduled for reorganization in April 2005.<br>▪ What to Look for on the New Tamper-Resistant Rx Forms, which describes Rx form security features, details preprinted prescriber requirements, details institution style forms for licensed health care facilities and limited exceptions for computer generated institution forms, and provides sample Rx forms.<br>▪ DHS Health Alert and Recall Information<br>▪ January 2005 The Script Newsletter<br>▪ Application Revisions<br>▪ Key Facts About Emergency Contraception in Armenian<br>▪ Additional approved security printers<br>▪ Updated version of the Pharmacy Laws and Regulations<br>▪ Index of new Pharmacy Laws and the effective dates |

- Board meeting and committee materials

**Fourth Quarter Web Additions/Revisions**

- Added the Pharmacists Licensure Exam statistical data for the period March 29, 2004 thru March 31, 2005.
- Posted Board and Committee meeting information and materials.
- Sent out subscriber alert notifications to the board's e-mail notification list.
- Spilt up meeting material packets for an easier download process.
- Added information on the new pharmacy laws that were either amended or added during the 2004 Legislative Session.
- Added Health Alerts and Recalls issued by the California Dept of Health Services.
- Updated the Board's position on Legislation and Bills of Interest page
- Added additional security printers (total 70)

2. **Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations.**
   - March 2004 Script published
   - January 2005 Script published
   - July 2005 Script being edited

3. **Update pharmacy self-assessment annually.**
   - October 2004 – revisions complete, being reviewed at October board meeting.
   - Approved at October 2004 board meeting. Noticed for adoption at January 2005 board meeting.
   - Board approved regulation change.
   - New version to be posted on web.

4. **Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.**

   **First Quarter C/E presentations:**
   - Board staff presented information to approximately 25 pharmacists regarding new controlled substances requirements at a leadership meeting of the Sacramento Valley Health System Society of Pharmacists (June 28).
   - Board staff presented information to law enforcement agencies about CURES and drug diversion (May 27 and 28, not previously reported).
   - Board staff presented information to audit staff of the Department of Health Services (June 30, not reported previously).
   - Board staff presented information about compliance with California's sterile compounding requirements and radio pharmacy on July 8 to a group of about 10 pharmacists to a group in Southern California.
   - Board staff presented information about the new prescribing requirements for controlled substances to physicians in San Luis Obispo on July 14, and to pharmacists and law

enforcement staff on July 15.

- Board staff presented information about prescribing and dispensing controlled substances under the new California requirements to a group of over 40 physicians and other health care providers on August
- Board staff presented information about drug diversion investigations to investigators of the Department of Justice on August 26th.
- Board staff presented information regarding the new requirements for controlled drugs to investigators and staff pharmacists of the Department of Health Services on September 8, and to more than 50 pharmacists, physicians and other health care providers at a presentation hosted by the Pharmacy Foundation of California and Catholic Healthcare West.
- Board staff provided a major presentation at the CMA's annual pain conference in Sacramento on September 10 to more than 600 providers.
- President Goldenberg and Supervising Inspector Nurse presented information about new controlled substances requirements to the San Diego ASCP Chapter on September 13.
- Staff presented information about quality assurance programs and sterile compounding to the Sacramento Valley Society of Health Systems Pharmacists on September 17.
- Staff presented information about the board and new controlled substances requirements to the UCSF Medical Center on September 21.
- Board staff presented information about drug diversion investigations to investigators of the Department of Justice on September 28.
- Staff presented information about the new controlled substances requirements to a group of approximately 100 pharmacists, physicians and other health care providers at St Mary's Medical Center in Orange County on September 30.
- Board staff represented the board at the Circle of Advisors Meeting (regarding emergency contraception) on October 5.
- Supervising Inspector Ratcliff was a speaker at the California Primary Care Association's Tenth Anniversary
- Conference 0n October 7th
- Board Member Jones represented the board as speaker at the Indian Pharmacist Association on October 9,
- where approximately 500 individuals attended.
- In October board presented a telephone *session on the* new controlled substances requirements with health care providers in Redding.
- Board staff presented information about new controlled substances requirements to Santa Clara Medical Society.
- Supervising Nurse provided information about the new controlled substances requirements to the general public at a HICAP meeting in October.

**Second Quarter C/E Presentations**

- The board staffed a booth at the Yreka Health Fair, where 450

| | |
|---|---|
| | people attended.<br>▪ The board staffed a booth at the Sixth Annual Los Angeles County Health Fair and Senior Exposition on October 7—nearly 1,000 people attended.<br>▪ On October 16 board staff hosted a booth at the Healthy Aging Summit in Sacramento where 700 people attended.<br>▪ Board staff provided consumer information at the Paso Robles Senior Center's Senior Health Fair to approximately 400 people on November 6.<br>▪ Board President Goldenberg speaker on importation at the CSHP's 2004 Seminar in Long Beach in November. More than 500 people attended.<br>▪ Supervising Inspector Robert Ratcliff gave the keynote address at CSHP's 2004 Seminar in Long Beach in November 2004.<br>▪ Supervising Inspector Ming presented an "Update and What's New in Pharmacy Compounding" at the CSHP's 2004 Seminar in Long Beach in November 2004.<br>➢ Board staff presented information about the board and the new controlled substances requirements on November 18 to the Orange County Chapter of the CPhA, approximately 80 pharmacists attended.<br>➢ Board Member Jones and Supervising Inspector Ratcliff presented information on prescribing and dispensing controlled substances to 70 pharmacists at an Indian Pharmacist Association Meeting in Artesia on December 10.<br>➢ Supervising Inspector Nurse presented information to the Northern California Pain Initiative Executive Committee on December 14, 2004 via teleconference to approximately 50 prescribers.<br>➢ Supervising Inspector Ratcliff will present information on prescribing and dispensing controlled substances to approximately 60 pharmacists to the South Bay Pharmacy Association on January 6, 2005.<br>➢ The board will participate as a sponsor at a brown bag consultation event with pharmacists hosted by KCRA TV and Rite Aid in Sacramento, about 6,000 people are expected to attend this event on January 8 and 9, 2005.<br>➢ Supervising Inspector Ratcliff will present information about new controlled substances law to approximately 50 pharmacists at Vietnamese pharmacists on January 12.<br>➢ Supervising Inspector Ratcliff will present information on new pharmacy law to Phi Delta Chi at USC on January 20.<br>➢ The board will staff a booth at the Consumer Protection Day event in San Diego on January 29, 2005. Department Director Charlene Zettel will be the keynote speaker.<br>➢ Board Member Jones will present a section at the CPHA's Outlook 2005 Meeting in San Diego in February 2005.<br>➢ Supervising Inspector Ratcliff will present information to 4th year students at Western's School of Pharmacy on February 10.<br>➢ Supervising Inspector Ratcliff will present information on prescribing and dispensing controlled substances to |

| | |
|---|---|
| | approximately 60 pharmacists to the San Fernando Pharmacy Association on February 16, 2005.<br>➢ Supervising Inspector will present information to 1st year students at UCSF's School of Pharmacy on February 22.<br><br>**Third Quarter C/E Presentations:**<br>➢ Supervising Inspector Ratcliff presented information on new pharmacy law to 85 pharmacists and students at Phi Delta Chi at USC on January 20.<br>➢ The board staffed a booth at the Consumer Protection Day event in San Diego on January 29, 2005. Department Director Charlene Zettel was the keynote speaker at this event attended by approximately 1,500 individuals.<br>➢ The board staffed an information booth for two days at CPhA's 2005 Outlook on February 18-19. Over 500 pharmacists and students attended.<br>➢ Board President Goldenberg met with deans from the California schools of pharmacy, CSHP, and CPhA at the CPhA's Outlook 2005 Meeting.<br>➢ Board Member Jones presented information on new dispensing requirements for controlled drugs at the CPhA's Outlook 2005 Meeting in San Diego in February 2005 to over 200 pharmacists.<br>➢ Supervising Inspector Ratcliff presented information on prescribing and dispensing controlled substances to approximately 90 pharmacists to the San Fernando Pharmacy Association on February 16, 2005.<br>➢ Supervising Inspector Ratcliff presented information to 100 1st year students at UCSF's School of Pharmacy on February 22.<br>➢ Supervising Inspector Ming and staff presented information on prescribing and dispensing controlled substances, and applying for the pharmacist licensure examination to 85 students at Western University on February 25.<br>➢ Executive Officer Harris presented information about the board to 1st year students at UCSF on March 1.<br>➢ The board staffed an information booth on March 12 at UCD's Healthy Aging Conference in Sacramento; over 1,000 people attended.<br>➢ Supervising Inspector Ming will present information about new prescribing and dispensing requirements for controlled drugs at the San Mateo County Pharmacists Association Meeting on March 17 to 480 pharmacist and pharmacy technicians.<br>➢ Board Member Schell presented information about pharmacy issues to a group of pharmacists in Butte County on April 7, 2005.<br>➢ Board Member Schell will present information on automated technology in pharmacies to pharmacy students during April 2005's Legislative Day.<br>➢ The board will staff a consumer information booth on April 30 in San Diego at the Better Business Bureau's 2005 Smart Consumer Expo<br>➢ The board will staff a consumer information booth on May |

7th in Sacramento at the 7th Annual Family Safety and Health Expo.

**Fourth Quarter**

- Supervising Inspector Nurse provided information about controlled substances dispensing requires in California to DEA agents from Oakland and San Jose on April 20.
- The board staffed a consumer information booth on April 30 in San Diego at the Better Business Bureau's 2005 Smart Consumer Expo, more than 300 people attended. DCA Director Zettel was one of the speakers
- Board Members Goldenberg and Conroy presented information about becoming involved and new pharmacy law to well over 100 UOP students on May 11.
- The board staffed a consumer information booth on May 7th in Sacramento at the 7th Annual Family Safety and Health Expo. ("Safetyville").
- Board President Goldenberg provided information about the challenges caused by the rising cost of prescription drugs at a Seniors Convention and Health Fair at the LA City Convention Center on May 7,where approximately 1,000 seniors were expected to attend.
- Supervising Inspector Nurse provided information about controlled substances dispensing requires in California to DEA agents from Sacramento and Fresno on May 16.
- The board staffed an information booth on May 19 at the City of Sacramento's employee health fair.
- The board staffed an information booth on May 21 at the Elk Grove community health fair, where approximately 200 people attended.
- Supervising Inspector Ratcliff provided information about new prescribing and dispensing requirements for controlled substances to pharmacist members of the California Employee Pharmacist Association on May 25.
- Supervising Inspector Ming provided information about new prescribing and dispensing requirements for controlled substances to 20Tenent Hospital staff directors on May 25.
- Executive Officer Harris provided information about California's security prescription forms for controlled drugs at the National Association of Boards of Pharmacy annual meeting. She also presented information about the California Health Communication Partnership's activities during this meeting.
- Supervising Inspector Ratcliff provided information about new prescribing and dispensing requirements for controlled substances on June 8 to the Hollywood-Wilshire Pharmacists Association.
- President Goldenberg will represent the board at the founding meeting of the California Pharmacy Leadership Council on June 29.

**5. Hold quarterly Enforcement Committee Meetings**

9/05: Meeting held. Discussed importation of prescription drugs,

proposed legislative changes to pharmacy technician and pharmacist recovery program, waiver requests for prescription kiosks, automated dispensing devices and proposed regulations to authorize the use of kiosks and automated dispensing devices.

12/05: Meeting held. Discussed importation, new pharmacy laws, held presentation on electronic pedigree considered two waivers of 1717(e), and proposed statutory change to require mandatory reporting of impaired licensees.
3/05: Meeting held. Discussed importation, proposed electronic prescribing standards, waiver requests, information on prescribing authority for naturopathic doctors, implementation of SB 151& SB 1307.

**Objective 1.5** — **To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2005.**

**Measure:** — **Percentage compliance with program requirements**

**Tasks:**

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

| **Pharmacists Recovery Program** | ***Q1*** | ***Q2*** | ***Q3*** | ***Q4*** |
|---|---|---|---|---|
| Total # of PRP Participants | 42 | 69 | 63 | 62 |
| Number Referred to PRP | 3 | 4 | 10 | 5 |
| Number Closed from PRP | 4 | 7 | 10 | 9 |

| **Probation Monitoring Program - # on probation** | ***Q1*** | ***Q2*** | ***Q3*** | ***Q4*** |
|---|---|---|---|---|
| Pharmacists | 105 | 106 | 108 | 103 |
| Pharmacies | 20 | 19 | 15 | 12 |
| Other | 23 | 23 | 24 | 23 |

| **Citation and Fine** | ***Q1*** | ***Q2*** | ***Q3*** | ***Q4*** |
|---|---|---|---|---|
| Citations Issued | 197 | 220 | 138 | 199 |
| Fines Collected | $113,136 | $119,406 | $136,476 | $59,386 |

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

   - **First and second quarter:** A citation and fine Access database is scheduled for development. Currently tracking of citation program activities is done on Enforcement CAS and Excel.
   - **Third Quarter:** Citation and Fine program database in developed. Users have been reviewing to ensure the capture of all program activities.
   - **Fourth Quarter:** Citation and Fine program database still in development.

**Objective 1.6**

**Respond to 95 percent of all public information requests within 10 days by June 30, 2005.**

**Measure:**

**Percentage response to public information requests within 10 days.**

**Tasks:**

1. **Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions.**
   - Teale Public Disclosure Screen – completed disciplinary actions are entered into the database on an on-going basis during third quarter staff will begin review of adding filed accusations to public disclosure screens.
   - Web Enforcement Look-Up – In production May 2004. No changes.

2. **Establish on-line address of record information on all board licensees-**

   - Licensee address of record information became available on-line to public in December 2003. *No changes.*

3. **Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests.**

| **Type of Requests Received** | ***Q1*** | ***Q2*** | ***Q3*** | ***Q4*** |
|---|---|---|---|---|
| Public | 31 | 32 | 27 | 24 |
| Licensees | 35 | 16 | 23 | 25 |
| Other agencies | 16 | 19 | 25 | 29 |
| License Verifications | 227 | 208 | 198 | 301 |
| **Time Frame Records Requests Responded To** | ***Q1*** | ***Q2*** | ***Q3*** | ***Q4*** |
| | Number and Percentage | | | |
| Within 10 days | 64 – 78% | 49 – 73% | 61- 81% | 70 – 90% |
| Over 10 days | 18 – 22% | 18 – 27% | 14 - 19% | 8 – 10% |
| **Time Frame License Verifications Responded To** | ***Q1*** | ***Q2*** | ***Q3*** | *Q4* |
| | Number and Percentage | | | |
| Within 10 days | 146 – 64% | 134 – 64% | 158- 80% | 270-90% |
| Over 10 days | 81 – 35% | 74 - 36% | 40- 20% | 31 – 10% |

| Objective 1.7<br><br>Measure: | **Initiate policy review of 25 emerging enforcement issues by June 30, 2005.**<br><br>**The number of issues** |
|---|---|
| **Tasks (Issues)** | 1. Reimportation of drugs from Canada.<br>▪ Importation of Drugs - 2004: discussed at every Enforcement Committee meeting and board meeting.<br>▪ 1/05: discussed at board meeting.<br>▪ 3/05: discussed at Enforcement committee meeting.<br>2. Modification to the Quality Assurance Regulation regarding patient notification.<br>3. Proposals regarding wholesale transactions.<br>▪ Sponsored legislation (SB 1307).<br>▪ 1/05 – SB 1307 became effective.<br>▪ 1/05 – participated in NABP Task Force to develop e-pedigree elements.<br>▪ 1/05 – participated in NABP Wholesaler's Distributors Regulatory meeting and participated in NABP Task Force to develop e-pedigree elements.<br>▪ 2/05 – implementation of SB 1307.<br>▪ 4/05 – presentation to board on pedigree software<br>▪ 6/05 – two presentations to Enforcement Committee on pedigree software.<br>4. Clarification regarding prescription records by authorized officers of the law.<br>5. Review of Pharmacy Law regarding the delivery of medications after the pharmacy is closed and a pharmacist is not present.<br>▪ Sponsored legislation SB 1913<br>▪ 1/05 – bill passed, SB 1913 effective<br>6. Off-site order entry of hospital medication orders (Bus. & Prof. Code Section 4071.1). Regulations adopted.<br>7. Prescriber dispensing.<br>8. Implementation of federal HIPAA requirements.<br>9. Prohibition of pharmacy-related signage.<br>10. Implementation of enforcement provisions from SB 361.<br>11. Implementation of SB 151 (elimination of the Triplicate).<br>▪ 1/05 – new changes to controlled substance law took effect. Continued c/e presentations.<br>▪ 2/05 – continued c/e presentations<br>▪ 3/05 – discussed Q & A at Enforcement Committee meeting.<br>▪ 4/05 – discussed at board meeting.<br>▪ 6/05 – discussed at Enforcement Committee meeting.<br>12. Dispensing non-dangerous drugs/devices pursuant to a prescriber's order for Medi-Cal reimbursement<br>13. Authorized activities in a pharmacy.<br>14. Review of Quality Assurance Program.<br>15. Limited distribution and shortage of medications.<br>16. Conversion of paper invoices to electronic billing.<br>17. Automated dispensing by pharmacies.<br>18. Public disclosure and record retention of substantiated complaints.<br>19. Evaluation of QA regulation<br>20. Biometric technology<br>▪ Statutory change (SB 1913), regulation proposal to implement. |

| | |
|---|---|
| | 21. Update of pharmacy laws related to PRP.<br>▪ 10/04 –board approved statutory changes.<br>▪ 2/05 – Legislation introduced – SB 1111.<br>22. Update of pharmacy law related to pharmacy technicians.<br>▪ 10/04 –board approved statutory changes.<br>▪ 2/05 – Legislation introduced – SB 1111.<br>23. Clean up of "Letter of Admonishment" provision.<br>▪ 10/04 –board approved statutory changes.<br>▪ 2/05 – Legislation introduced – SB 1111.<br>24. Use of "kiosks: for drop-off of prescriptions.<br>▪ 10/05 – board approved waiver for kiosks and regulation change<br>25. Use of self-services dispensing units for pick-up of refill prescriptions.<br>▪ 10/04 – board approved statutory changes<br>▪ 1/05 – board approved second waiver<br>▪ 4/05 – board approved third waiver in conjunction with a study.<br>▪ 6/05 – request to require "Pharmacy Service Plans" for approved waiver.<br>26. Mandatory reporting of impaired licensees.<br>▪ 1/05 –board approved statutory change<br>▪ 3/05 – SB 1111 introduced<br>27. Electronic Prescribing Standards for the implementation of the Medicare Drug Improvement and Modernization Act (MMA) of 2003.<br>▪ 3/05 – Discussed at Enforcement Committee meeting – no action necessary.<br>28. Prescribing Authority for Naturopathic Doctors<br>▪ 2/05 – Met with Bureau of Naturopathic Doctors and other interested parties regarding proposed legislative changes to address inconsistencies in pharmacy law.<br>▪ 2/05 – Requested legal opinion from DCA.<br>▪ 4/05 – Opinion provided to Board<br>29. 6/05 – Pharmacy Law clarification regarding pharmacist interns, orally and electronically transmitted prescriptions, and filling of non security Rx forms for controlled substances.<br>30. 6/05 – Use of automated drug delivery systems in clinics.<br>31. 6/05 – Request to repeal CCR 1717.2<br>32. 6/05 – Legal requirements and process for Petitions for Reconsiderations |
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