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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.