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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE MEETING
MINUTES

DATE: March 29, 2011

LOCATION: First Floor Hearing Room
400 R Street
Sacramento, CA 95816

COMMITTEE MEMBERS PRESENT:
Kenneth Schell, PharmD, Chair
Ramón Castellblanch, Public Member
Deborah Veale, RPh
Shirley Wheat, Public Member

COMMITTEE MEMBERS NOT PRESENT: Tappan Zee, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Tessa Miller, Staff Analyst

Call to Order

Chair Ken Schell called the meeting to order at 1:30 p.m.

A. LEGISLATION REPORT

1. Board-Sponsored Legislation

a. Senate Bill 431 (Emmerson) Pharmacies: regulation

Chair Schell highlighted the following sections:

1) Sections 4104, 4105 and 4112 – Enforcement Enhancements

The following provisions were created to help secure elements of the Consumer Protection Enforcement Initiative and are currently in SB 431:

a. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure

This provision will specify that a pharmacy shall provide the board, within 14 days, evidence of licensee's theft or impairment. It will also require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a copy of the audit results within another 30 days.

b. §4105 – Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

This provision will specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board.

c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

This provision would provide that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, to provide pharmacist related services to Californians.

2) Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine to Reverse Distributors

Over the last several years the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet. The board voted in January 2010 to pursue sponsorship of such legislation that includes the provisions below, but they were not advanced in the prior session.

a. Add Section 4126.7 – Reverse Distributor

Specifies that a reverse distributor may not accept previously dispensed medicine and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines "dispensed" for purposes of this section only.

b. Amend Section 4081 – Records of Dangerous Drugs and Devices Kept Open for

Inspection; Maintenance of Records, Current Inventory

Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a hazardous waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines "hazardous waste hauler" for purposes of this section only.

c. Amend Section 4126.5 – Furnishing Dangerous Drugs by a Pharmacy

Authorizes a pharmacy to furnish drugs to a hazardous waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall.

Discussion

Executive Officer Virginia Herold provided that SB 431 is being amended to implement the provisions regarding reverse distributors. She indicated that the bill will be heard in the last meeting of the Senate Business, Professions and Economic Development in April 2011.

Ms. Herold provided that at the October 2010 Board Meeting, the board voted to pursue an omnibus provision to eliminate a reference to the previous pharmacists examination in Business and Professions Code section 4200. She stated that this modification will be inserted into the omnibus bill, which has not yet been introduced.

No public comment was provided.

2. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

a. Board of Pharmacy/Licensing

AB 377 (Solorio) Pharmacy: Centralized Hospital Packaging

Chair Schell provided that this bill provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. He stated that the bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified.

Chair Schell provided that the bill is scheduled for hearing for April 12, 2011 in the Assembly Health Committee.

Ms. Herold provided that the board was the origin of the initial provisions in this bill, and was encouraged to prevent medication errors and improve compliance with recalls in hospitals.

The committee postponed further discussion of AB 377 in order to hear additional comments regarding SB 431.

Deborah Veale asked whether the board has received any comments regarding SB 431.

Ms. Herold provided that there is concern that pharmacies do not have time to conduct an audit of every drug each time an employee is arrested. She clarified that an audit of what led to the action that the pharmacy took with respect to the employee is required and is not required for every drug in the pharmacy.

Joshua Room, Deputy Attorney General, provided that the language has not been modified to match the board's action at the February 2011 Board Meeting to amend Section 4104 to clarify that a pharmacy shall provide the board within 14 days evidence of a licensee's theft or impairment and require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a copy of the audit results within 30 days of the initial report to the board.

Ms. Veale expressed concern regarding the records requirement under Section 4105 that requires licensees to provide the board with requested records within 72 hours of the time the request was made.

Ms. Herold provided that this section is intended to define "readily retrievable" and is consistent with record requirements for many other states. She stated that the board has received a comment suggesting that this requirement be modified to five working days.

Ramón Castellblanch asked whether the reverse distributor provisions under SB 431 will help to facilitate drug take-back programs.

Ms. Herold provided that these provisions do not apply to drug take-back programs and instead define that a reverse distributor cannot handle drugs that have been dispensed by a pharmacy.

Chair Schell expressed concern regarding pharmacies being an appropriate place to accept returned drugs.

Dr. Castellblanch encouraged the board to address the issue of drug take-back.

The committee resumed its discussion of AB 377.

Assistant Executive Officer Anne Sodergren provided an overview of the bill. She stated that it will benefit the patient by allowing for the delivery of barcoded unit-doses to in-patient's bedsides.

Ms. Herold indicated that this bill was developed in response to the recalls of Heparin in 2008.

Mr. Room sought clarification regarding the provision specifying that a hospital pharmacy may be located outside of a hospital on either the same premises or separate premises, located within 100 mile radius.

Ms. Herold indicated that this is an arbitrary number identified by the author's office.

Public Comment
Steve Gray, representing Kaiser Permanente and the California Pharmacists Association (CPhA), provided comment in support of the bill. He discussed the value of barcoding and advised that not all drugs currently come in barcoded unit dose packages. He encouraged the committee to recommend that the board support this bill.

The committee offered no position recommendation.

AB 399 (Lowenthal, Bonnie) Corrections: Offender Pharmacies

Chair Schell provided that this bill would require the Department of Corrections and Rehabilitation to license all distributions centers and facilities with the board as part of its comprehensive pharmacy services program.

Chair Schell provided that this bill has been referred to the committees on Business and Professions and Consumer Protection and Health.

Ms. Sodergren reviewed an overview of the history on this bill. She stated that last year a bill, AB 2747 (B. Lowenthal, 2010), contained similar provisions but was vetoed. Ms. Sodergren indicated that the 2010-11 Budget trailer bill incorporated many of the provisions of AB 2747 but does not mandate licensing of correctional facilities by the board as would have been required in AB 2747. She clarified that AB 399 has been designed to enhance some the mandates in the Budget trailer bill. Ms. Sodergren provided that the board did not have a position on the previous bill.

Ms. Sodergren clarified that the centralized pharmacy system is not required under existing law to be licensed with the board. She stated that this bill would require licensure.

Supervising Inspector Robert Ratcliff provided an overview of the board's current licensure in this area. He indicated that all pharmacies in the current prison system are licensed with the board.

Public Comment
Steve Gray provided comment regarding the lack of healthcare and standards provided in the California correctional facility system. He discussed that this bill will ensure professional quality control in these facilities. Dr. Gray urged the board to support this bill.

MOTION: To recommend to the board to establish a position of Support on AB 399.

M/S: Veale/Castellblanch

Support: 4 Oppose: 0 Abstain: 0

Additional Comment
Dr. Gray requested an opportunity to point out a technical problem in SB 431. He discussed that courts in California have interpreted the term "authorized officer of the law" as being broad. Dr. Gray questioned whether it is intended that authorized officers of the law have access to a pharmacy's records within 72 hours as required in the bill. He requested that the board reconsider this language.

Chair Schell indicated that this requirement is required under existing law.

Kristy Shellans, DCA Staff Counsel, clarified that current law requires that the records be made available for inspection. She clarified that SB 431 will require that the records be provided within 72 hours.

AB 847 (Lowenthal, Bonnie) Pharmacy: Clinics

Chair Schell provided that this bill would expand these provisions to additionally authorize an outpatient setting or an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing, subject to the requirements applicable to surgical clinics. He stated that the bill would delete the requirement that a clinic operating under these provisions be licensed by the California State Board of Pharmacy and would make that licensure optional.

Chair Schell provided that this bill has been referred to the Assembly Health Committee.

Ms. Sodergren provided that there has been several legislative remedies that have been offered in response to a lawsuit (*Capen v. Shewry* (2007)) that the California Department of Public Health (CDPH) was involved in regarding the regulation of a physician-owned ambulatory surgical clinic. She stated that as a result of the "Capen decision," the board could no longer issue permits to ambulatory surgical clinics with physician ownership.

Ms. Sodergren provided that previous legislation in this area either expanded licensure of a surgical clinic to include those licensed by CDPH, those certified to participate in the Medicare Program and those accredited by an approved agency.

Ms. Sodergren provided that AB 847 will allow clinics to purchase drugs at wholesale and dispense from a common drugs stock. She discussed that this could result in a significant deficiency in that no person would be responsible for ensuring the safety of the drugs being used in such a clinic as none of the oversight that currently exists would apply.

The committee discussed this bill and expressed concern regarding the lack of regulatory oversight. The committee evaluated whether oversight in this area by the board should also include oversight by CDPH.

Ms. Veale offered a proposal to oppose this bill unless amended to include a requirement for licensure by the board.

Chair Schell discussed that the board has jurisdiction over the practice of pharmacy; and as such, it may only be necessary for the board to have oversight over these clinics.

Public Comment

Lori Rice, representing the UCSF School of Pharmacy, sought clarification regarding the board's current oversight of these clinics with respect to drugs that are not purchased from wholesale.

Ms. Herold provided that the board currently has no authority over these clinics unless they hold a clinic license with the board. She stated that each prescriber in a clinic that is not licensed must have his or her own drug stock. Ms. Herold indicated that the Medical Board has jurisdiction over physician-owned drug stock.

MOTION: To recommend to the board to establish a position of Oppose Unless Amended on AB 847. Amend to establish the Board of Pharmacy has the regulatory oversight for these entities.

M/S: Veale/Castellblanch

Support: 4 Oppose: 0 Abstain: 0

SB 100 (Price) Healing Arts

Chair Schell provided that this bill would authorize the board to issue a clinic license to a clinic that is owned in whole, or in part by a physician.

Chair Schell provided that this bill has been referred to the Health Committee and Business, Professions and Economic Development Committee.

Ms. Sodergren provided that this bill will also allow for the licensure of surgical clinics that are owned in whole or in part by physicians by the California Department of Public Health. She stated that the author's office indicates that several of the provisions contained in this bill will be removed, but the changes affecting the board will remain.

Ms. Herold provided that this bill would be consistent with the board's amendment to AB 847.

Ms. Veale offered a proposal to support this bill.

Dr. Ratcliff discussed that there is no definition for the term "purchase at wholesale." He recommended that clarification be provided for this term.

Ms. Sodergren provided that the board can pursue a legislative fix for this concern next year.

MOTION: To recommend to the board to establish a position of Support on SB 100.

M/S: Veale/Castellblanch

Support: 4 Oppose: 0 Abstain: 0

SB 632 (Emmerson) Pharmacy

Chair Schell provided that this bill would prohibit a pharmacist from interchanging or substituting an opioid analgesic drug for an opioid analgesic drug incorporating a tamper resistant technology unless the opioid analgesic drug to be interchanged or substituted is described on a list to be prepared by the board. He stated that in those situations where the drug is not on the board's list, the bill would require the pharmacist to obtain consent from the prescriber prior to an interchange or substitution.

Chair Schell provided that this bill was recently amended and has been referred to the Rules Committee.

Chair Schell referred to the amended language that was provided to the committee and the members of the public. (A copy of this language is attached, following this meeting summary.)

Ms. Herold provided that this bill creates a do not substitute provision for tamper resistant drugs. She stated that the manufacturer of these products has requested that states pursue this provision as the FDA has chosen not to move in this direction.

Mr. Room provided that this goal may already be accomplished under current laws regarding substitution.

Ms. Veale expressed concern that this bill may be creating a solution for an area where there is not currently a problem.

Chair Shell provided that he perceives this bill to be an economic issue rather than a solution.

Mr. Room discussed that this bill would have a workload impact on the board as it requires that the board promulgate the list of opioid analgesic drugs.

Public Comment
Steve Gray, representing Kaiser Permanente, discussed the economic impact this bill will have on vulnerable patients. He urged the board to oppose this bill.

Lori Rice stated that support of this bill would send the wrong message to manufacturers that unique drugs are exempt to substitution. She encouraged the board to oppose this bill.

MOTION: To recommend to the board to establish a position of Oppose on SB 632.

M/S: Veale/Castellblanch

Support: 4 Oppose: 0 Abstain: 0

b. Controlled Substances/Marijuana

AB 507 (Hayashi) Pain Management

Chair Schell provided that this bill would exempt from the unprofessional conduct provisions, any holder of a license who has a medical basis for furnishing dangerous drugs or prescription controlled substances, including for pain or a condition causing pain.

Chair Schell provided that this bill is scheduled for hearing on April 5, 2011 by the Assembly Health Committee.

Ms. Sodergren provided that the proposed amendment to the bill could limit the board's ability to discipline a pharmacist's license when they fail to exercise their professional judgment.

Ms. Shellans discussed that there are two main components under a pharmacist's corresponding responsibility including to ensure that the prescription was written for a legitimate medical need and to identify any excessive furnishing.

Mr. Room provided that from a prosecution point of view, this will reduce, if not eliminate, the board's ability to pursue excessive furnishing cases. He stated that the proposed amendment creates some additional challenges in that the board will need to establish that the prescriptions were not provided for legitimate medical purposes, requiring the employment of medical experts. Mr. Room indicated that the use of such experts will increase the cost and the difficulty of pursuing these cases.

Ms. Shellans provided an example in which the board revoked a license involving the excessive furnishing of large quantities of controlled substances. She stated that this revocation was based on the board's current authority.

Chair Schell discussed that some pharmacies may refuse to fill certain prescriptions based on the belief that the board will go after pharmacies that dispense certain types of controlled substances. He stated that perhaps one of the motivations for this bill is to ensure that pharmacists will not get into trouble with the board for filling such prescriptions.

Ms. Herold provided that the Licensing Committee is currently evaluating topics for possible areas of mandatory continuing education. She stated that the board may consider pain management as a possible topic.

Dr. Castellblanch offered a proposal to oppose this bill.

MOTION: To recommend to the board to establish a position of Oppose on AB 507.

M/S: Castellblanch/Veale

Support: 4 Oppose: 0 Abstain: 0

SB 847 (Correa) Medical Cannabis Licensing Act

Chair Schell provided that this bill would establish the Medical Cannabis Licensing Act to require that a producer, distributor, or seller to be licensed by the California Department of Public Health (CDPH) to engage in the production, distribution, or sale of medical marijuana, and would require the license to be renewed every 12 months.

Chair Schell provided that this bill is scheduled for hearing on April 27, 2011 by the Senate Governance and Finance Committee.

Ms. Sodergren provided that there is a provision in the bill that would specify that the board assist in the development of the inspection program that will be used by CDPH.

It was clarified that the board will have no jurisdiction over these entities.

Chair Schell discussed that it would be helpful to understand why the board's involvement is being requested.

Ms. Sodergren provided that efforts to speak with author's office were unsuccessful.

The committee discussed its involvement with this issue and whether or not it is necessary to make a recommendation to the board.

Shirley Wheat stated that this issue in not within the board's realm. She suggested that the committee not offer a recommendation.

Public Comment
Steve Gray expressed concern regarding this measure. He discussed that the majority of marijuana in California is not being used for legitimate medical purposes. Dr. Gray suggested that CDPH should consider developing potency, quality, and purity standards for marijuana.

Ms. Veale offered a proposal to watch this bill with expressed concern.

MOTION: To recommend to the board to establish a position of Watch with Express Concern.

M/S: Veale/Castellblanch

Support: 4 Oppose: 0 Abstain: 0

The committee recessed for a break at 3:06 p.m.

The committee reconvened at 3:21 p.m.

SB 786 (Dutton) Pharmacy: Clinics

Chair Schell provided that this is a spot bill and has been referred to the Rules Committee.

No public comment was provided. The committee took no action.

c. Reporting Requirements/Records

SB 260 (Canella) Controlled Substances

Ms. Sodergren provided that this bill was recently amended to establish penalties associated with the diversion of controlled substances. She advised that the bill no longer impacts the board.

No public comment was provided. The committee took no action on this item.

SB 315 (Wright) Ephedrine and Pseudoephedrine

Chair Schell provided that this bill would provide, in addition, that any person who obtains ephedrine, pseudoephedrine, phenylpropanolamine, and specified related drugs without a prescription, as specified, shall be guilty of an infraction or a misdemeanor.

Chair Schell provided that this bill is scheduled for hearing on April 5, 2011 by the Senate Public Safety Committee.

Public Comment
Kent Shaw, representing the Office of the Attorney General, discussed the methamphetamine problem in California. He explained that pseudoephedrine is the essential precursor for making methamphetamine. Mr. Shaw provided that pseudoephedrine purchased (smurfed) from retail outlets in California is the exclusive source of this precursor. He indicated that the only viable method to eliminate methamphetamine production in California is to control this precursor by requiring a prescription.

Mr. Shaw reviewed similar efforts by other states including Oregon and Mississippi which has resulted in a significant reduction in methamphetamine labs and methamphetamine production in those states.

Mr. Shaw urged the committee to recommend support of SB 315.

Ms. Veale asked how requiring a prescription will impact the smurfing issue.

Mr. Shaw provided that he believes that this will deter people as they will now be required to be seen by a doctor to obtain a prescription. He discussed that prescribers often prefer not to prescribe this product as there is typically a more effective alternative. Mr. Shaw indicated that since Oregon required a prescription for pseudoephedrine, there has not been one documented case of a prescription pseudoephedrine diverted to manufacture methamphetamine.

Dr. Castellblanch asked who the manufacturer of pseudoephedrine is.

Mr. Shaw provided that there are several different manufacturers. He stated that this bill will only impact 15 products and their generic equivalents. Mr. Shaw indicated that there are 130 alternative products that are readily available.

Ms. Wheat expressed concern that requiring a prescription will negatively impact patients who have a legitimate need for pseudoephedrine.

Mr. Shaw provided that Oregon and Mississippi have not experienced any consumer concern in this area.

Chair Schell discussed other methods and products used to manufacture pseudoephedrine such as farm fertilizer products. He asked whether it would be more productive to regulate these products.

Ms. Shaw provided that these methods and products are not used in California to manufacture methamphetamine.

Ms. Herold asked why the bill does not include a tracking system for these products.

Mr. Shaw provided that once the bill is passed, there will be efforts to include the tracking of these products in the CURES system.

Dr. Ratcliff asked whether sales figures have been evaluated to indentify pharmacies that are excessively furnishing this product.

Mr. Shaw provided that attempts to obtain this information have been unsuccessful as it is considered proprietary information.

Public Comment

Steve Gray, representing Kaiser Permanente, indicated that Kaiser does not support the scheduling of pseudoephedrine and would instead recommend that an interview between the pharmacist and the patient be required to verify that the medication is being dispensed for legitimate medical need.

Dr. Gray provided that Kaiser facilities located in Oregon have experienced an increase in the number of patients who specifically request a prescription for pseudoephedrine during office visits.

Chair Schell expressed concern regarding the alternative offered by Dr. Gray. He discussed that this may subject the pharmacists to threats or possible harm.

Lori Rice, representing the UCSF School of Pharmacy, asked whether this issue is being discussed at the national level. She also asked whether the American Pharmacists Association (APHA) or the American Society of Health-System Pharmacists (ASHP) has provided any input regarding the scheduling of pseudoephedrine.

Chair Schell provided that he cannot speak to the efforts of these organizations; but is aware that this issue has been addressed by the National Association of Boards of Pharmacy (NABP).

Dr. Castellblanch encouraged the committee to consider the evidence from Oregon and Mississippi and to take action on this item.

The committee discussed the importance of this issue with respect to consumer safety and requested input form board staff.

Ms. Herold expressed concern regarding how scheduling pseudoephedrine in California will prevent smurfers from obtaining this product through mail order.

Mr. Shaw provided that mail order has not been an issue and is not perceived to be an issue in California. He stated that there is a federal law that provides control in this area.

Ms. Wheat suggested that the committee recommend that the board generally support this bill.

Dr. Castellblanch offered a proposal to support this bill.

Chair Schell spoke in support of the proposal made by Dr. Castellblanch. He requested that board staff seek input from professional organizations as well as information regarding the department's position on this bill.

Ms. Sodergren provided that the department currently has no bill positions due to a vacancy in the agency secretary position.

MOTION: To recommend to the board to establish a position of Support on SB 315.

M/S: Castellblanch/Veale

Support: 4 Oppose: 0 Abstain: 0

SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System

Chair Schell provided that this bill would revise Schedule I and Schedule II to add additional opiates, revise Schedule III to add additional depressants, anabolic steroid products, and materials, compounds, mixtures, or preparations containing chorionic gonadotropin, a hormone, and Schedule IV to add additional depressants and stimulants.

Chair Schell provided that the bill was amended on March 22, 2011 and referred to the Rules Committee.

Kent Shaw provided an overview of this bill including amendments to provide additional requirements and sanctions for Security Printers to deter fraudulent prescriptions and illegal distribution of controlled substances and to authorize the Department of Justice (DOJ) to initiate administrative enforcement actions to prevent the misuse of the CURES information. He indicated that the existing list of Schedule II-IV controlled substances is being updated to conform with the federal controlled substances list.

Ms. Sodergren discussed some of the challenges expressed by pharmacies with regards to changes made to prescription forms and a failure to implement a transition period. She advised that this bill will implement a transition period for this concern.

Ms. Veale offered a proposal to watch this bill.

MOTION: To recommend to the board to establish a position of Watch on SB 360.

M/S: Veale/Schell

Support: 4 Oppose: 0 Abstain: 0

d. Healing Arts/DCA

Chair Schell explained that the following bills indirectly impact the board.

The committee reviewed two bills of concern, AB 675 and AB 958.

<u>AB 675 (Hagman) Continuing Education</u>

Ms. Sodergren provided that this bill would provide, if applicable, that continuing education (CE) courses, as specified, that advance or promote labor organizing on behalf of a union, or that advance or promote statutory or regulatory changes, political candidates, political advocacy, or political strategy shall not be considered content relevant to the practice regulated by the board and shall not be acceptable for meeting requirements for licensure renewal.

Ms. Sodergren provided that this bill would appear to impact the board's current policy as well as the proposed regulation change currently under promulgation that awards licenses CE to attend a board meeting.

Ms. Shellans suggested that the committee authorize staff to confirm with the author's office whether or not this bill will impact the board's proposed regulation.

The committee instructed board staff to seek clarification from the author's office. Dr. Castellblanch cautioned the committee from supporting provisions that impede rights of free speech.

No public comment was provided.

AB 958 (Berryhill) Regulatory Boards: Limitation Periods

Ms. Sodergren provided that this bill would require the board to file an accusation against a licensee within one year after the board discovers the act or omission alleged as grounds for disciplinary action.

Ms. Sodergren discussed the board's current resource and staffing challenges and stated that board staff would be unable to meet the necessary timelines mandated in this bill which would result in the board's inability to pursue disciplinary action against licensees that undermine consumer protection.

Ms. Wheat provided comment in opposition to this bill. She discussed there are certain things beyond the board's control which would impede staff's ability to meet this timeframe.

Ms. Wheat offered a proposal to oppose the bill.

Ms. Herold discussed challenges the board may encounter in attempting to meet this timeline including rushed investigations resulting in draft and subsequently amended accusations that may lead to further delays.

MOTION: To recommend to the board to Oppose AB 958.

M/S: Wheat/Schell

Support: 4 Oppose: 0 Abstain: 0

Chair Schell indicated that the following spot bills do not require action by the committee.

- AB 1003 (Smyth) Professional and Vocational Licenses
  Recent Action: Referred to Rules Committee.

- AB 1328 (Pan) Professions and Vocations

  Board staff was advised that this measure will not be moving forward.

- SB 231 (Emmerson) Regulatory Boards: Healing Arts

  Board staff was advised that this measure will not be moving forward.

- SB 227 (Wyland) Business and Professions: Licensure

Recent Action: Referred to Rule Committee

- SB 538 (Price) Healing Arts

  This bill was recently amended and is now a sunset extension bill for the Board of Registered Nursing.

- SB 544 (Price) Healing Arts

  This bill was recently amended and is now authorizing the dental board to use a collection fee as specified.

- SB 667 (Wyland) Healing Arts

  Recent Action: Referred to Rules Committee

e. Other

AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products

Chair Schell provided that this bill would impose specified requirements on providers of blood clotting products for home use, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. He stated that this bill would require the California State Board of Pharmacy to administer and enforce these provisions.

Ms. Shellans provided that it is unclear how the board will enforce these provisions.

Ms. Sodergren discussed possible implementation challenges for the board. She explained that the board may not be in a position to assess the clinical experience of the provider to ensure they have sufficient experience to know when patients have an appropriate supply of clotting products on hand as required. Ms. Sodergren stated that it is unclear if the board would have jurisdiction over the nursing home services and the quality of the care provided.

Ms. Veale spoke in opposition to the bill. She discussed that the industry appears to be trying to have the board implement something that they are unable to do in the open market.

Public Comment
Steve Gray, representing Kaiser Permanente, discussed that this bill is an improvement of SB 971 (Pavley). He provided comment regarding the high cost for these drugs. Dr. Gray recommended that the board watch this bill.

Chair Schell encouraged the committee to recommend that the board watch this bill.

Ms. Veale offered a proposal to watch this bill.

MOTION: To recommend to the board to establish a position of Watch on AB 389.

M/S: Veale/Wheat

Support: 4 Oppose: 0 Abstain: 0

AB 604 (Skinner) Needle Exchange Program & SB 41 (Yee) Hypodermic Needles and Syringes

Chair Schell Provided that AB 604 would authorize the State Department of Public Health to authorize, as specified, certain entities to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes.

Chair Schell provided that SB 41 would delete the prohibition against any person possessing or having under his or her control any hypodermic needle or syringe, except in accordance with the aforementioned regulatory provisions.

Chair Schell provided that the board has historically established positions of support on bills in this area.

Dr. Castellblanch provided comment regarding the importance of this issue. He stated that there is ample evidence indicating that needle exchange reduces the prevalence of HIV, AIDS and other diseases.

Dr. Castellblanch offered a proposal to support both bills.

No public comment was provided.

MOTION: To recommend to the board to establish positions of Support on AB 604 and SB 41.

M/S: Castellblanch/Schell

Support: 3 Oppose: 0 Abstain: 1

SB 514 (Simitian) Dextromethorphan: Sale to Minors Prohibited

Chair Schell provided that this bill would make it an infraction for any person in an over-the-counter sale to, without a prescription, willfully and knowingly deliver to a person under 18 years of age a nonprescription drug containing dextromethorphan.

Chair Schell provided an overview of the effects of dextromethorphan. He discussed that the intent of this bill is to minimize drug abuse of this product.

Ms. Veale offered a proposal to support this bill.

No public comment was provided.

MOTION: To recommend to the board to establish a position of Support on SB 514.

M/S: Veale/Schell

Support: 4 Oppose: 0 Abstain: 0

SB 850 (Leno) Medical Records: Confidential Information

Chair Schell provided that this bill would expand those provisions to require that every provider of health care, health care service plan, pharmaceutical company, and contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of written or electronic medical records do so in a manner that preserves the confidentiality, accuracy, and integrity of the information contained in the record.

The committee discussed the workload involved with reviewing the accuracy of a large volume of records.

Ms. Sodergren provided that the author's office indicated that this legislation is intended to ensure the integrity and management of both paper and electronic records. She indicated that the author did not speak specifically regarding the accuracy aspect but would assume that it is intended that the paper records match the electronic records.

Ms. Herold discussed that these provisions may be linked to the Confidentiality and Medical Records Act.

Dr. Castellblanch asked who is responsible for the enforcement of this area.

Ms. Sodergren provided that the board provides enforcement in this area. She indicated that the board opened 76 cases alleging violations regarding patient confidentiality over the past three years. Ms. Sodergren discussed electronic records relevant to pharmacy including faxes and prescription transfers.

Ms. Veale sought clarification regarding federal standards in this area.

Chair Schell discussed that these standards, and similar privacy standards in other states, are more stringent than the federal standards.

Public Comment
Steve Gray, representing Kaiser Permanente, expressed concern regarding the requirement to maintain the integrity and accuracy when destroying electronic records. He suggested that this wording be addressed with the bill's author.

Dr. Gray suggested that the board address electronic memory as a topic in the *Script*. He explained that memory in electronic equipment is retained until the buffer is emptied and could be mined and used for diversion.

Dr. Gray requested that the committee hear additional comments regarding SB 514. He expressed concern that the pharmacist will have to verify the age of the patients. Dr. Gray encouraged the committee to reconsider its position on this bill.

The committee discussed that the board will have an opportunity to consider this position at the next board meeting.

Ms. Veale offered a proposal to watch SB 850.

MOTION: To recommend to the board to establish a position of Watch for SB 850.

M/S: Veale/Castellblanch

Support: 4 Oppose: 0 Abstain: 0

B. Public Comment for Items Not On the Agenda

No public comment was provided.

The meeting was adjourned at 5:13 p.m.

AMENDED IN SENATE MARCH 24, 2011

SENATE BILL No. 632

Introduced by Senator Emmerson

February 18, 2011

~~An act to amend Section 4037 of the Business and Professions Code,~~ *An act to add Section 4052.6 to the Business and Professions Code,* relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 632, as amended, Emmerson. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. ~~Existing law defines the term "pharmacy" for the purposes of these provisions.~~ *A violation of the law is a crime. Existing law authorizes a pharmacist filling a prescription order for a drug product prescribed by the trade or brand name to substitute a generic drug product, subject to specified requirements. Existing law also authorizes a pharmacist filling a prescription order for a drug product to select a different form of medication with the same active chemical ingredients, as specified, if certain requirements are met.*

This bill would ~~make a technical, nonsubstantive change to that provision.~~ *prohibit a pharmacist from interchanging or substituting an opioid analgesic drug, as defined, for an opioid analgesic drug incorporating a tamper resistant technology, as defined, unless the opioid analgesic drug to be interchanged or substituted is described on a list to be prepared by the board. In those situations where the drug is not on the board's list, the bill would require the pharmacist to obtain consent from the prescriber prior to an interchange or substitution. The bill would make findings and declarations in that regard. Because*

a violation of these requirements by a pharmacist would constitute a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: ~~no~~ *yes*.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Opioid use and abuse has increased greatly in the United States since the 1990s and continues to rise. While the benefits of these products in treating and managing pain are widely recognized, the potential for misuse and abuse of these products has long been a concern of manufacturers, federal and state law enforcement, health care providers, legislators, and regulators.

(b) Studies show that addicts tend to crush or otherwise break down time-released products into a form that can be snorted or injected for a more intense high. Thus, formulations that make it more difficult to crush or otherwise manipulate those products may mitigate the potential for abuse.

(c) Pharmaceutical manufacturers have invested enormous research and development resources in both creating novel technologies that may help deter the inappropriate use of opioid medications and testing those products against other opioid formulations.

(d) The United States Food and Drug Administration (FDA) has afforded priority review to new drug applications for opioids incorporating tamper resistant technologies. However, the FDA has been reluctant to permit claims that those products actually mitigate the potential for abuse without additional research. Companies continue to develop post approval data in the overall patient population; however, that effort will take many years. Products incorporating tamper resistant technologies can play an important role today in offering health care providers the

opportunity to prescribe products incorporating tamper resistant technologies that provide advantages in reducing the potential for misuse and abuse of opioids.

(e) Given the critically important public health and law enforcement goals of preventing the abuse and misuse of opioids, the Legislature should approve policies that encourage manufacturers to develop opioid products with tamper resistant technologies and promote efficient use of scarce health care resources.

(f) Health care providers should have the ability to write prescriptions for opioid products incorporating tamper resistant technologies when, in their medical judgment, those prescriptions are medically necessary.

SEC. 2. Section 4052.6 is added to the Business and Professions Code, to read:

4052.6. (a) For the purposes of this section, the following definitions shall apply:

(1) "Opioid analgesic drug" means a drug in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release form and whether or not combined with other drug substances to form a single tablet or other dosage form.

(2) "Opioid analgesic drug incorporating a tamper resistant technology" means an opioid analgesic drug listed as such by the board pursuant to subdivision (b).

(b) (1) For the purposes of carrying out the provisions described in subdivision (c), the board shall create a list of opioid analgesic drugs that incorporate a tamper resistant technology. A drug shall not be included on the list unless the following requirements are satisfied:

(A) The drug manufacturer or distributor submits evidence to the board that the opioid analgesic drug incorporates a tamper resistant technology.

(B) The opioid analgesic drug has been approved by the United States Food and Drug Administration (FDA) pursuant to an application that includes at least one human tampering or abuse potential study or a laboratory study comparing the tamper or abuse resistant properties of the drug to one or more opioid analgesic drugs that have been approved by the FDA and serve as a positive control.

(2) The list shall include a determination by the board as to which opioid analgesic drugs incorporating tamper resistant technologies provide substantially similar tamper resistant properties, based solely upon studies submitted by the drug manufacturer.

(3) Nothing in this subdivision shall be construed to require that a drug included on the list bear a labeling claim with respect to reduction of tampering, abuse, or abuse potential at the time of listing.

(c) (1) Notwithstanding Sections 4052.5 and 4073, a pharmacist shall not interchange or substitute an opioid analgesic drug, brand, or generic, for an opioid analgesic drug incorporating a tamper resistant technology unless the opioid analgesic drug that is interchanged or substituted is included on the list described in subdivision (b).

(2) If the opioid analgesic drug is not on the list described in subdivision (b), the pharmacist shall obtain consent from the prescribing physician and surgeon prior to an interchange or substitution. The consent may be obtained by telephone or through any other electronic communication.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

~~SECTION 1. Section 4037 of the Business and Professions Code is amended to read:~~

~~4037. (a) "Pharmacy" shall mean an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous~~

~~drugs, or dangerous devices are furnished, sold, or dispensed at retail.~~

~~(b) "Pharmacy" shall not include any area in a facility licensed by the State Department of Public Health where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.~~

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