



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

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

DATE: October 29, 2008

LOCATION: Radisson Hotel – San Francisco Airport Bay Front
5000 Sierra Point Parkway
Brisbane, CA 94005

BOARD MEMBERS

PRESENT: Robert Graul, RPh, Chairperson
Andrea Zinder, Public Member
Robert Swart, PharmD
Bill Powers, Public Member
Shirley Wheat, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kristy Schieldge, Senior Staff Counsel
Tina Thomas, Analyst

Chairperson Graul called the meeting to order at 4:08 p.m.

I) Requests for legislative regulatory proposals for 2009

A) Proposed Legislation

1) Immunizations by Pharmacists Pursuant to Published Recommendations for the Advisory Committee on Immunizations Practices – Senate Business & Professions Code (B&PC) §4052.8

Chairperson Graul stated that at the April 2007 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices.

Chairperson Graul explained that, beginning in November 2007, board staff worked with stakeholders to address questions as well as to elicit support for this proposal. He added, however, that in April 2008, after consideration it was decided not to move the proposal in 2008. It is being brought before the board for consideration and possible sponsorship in 2009.

Chairperson Graul indicated that, should the committee and board pursue this proposal, board staff will immediately begin working closely with key stakeholders to build a strong coalition in support of this legislation.

Chairperson Graul noted that a copy of the proposed language as well as a copy of the Adult and Adolescent Immunization Schedules are contained within the board packet provided.

Public Comment:

Steve Gray (Kaiser Permanente) stated that, on behalf of Jeff Goad, he would provide background on the issue at hand. He stated that the problem lies with a lack of immunizations being given to the public as a whole. He added that allowing pharmacists to administer immunizations would improve the overall immunization rate across the board due to simplicity, cost of access, and a relationship built between patients and their community pharmacist. He noted that there have been immunization allowances conducted by pharmacists across the country for many years; however, under current law a physician must sign a protocol to participate with a pharmacy. The problem arose when physicians began to receive notification that this type of protocol was not standard medical practice and would not be covered under their malpractice insurance. Dr. Gray noted that, although the very large pharmaceutical organizations are not deterred by this, and continue to participate with physicians, the smaller and medium-sized corporations cannot support that type of assistance from physicians. He noted that Kaiser supports this legislation as a good measure to protect public health, even though they are not participating as they have other departments who already provide the service.

Andrea Zinder asked for clarification that retail-chain pharmacies that currently offer immunizations are doing so under the protocol of a physician.

Dr. Gray confirmed that they would be conducting immunizations under a protocol of a physician if they can find one or if they can be self-insured and hire a physician.

Ms. Zinder asked if the physician would need to be licensed in California.

Dr. Gray responded that it is unclear and so he can not comment.

Ms. Zinder asked if there would be protocol for specific immunizations if legislation were to pass.

Virginia Herold responded that protocol has been developed for specific immunizations recommended by the Center for Disease Control. She noted that the proposal would not include the Pediatric Schedule, so that young children would not be covered.

Chairperson Graul indicated that the recommended schedule of adult immunizations was contained within the board packet.

Dr. Gray stated that the schedule was drafted in line with what the CDC recommends from the Advisory Committee on immunization practices. He added that it was written to allow for additional vaccinations if recommended in the future.

Ms. Herold noted that this legislation was approved by the board last year for sponsorship; however the board chose not to move forward as there were concerns by the California Medical Association (CMA).

Bill Powers asked what the relationship is currently with CMA.

Ms. Herold responded that there are a couple of people who have approached CMA from a policy perspective at the physician level. She added that Dr. Goad (Spelling) has experts who are willing to discuss the issue with CMA. She stated that it would be incumbent on the board if they should choose to move forward in this area. Ms. Herold said that typically, these kinds of immunizations are a problem for physicians (due to storage requirements, expiration dates, etc.) and pharmacies that are positioned in terms of providing direct patient care to administer these. She added that she feels it is far more appropriate for patient care, that the specific pharmacist who is going to administer immunizations step forward and accept responsibility and professional obligation that goes with administering the drug.

Dr. Gray noted that, within the proposed legislation, the pharmacist must complete a rigorous nationally accredited course and continuing education. He added that there has been a change under Medicare Part D, where immunizations will now be covered for seniors (within Part D rather than Part B).

There was discussion on the type of immunizations which would be covered for seniors under Medicare Part D.

Shirley Wheat asked about the safety of immunizations during the time of a pharmacist shortage. She stated that she is in support of more accessibility for patients to immunizations; however, she is concerned about the consequences and responsibility for patients in the event of reactions, etc.

Chairperson Graul explained the recordkeeping requirements involved for any immunizations, to assess any concern for allergies, etc. He noted that there has been improvement in the area of proper storage, temperature, etc. within pharmacies. He also discussed the concern over workload and felt that it is feasible for pharmacies to conduct the immunizations.

Robert Swart reviewed the extent of training required in addition to the coursework. He stated that there will need to be regulations in place to ensure that pharmacists are completing all supporting training needed.

There was discussion on travel vaccines, and it was noted that they are not covered under the schedules provided and therefore are not included in this proposal.

Ms. Wheat asked if the board would be responsible for enforcement of administering the immunizations and disposal of the syringes utilized.

Ms. Herold explained that the pharmacies are already educated and have policies in place regarding proper storage and disposal of syringes used for immunizations. She noted that there will be many pharmacies who will not want to take on the administering of immunizations, as it will add more staffing requirements to be specially trained. She added, however, that for those who are interested in pursuing qualifications for providing the service, it will be a benefit to the public.

Chairperson Graul pointed out that the accessibility advantage applies in more than just a rural setting. He noted the challenges with scheduling appointments with physicians, and indicated that it will be likely that patients will appreciate the ease of visiting their local pharmacy instead.

Ms. Zinder asked for clarification on how the legislation will expand the service beyond what is already being offered.

Chairperson Graul stated that it solidifies the program to allow for consistency through standardization.

Anne Sodergren added that it also strengthens the requirements for any pharmacist to administer immunizations irrespective of whether or not they do so pursuant to the CDC guidelines or through protocol.

Bryce Docherty (California Society of Health-Systems Pharmacists) stated that they will strongly support the bill, as they were supportive of the bill last year. He commended the board for their efforts in this regard and noted that CSHP is open to any discussion with the board in the future.

Chairperson Graul noted that this legislation will require a board base of support, and asked those in attendance to share that need with others within industry.

Lynn Rolston (California Pharmacists Association) stated that they are in support of the bill and will work with their chronic care coalition partners. She added that this is another way to significantly increase access.

Dr. Gray noted that, by putting this into the statute, it becomes part of the scope of practice of a pharmacist. Consequently, it is automatically covered under their personal liability insurance. He also added that, for most vaccines, there are federal funds in place for the rare incident of vaccine reactions to patients.

MOTION: To recommend to the board to pursue legislation to allow a pharmacy to initiate and administer and immunization pursuant to the Advisory Committee on Immunization Practices Adult and Adolescent Immunization Schedule.

M/S: BP/RS

Support: 4 Oppose: 0

2) Omnibus Provisions Included in SB 1779 (Senate Business and Professions Committee) Vetoed by the Governor

The committee discussed the omnibus provisions previously approved for inclusion in the 2008 Omnibus bill. Many of these changes were recommended in SB 1779 as Omnibus provisions. However, the bill was vetoed by the Governor.

Section 4160 – Wholesaler Licenses

This section requires amendment to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications

This section requires amendment to clarify the procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has occurred. In addition this section allows for the use of an interim pharmacist-in-charge, for a period not greater than 120 days, when a pharmacy is unable to identify a permanent new pharmacist-in-charge within 30 days as required.

Section 4161 – Non-Resident Wholesaler; Requirements

This section requires amendment to further clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC 4043.

Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked

This section requires amendment to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action

This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.

Section 4329 – Nonpharmacists; Prohibited Acts

This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

Section 4330 – Proprietors; Prohibited Acts

This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions.

A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy

This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation

Section 4362 – Entry Into Pharmacists Recovery Program

This section requires amendment to specify the administrative co-pay participants pay.

H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature

This section requires amendment to require that a clinic that dispensed schedule III and schedule IV controlled substances must report to CURES.

Section 733 – Dispensing Prescription Drugs and Devices

Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities

Section 4040 – Prescription; Content Requirements

Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist

Section 4060 – Controlled Substance – Prescription Required, Exceptions

Section 4076 – Prescription Container – Requirements for Labeling

Section 4111 – Restrictions on Prescriber Ownership

Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner

H&SC 11150 – Persons Authorized to Write or Issue a Prescription

Public Comment:

Heidi Barsuglia (California Retailers Association) provided suggestions to language as currently provided. She referenced a change within §4062 subsection (c), and suggested the language to state “except as otherwise provided in §4110” for consistency. She also referenced §4110 subsection (c) and recommended adding language to allow for mobile pharmacy when under construction or undergoing remodel.

MOTION: To move the addition of suggested changes made in §4062 subsection (c) and §4110 subsection (c) as specified.

M/S: BP/AZ

Support: 4 Oppose: 0

3) Nonresident pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation – Amend B&PC §4112

Chairperson Graul stated that board staff is recommending amendment to §4112 of the Business and Professions Code to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state. This change should be noncontroversial and could be included as an omnibus provision.

MOTION: To amend §4112 of the Business and Professions Code to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state. (check with Anne if OK)

M/S: AZ/BP

Support: 4 Oppose: 0

4) Pharmacists: Biennial Renewal – Amend B & PC §4401

Chairperson Graul stated that board staff recommends amendment to §4401 of the Business and Professions Code (B&PC) to explicitly require that a pharmacist notify the board of any misdemeanor to felony convictions or whether any disciplinary action has been taken as specified subsequent to the licensee's last renewal.

Chairperson Graul said that the committee may also want to consider amendment to B&PC 4403 to require the same of pharmacy technicians and designated representatives.

Chairperson Graul explained that, several months ago, board staff sought to make changes to the renewal forms for these licensees; however, were advised by counsel that they have no specific statutory requirements to require this information. At that time staff was advised that a statutory change would be required.

Chairperson Graul indicated that there was a recent series of articles published about the enforcement activities of the Board of Registered Nursing, focusing on their handling of criminal conviction investigations. He stated that that Board of Pharmacy is again pursuing these changes with the board's legal counsel in the hopes of obtaining permission to implement these changes in advance of the explicit statutory authority. Chairperson Graul noted that the earliest these changes would be implemented would be for licensees with an expiration date in February 2009. Alternatively, board staff is exploring the ability to pursue emergency regulations.

Public Comment:

Steve Gray (Kaiser Permanente) recommended that the language include intern pharmacists.

Ms. Sodergren stated that this change is only as a condition of renewal. She added that intern licenses are not renewable and that part of the application process for interns includes a verification of any criminal felonies or convictions.

Ms. Herold added that this legislation is an important piece relating to licensure of pharmacists, technicians and designated representatives. She noted that, in the case of interns, it is not feasible to catch them during a renewal. She indicated that, conducting the verification at the time of renewal provides for a timely update.

Dr. Gray asked if there is anything that would currently put the onus on the intern to report convictions, outside of during the application process.

Ms. Herold stated that there is not.

Dr. Gray suggested that the board consider pursuing such for interns as well.

Ms. Herold responded that they would consider it.

MOTION: To pursue legislation changes to B & PC 4401 and 4403 to require pharmacists, pharmacy technicians and designated representatives

M/S: BP/SW

Support: 4 Oppose: 0

5) Request from Pharmacy Foundation of California for Clarification of B & PC §4076

Chairperson Graul stated that, at the July 2008 Board Meeting, the board heard a request from Dr. Steve Gray, representing the California Pharmacy Foundation. Chairperson Graul explained that the Foundation is requesting that the board sponsor legislation that will clarify a pharmacist's authorization within Business and Professions Code §4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient. He noted that one of the Foundation's primary focuses is on the reduction of medication errors and they believe that clarifying when and how a pharmacist is authorized to place the additional information within the prescription label will improve patient outcomes.

Chairperson Graul explained that, at that time of the July Board Meeting, it was recommended that this matter be referred to the Legislation and Regulation Committee for discussion and to recommend if it is feasible to pursue this proposal in 2009 with its anticipated legislative calendar.

Chairperson Graul noted that the suggested amendment, which could achieve the desired outcome, was contained within the committee packet provided.

Board Discussion:

Mr. Powers stated that they are currently engaged in the process in determining recommendations to the legislature in regards to what should be placed on prescriptions labels. He referenced the mandate of SB 472, and noted that the board is receiving surveys provided by the public the board. Mr. Powers stated concern that there may be situations where patients may not want the purpose listed on the label.

Ms. Sodergren responded that the board cannot make any changes to B & PC 4076, and that the intent of the bill is to place the purpose (rather than the condition) on the label if it is requested by the patient.

Chairperson Graul provided clarification within the amended language, explaining that the prescriber requirement to provide the purpose has been removed. He noted prior discussion with members of the industry in regards to physicians prescribing medication even though they are not yet fully clear of the diagnosis because of pending lab work, etc. and would not be able to indicate a condition for the label. He also explained the concern by members of industry in terms of requiring a purpose on every label, as some prescriptions are not picked up by the patient themselves. Chairperson Graul gave an example of a patient requesting the purpose be placed on the label, and what challenges may arise.

Mr. Powers asked how patients will know that they can request that the purpose be placed on their label.

Chairperson Graul suggested a public awareness campaign.

Ms. Herold emphasized the strong testimony which has come forth via SCR 49 and allowing patients to better manage their medication. She suggested the option to have “Purpose: _____” printed on the label, prompting patients to ask why it is not filled in.

Dr. Swart expressed concern with the proposal, including the issue of writing a purpose based on what the patient indicates, because of the informal terms often used by patients to describe their diagnosis.

Public Comment:

Dr. Gray referenced SCR49, and indicated that the biggest problem is that patients forget what their drugs are for after taking them home and storing them with other medications. He stressed the value in having the purpose placed on the label. He added that, when the task force approached pharmacists regarding placing the purpose on labels, there was a full range of responses in terms of whether they think they can work with the labeling requirements being suggested. Dr. Gray noted the results of the surveys being conducted by the board, and that placing the purpose on the label was one of the top requests indicated. He added the concern within assisted living facilities, which are regulated by the California Department of Social Services. He noted that the providers of those facilities who are assisting seniors with their medications are low paid staff members, and stated that labeling the purpose on the prescriptions would assist in avoiding medication duplicates and errors.

MOTION: To pursue amendment to B & PC 4076 to include the purpose of the medicine.

M/S: BP/SW

Support: 4 Oppose: 0

6) Return and Disposal of Hypodermic Needles and Syringes – Add B & PC 4146

This proposal was previously approved by the board and as such was not discussed during the committee meeting.

II) Proposed Regulation Language

Amend Title 16 CCR 1715 – Self Assessment Forms for Community and Inpatient Pharmacies

This section establishes requirements for the pharmacist-in-charge (PIC) or designated representative-in-charge of a licensed pharmacy or wholesaler, respectively, to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form is to assist pharmacies and wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, this form makes the pharmacy inspection process more meaningful and provides relevant information to pharmacies and their PIC.

Board staff is working on updates to the Self-Assessment forms to incorporate changes made in pharmacy law since its last revision in 2007. As these forms are incorporated by reference in §1715, the board must pursue a regulation change to require use of the new form.

The proposed changes to 16 CCR §7175 were provided within the board packet. Additionally, copies of the revised self-assessment forms were provided during the meeting for committee consideration.

Ms. Sodergren explained that completion of the self-assessment forms is required under Title 16 CCR §1715 by pharmacies and wholesalers. The forms are required to be completed every two years, as well as whenever there is a change in the PIC or DRIC. She further explained that the forms are a compilation of pharmacy law which are used by the pharmacy or wholesaler to evaluate their facility and ensure that they are in compliance with those law requirements.

Ms. Sodergren indicated that the forms have been updated, and that changes are notated with underline and strike out. She explained that, because they are incorporated by reference, the board must pursue a section 100 change to update the forms to include the changes of pharmacy law. Ms. Sodergren noted that this can be done as section 100 changes, as opposed to a formal regulation change, since they are not creating any requirements and it is existing law.

MOTION: TO pursue section 100 changes to update the Self-Assessment forms incorporated by reference in CCR §§1715 and 1784.

M/S: AZ/RS

Support: 3 Oppose: 0

(Bill Powers not present)

III) Public Requests for Future Legislation and Regulatory Proposals

There were no requests for future legislation or regulatory proposals.

IV) Public Comment

No comments were provided.

The meeting was adjourned at 4:55 p.m.