

California State
Board of Pharmacy

Legislative Program Overview

A Report to the Chair of the Assembly
Business and Professions Committee

February 2010

*CALIFORNIA STATE
BOARD OF PHARMACY*



*BE AWARE & TAKE CARE:
Talk to your pharmacist!*

Forward

This report has been written in response to a January 2010 request from the Chair of the Assembly Committee on Business and Professions seeking information about how the California State Board of Pharmacy develops and sponsors legislation. Executive staff of the board prepared this report.

Accordingly for each bill sponsored by the board, information is organized by topic headings, according to parameters set by the Chair in her request:

- Originator of the bill
- Criteria for sponsorship and consideration of consumer protection factors
- Research and approval timeline
- Summary of issues that arose during the Legislative Process

Introduction

The California State Board of Pharmacy is a consumer protection agency charged with enforcement of the state's Pharmacy Law. The board has 13 major regulatory programs that regulate both the individuals and firms that procure, ship, store and dispense prescription drugs and devices to the state's health care providers and patients, both from within and outside California.

The board is comprised of 13 members; seven pharmacists and six public members. Four of the public members and all seven pharmacists are appointed by the Governor, the Assembly and the Senate each appoint one public member. At the time of this report, the board is comprised of four pharmacists and six public members. There are three pharmacist positions vacant.

The board is mandated under California Business and Professions Code section 4001.1 that:

Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

The Board of Pharmacy organizes its activities according to a strategic plan, which is reviewed and revised annually. This plan is divided into five strategic areas that are managed by a committee of the board:

- Enforcement
- Licensing
- Communication and Public Education
- Legislation and Regulation
- Organizational Development

Committee members and the chairperson are appointed by the board president on an annual basis.

In this report, the functions and activities of the board and its Legislation and Regulation Committee will be discussed.

The goal of the Legislation and Regulation Committee is to advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy. The board's vision is: "Healthy Californians through quality pharmacist's care."

The board's mission is: "The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement."

Pursuant to this mission and vision, all legislation advocated by the board, whether sponsored or reviewed, must either benefit the public with respect to pharmacist's care or advance the board's ability to license and enforce provisions that support pharmacist's care. In this vein, consumer protection is more than enforcing licensing standards and initiating enforcement actions. It includes devising and implementing prevention strategies for the misuse of dangerous drugs and devices, and eliminating unnecessary barriers to access to vital health care resources. As a regulator of a dynamic profession, it is necessary for the board to maintain vigilance to ensure outdated laws are updated or repealed, and new laws, reflecting new practices or responding to emerging issues, are enacted. Legislation and regulations involving licensing and enforcement activities of the board must be continually evaluated to ensure that minimum standards for competency in the professions are set and maintained.

Each year, the board typically sponsors at least one bill. The origin of legislative proposals comes from:

1. Issues before the board or Administration,
2. Comments addressed to the board from members, stakeholders and the public,
3. Investigations conducted by the board,
4. Health care issues affecting patients and drug distribution,
5. Board staff.

Legislation and promulgation of regulations are necessary to keep Pharmacy Law current. Health care continues to undergo dramatic changes as new technology and new medications compete with costs to drive down the expenses related to health care. Emerging technology that can provide enhanced health care at lower overall expense to the health care system sometimes cannot be used without changes in law. Emerging enforcement matters and health care issues also are the impetus for board-sponsored legislative proposals. Issues in public health or board initiatives frequently necessitate a legislative or regulation response.

But the board also responds to legislative proposals of others, not by sponsoring the proposal but by providing technical assistance to aid implementation or supporting those proposals that advance or opposing those that compromise the board's consumer protection mandate.

As stated in its 2002 Sunset Report: the rapid advance of health care technology (e.g., automation, communications and clinical innovations), workforce issues (e.g., persistent shortages of pharmacists and other health care professionals, geographic and socioeconomic imbalances in the distribution of pharmacies and pharmacists), demographic changes (e.g., aging population, rapidly increasing numbers of consumers from distinct racial, ethnic and linguistic backgrounds), and marketplace issues (e.g., consolidation, growth in chain pharmacies, direct-to-patient advertising of prescription medications, mail order pharmacies, internet pharmacies, rapidly rising drug costs and rapid increases in prescription volumes) increase the complexity of the board's policymaking activities.

Without a legislative program, the board would have significant challenges in moving forward towards its vision of "healthy Californians through quality pharmacist's care." Without seeking or responding to statutory change, the board would be passive and inactive to emerging health care issues. Outdated laws would remain on the books, and innovation and change to improve the public health would be impeded. This is not characteristic of a dynamic consumer protection program, a vigorous public health program or a desirable characteristic for a program regulating those who provide health care on behalf of California's citizens. Pursuing legislative and regulatory changes therefore are necessary components of the board's consumer protection mandate.

The board does its decision making in public, and seeks the participation of the public and other stakeholders in the process. Meeting agendas are placed online and distributed in hard copy form at least 10 days before a meeting. A "subscriber alert" is also emailed to interested parties who have signed up to be notified about board activities through the board's email contact list. Additionally, meeting materials that are provided to board members are also put online at the same time they are distributed to the board, and the availability of the meeting materials is announced via a subscriber alert.

Each year the board holds at least four full public board meetings, where the board acts on matters before it, including legislative and regulation proposals affecting consumers or the board's jurisdiction. In advance of any board meeting, the board usually schedules a committee meeting of the board's strategic committees so an in-depth

discussion of emerging issues is permitted. These meetings are also accessible to the public. Finally, meeting minutes are posted online to allow those who are interested in following board activities to do so without having to attend the meetings in person.

Administration Review of Proposals

The board works closely with the Department of Consumer Affairs to secure its legislative objectives. As an executive branch agency, concerns of the Administration are important to the board. If unaddressed, such concerns could result in an oppose position or a veto if the legislation reaches the Governor. Accordingly, the board notifies the Administration of its annual legislative proposals once determined (usually following the October or the January board meetings). The board also conducts its decision making in public board meetings where the department is present.

For legislation sponsored in 2009, the board made its decisions at the October 2008 board meeting, and within one day of the meeting, notified the State and Consumer Services Agency as well as the legislative staff of the Department of Consumer Affairs about its proposals.

For legislation the board will sponsor in 2010, the board finalized its legislative agenda at the January 2010 board meeting, and notified the Department of Consumer Affairs Legislative Affairs Office the next business day.

Throughout any legislative session, updates to the Administration are provided in response to their inquiries before bills are up in committee hearings as well as in monthly reports to the DCA director. Additionally the board's staff works closely with departmental legislative and budget staff on all legislative matters as the session progresses.

Board-Sponsored Legislation 2009 and 2010

2009

AB 977 (Skinner), Immunizations (two-year bill)

AB 1071 (Emmerson), Board of Pharmacy Fees, Chapter 270, Statutes of 2009

SB 470 (Corbett), Addition of Purpose to Prescription Labels, Chapter 590, Statutes of 2009

SB 819 (Yee/ Senate Business, Professions and Economic Development Committee), Health Care Boards Omnibus Bill, Chapter 308, Statutes of 2009

SB 821 (Senate Business, Professions and Economic Development Committee), Health Care Boards Omnibus Bill, Chapter 307, Statutes of 2009

2010

Unnumbered bill – provisions for the Senate Business, Professions and Economic Development Committee Health Boards Care Omnibus Bill

Unnumbered bill – provisions to enhance the board’s enforcement program

No bill planned, provisions approved – Standards for reverse distributors/wholesalers

Specific details about each of these proposals are provided on the following pages.

In Closing

The Board of Pharmacy is pleased to share this report with the Chair of the Assembly Business and Professions Committee.

The Board of Pharmacy's legislative program is one component the board activates to fulfill its consumer protection mandate. Legislative proposals are developed during public meetings, with input from stakeholders. During any legislative session, once legislation is introduced, amendments are made to remove opposition or clarify provisions. This is the legislative process.

The board seeks comments that will enable it to maintain or improve its level of excellence in seeking, providing and improving consumer protection. This is part of the public feedback built into every Board Meeting and Legislation and Regulation Committee Meeting.

Finally, activities performed in pursuing legislation support the board's vision of “healthy Californians through quality pharmacist care,” and the board’s mission.

2009 Legislation Sponsored by the Board of Pharmacy:

AB 977 (Skinner)

Bill Originator

Dr. Jeff Goad, Professor, University of Southern California

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Increase access to life-saving vaccinations.

Consumer Protection Factors

1. Vaccines are a safe, effective, and efficient means to prevent sickness and death from infectious diseases as reported by the United States Department of Health and Human Services (HHS).
2. The federal Centers for Disease Control and Prevention report that 220,000,000 persons should get the influenza vaccination annually; however, fewer than 100,000,000 do.
3. According to Families USA, 12.1 millions Californians are uninsured.
4. Pharmacists represent the third largest health professional group in the United States and are on the frontline of preventative care.
5. Pharmacists are trained to screen, administer, and properly deal with any adverse events that may arise from vaccines.
6. Pharmacists are the most accessible health care provider – they interact with patients without an appointment.
7. Pharmacists have four years of professional training post baccalaureate degree to earn their PharmD degree, and many pursue post-doctorate residencies in addition.
8. Pharmacists have a formal national immunization training program based on the CDC's "Pink Book" guidelines.

9. Since 1995, Pharmacy Law has allowed a pharmacist to administer immunizations pursuant to a protocol with a physician. Since that time, pharmacists have safely initiated and administered thousands of immunizations to Californians. Patients seem comfortable obtaining these immunizations from pharmacists.
10. The proposal establishes additional standardized training, continuing education and reporting requirements.

Background

The CDC reports that vaccine-preventable disease levels are at or near record lows; however, the CDC notes that it cannot take high immunization coverage levels for granted. "To continue to protect American's children and adults, we must obtain maximum immunization coverage in all populations, establish effective partnerships, conduct reliable scientific research, implement immunization systems, and ensure vaccine safety."

Research and Approval Timeline

Assembly Bill 977, as initially introduced, would have allowed specially trained pharmacists to administer specific vaccines to patients. These vaccines are those recommended by the Centers for Disease Control. There are 10 of these that are recommended for adolescents aged 7-18, and 10 vaccines that are recommended for adults.

The origin of the concept was a presentation made to the board's Licensing Committee Meeting in March 2007, where the board heard a presentation by USC School of Pharmacy Professor Jeff Goad. Dr. Goad provided information about the CDC's concerns about immunization rates in some patients given the benefits of vaccines. He described the training of pharmacists in today's schools of pharmacy with respect to immunizations. The board agreed to proceed with legislation to allow specially trained pharmacists to administer immunizations pursuant to CDC protocols, and under specific conditions.

Over the following 18 months, the board developed language, but did not initiate work on finding an author due to other workload priorities and staffing commitments.

The immunization legislative proposal was brought by staff to the board in the fall of 2008, where at the October 2008 Board Meeting, the board approved the language. Approval was based on:

1. Improving access of patients to vaccines, should it result in increased immunization rates, is a public health issue that will improve the overall health of the public.

2. The integration of vaccination training as part of the education of pharmacists and ongoing training programs for licensed pharmacists prepares them to administer vaccines.
3. Immunization clinics, especially for flu, are well received by the public, and the board has never received a complaint from a consumer regarding a pharmacist-administered vaccination.
4. The Advisory Committee for Immunization Practices of the CDC develops the parameters for administration of vaccines in the US.
5. The proposal would in part address the objectives of the California Department of Public Health, voiced directly to the board in various board meetings in preparing health care providers to prepare for emergency response situations due to disasters, pandemics (e.g., H1N1 vaccinations) or terrorism. The board has worked over the years on preparing pharmacies and pharmacists to prepare for such emergency responses in accordance with the CDPH's objectives.

Bill History

This bill was introduced on February 26, 2009 and was amended six times, most recently January 25, 2010. The bill is currently referred to the Senate Health Committee and the Senate Business, Professions and Economic Development Committee.

Summary of Issues

The following summary is that of the board's executive staff and provides their opinions and understanding of what has occurred during the deliberations of the legislative process.

The introduced version of AB 977 met with opposition from the California Medical Association, other physicians' groups and the California Nurses Association that was not resolvable. The board scaled back the proposal before the first policy hearing in the Assembly Business and Professions Committee to include only influenza and pneumococcal vaccines. Why was this approach selected?

- Combined – influenza and pneumonia are the 8th leading cause of death in people of all ages and the 7th leading cause of death in people over the age of 65.
- During most influenza seasons, up to 20 percent of the people in the US may be infected with the influenza virus. Influenza immunization can reduce physicians' visits, lost work days and reduce antibiotic use.

- Over 30 percent of Californians were without health insurance in the spring of 2009.
- One of every 20 people who get pneumococcal pneumonia dies from it.
- This would have aided the California Department of Public Health's plans to identify immunizers to administer H1N1 vaccines to Californians.

Thus, this version of the bill contained the focus of the board's goals in seeking this proposal, although substantially scaled back.

However, the two vaccine version of AB 977 was also strongly opposed, and resolution could not be reached in April 2009 before the legislative deadline for policy committees to pass bills in the house of origin. The bill was amended to direct the California Pharmacists Association to do a study of protocols. This version of the bill never had a hearing, nor did the board take a position on it. The bill became a two-year bill.

In an attempt to resolve opposition from the medical community, another approach considered and discussed with the author's office and other proponents of the bill would have resulted in the state (Medical Board and Board of Pharmacy) developing a general protocol under which pharmacists could administer influenza and pneumococcal vaccines. The development of such a protocol had occurred in the past for pharmacists to provide emergency contraception.

This concept became the origin for the provisions in the January 4, 2010 version of the bill, which was drafted by board staff in November 2009, reviewed by AB 977 supporters, and sent to the author's chief of staff on November 24, 2009. The Medical Board's staff was notified of the proposed amendment, and they indicated that their board might have problems with the two immunizations specified in the bill, but a review by their board would not occur until the end of January.

In December 2009, the author's office worked directly with the California Medical Association on resolving the CMA's still strong opposition to the board's proposed draft amendments (for a joint Medical Board/Pharmacy Board protocol for flu and pneumococcal vaccines). The board was not involved in these discussions. At some point, negotiations between the author's office and the CMA resulted in the CMA drafting amendments that if incorporated in AB 977, would change their position to neutral. These amendments were put into the bill on January 5, during the Assembly Health Committee Hearing, and would appear in print as the January 6 version of AB 977.

On January 4, 2010, the bill was amended to authorize pharmacists to administer flu and pneumococcal vaccines to any person 11 years of age and older pursuant to a standardized protocol developed by Board of Pharmacy and the Medical Board of California. This version also specified training, continuing

education requirements and record keeping for any pharmacist immunizing under its provisions.

Next, the bill was amended again during the Assembly Health Committee on January 5 (published as the January 6 version), with CMA's proposed changes. This scaled back version of the bill would require the Board of Pharmacy and the Medical Board to develop a protocol for administration of flu vaccines by a pharmacist to an adult. The program would be a four-year pilot program and mandate a report to the Legislature one year prior to sunset of the provisions.

Because of conflicting schedules and absences over the holidays, combined with the tight legislative deadlines needed to pass two-year bills in the house of origin in January 2010, the board did not actually see the proposed amendments in a mock-up form until immediately before the Assembly Health hearing. As such, the executive officer indicated during the hearing that the board could support the proposed amendments if existing law remained in section 4052, and the proposed new state protocol was created as a new provision. This was the essence of the CMA amendments.

The bill was passed by the Assembly Health Committee, and referred to the Assembly Business and Professions Committee for hearing on January 12.

On January 11, the board learned from the author's office that the chair of the Assembly Business and Professions Committee wanted additional amendments in AB 977 that would be inserted during the Assembly Business and Professions Committee hearing on January 12 to require the Medical Board solely to develop the protocol. The executive officer indicated that she would not testify because she wanted to see the proposed amendment. However, at the request of the author's office, she agreed to come.

During the Assembly Business and Professions Committee hearing, the bill was passed with an amendment during the hearing. The amendments were not in print prior to the hearing, not made available to the board, and had been negotiated without the board's participation or knowledge.

During the hearing, the author's office, the lobbyist for the California Pharmacists Association and the committee chair agreed on the negotiated amendment that the Medical Board would solely be responsible for developing the protocol. The executive officer stated during the hearing that the board could support the amendment but noted that regulations by the Board of Pharmacy would likely be needed to implement the protocol, which had been required for the emergency contraception protocol done five years earlier. The bill was passed by the committee, and amendments printed on January 13.

On January 13, the board's executive officer was contacted by the Assembly Appropriations consultant, to identify the potential fiscal impact of AB 977, and was alerted that AB 977 was a likely candidate for suspense. After January 14, there was no further update from the Appropriations Committee.

Meanwhile, on January 20 and 21, 2010, the January Board Meeting took place. The board also held a Legislation and Regulation Committee meeting at the end of the day on January 20. As one piece of business, the committee reviewed the January 6 version of the bill.

The board staff who prepare meeting materials for the board inadvertently failed to provide the January 13 version of the bill which likely appeared in print as the packet materials were being compiled.

This oversight was repeated during the Legislation and Regulation Committee report during the January 21 Board Meeting. During the Board Meeting on January 21, the board voted to support the January 6 version of the bill, unaware that AB 977 had been more recently amended. Moreover, because the bill had been targeted for suspense, the board's staff thought the bill would die on the suspense file and focused its attention during the meeting to other pressing regulation issues.

Near the end of the January, the board learned that the bill had been passed by the Assembly Appropriations Committee on January 21 while the Board Meeting was underway. Also at the end of January, via a media inquiry from the *Sacramento Bee* seeking clarification on a controversy that occurred during the floor vote, the board learned that AB 977 had been passed by the Assembly.

The current version of the bill (January 25, 2010), substantially scales back what the board initially proposed in October 2008. More recently, on February 23, the Department of Consumer Affairs took an oppose position on the bill because there has been no problem demonstrated with provisions in existing law regarding physician and pharmacist protocols, nor a shortage of locations for patients to receive flu vaccines.

The next meeting of the board is April 21 and 22, 2010, where the board will consider its position on AB 977.

Support

California Pharmacists Association
California Retailers Association

AB 1071 (Emmerson)

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 5: Achieve the board's mission and goals.

Outcome: An effective organization.

Overall Legislative Intent

Ensure the financial solvency of the board.

Consumer Protection Factors

1. Business and Professions Code Section 4001 establishes the California State Board of Pharmacy which is vested with the administration and enforcement of Chapter 9, Division 2 of the Business and Professions Code.
2. The board regulates almost 120,000 licensees.
3. In fiscal year 2008/09, the board received over 16,000 applications, issued almost 12,000 licenses, and renewed over 50,000 licenses.
4. In fiscal year 2008/09, the board initiated over 2,700 investigations, completed over 2,100 investigations, issued 965 citation and fines, referred 136 cases to the Office of the Attorney General, revoked 32 licenses, and formally disciplined an additional 34 licensees. It also collected \$1.2 million in citations.

Background

Beginning in 2008, many of the board's fees were increased to their statutory maximum because board-authorized expenditures exceeded annual revenue. This was done via a regulation change pursuant to the Administrative Procedure Act. The statutory maximum fee levels were established in statute in 1987.

A review of the Consumer Price Index reveals that the cost of consumer goods has risen steadily since 1988 by approximately 85 percent; however, board fees have remained unchanged.

The board's licensee population has grown 20 percent over the last five years, yet the size of the board's staff remains relatively constant until July 2009.

Research and Approval Timeline

During each quarterly board meeting, board members are provided with a budget update including a fund condition report. Over the last few years, expenditures have exceeded revenue, resulting in a depletion of the board's fund. In 2008, a DCA fund condition report predicted a fund deficit by 2011/12.

In 2008 the board commissioned an independent fee audit to determine the unit cost to process applications and license renewals. The audit reaffirmed that the board's expenditures were exceeding its revenues resulting in the draining of the contingent fund balance. The audit concluded that the board's current fee structure was insufficient to maintain the legislatively mandated 12-month reserve requirement and noted that the board's fund condition will continue to drop until it eventually exhausts all reserves and a deficit would occur.

During the July 2008 Board Meeting, the board discussed the initiation of an independent fee audit as a precursor to pursuing a statutory change in the board's fees.

In October 2008, the board again publicly discussed the need to pursue a statutory fee increase and noted that a fee audit was underway.

During the January 2009 Board Meeting, the board heard a presentation by the independent auditor on the findings and recommendations of the audit. Also during this meeting, the board voted to increase licensing fees at an amount that would be sufficient to remedy the board's fund condition and fulfill fiduciary requirements for the next five years.

Bill History

The bill was introduced on February 27, 2009. As initially introduced, the bill only addressed the increase in board licensing and renewal fees. The bill was later amended on September 2, 2009 to include provisions to extend the sunset dates for various boards within the Department of Consumer Affairs. The bill was enrolled on September 17, 2009 and chaptered on October 11, 2009.

Summary of Concerns

No concerns were raised and no opposition was on file for this proposal.

SB 470 (Corbett)

Bill Originator

Pharmacy Foundation of California

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy

Outcome: Improve the health and safety of Californians.

Goal 4: Provide relevant information to information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Overall Legislative Intent

Reduce medication errors.

Consumer Protection Factors

1. According to the Archives of Internal Medicine Report, in 2004, 34 Americans were being killed each day because of medication errors that occur in their home.
2. The Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.
3. Recommendation 2 from the SCR 49 Panel (see below) provides, "Require that the intended use of a medication be included on all prescriptions and require that the intended use of medications be included on medication labels/labeling unless disapproved by the prescriber or the patient."
4. Up to one-half of all medications are taken incorrectly or mixed with other medications that cause dangerous reactions that can lead to injury and death.

Background

In 2005, Senator Jackie Speier authored SCR 49 which called for the creation of an expert panel to 1) study the causes of medication errors in the community setting and 2) recommend changes in the health care system that would reduce errors associated with over-the-counter and prescription medications in the outpatient setting. Over the course of one year, the panel met and heard

testimony from members of academia, consumer groups and various health professionals. The result of the panel's work was a comprehensive report summarizing medication errors and the outcomes of such errors as well as recommendations to mitigate errors.

A copy of the SCR 49 report can be found on the board's Web site.

Subsequent to the SCR 49 report, in 2007 Senator Corbett introduced SB 472, creating the California Patient Medication Safety Act of 2007 to standardize the prescription label and make it patient-centered. Specifically, this bill directed the board to develop a standardized patient-centered prescription label for medicine dispensed to California patients after January 1, 2011.

To facilitate implementation of the requirements contained within SB 472, the board held public meetings to elicit input from consumers as well as conducted individual consumer surveys. The board posted its survey document on its web site to allow for electronic submission, published the survey document in a statewide AARP newsletter, mailed the survey to various consumer groups, and attended and disseminated the surveys at various public events and health fairs statewide. Also, in conjunction with the Pharmacy Foundation of California, the board developed and deployed a radio survey of the public about prescription container labels.

A full report of the board's development of the regulation requirements for prescription container labels as directed by SB 472, including survey results, can be found on the board's Web site.

Research and Approval Timeline

During the July 2008 Board Meeting, the board heard a request from Steve Gray, PharmD, representing the Pharmacy Foundation of California. The Foundation requested that the board sponsor legislation to 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. One of the Foundation's primary focuses is on the reduction of medication errors, and the Foundation believes that clarifying when and how a pharmacist is authorized to place the additional information within the prescription label will improve patient understanding and outcomes.

Consistent with the board's general process to consider legislative proposals, this issue was referred to the Legislation and Regulation Committee for discussion.

During the October 2008 Legislation and Regulation Committee Meeting, the committee discussed the proposal in detail. The proposal was consistent with the recommendations of the SCR 49 Medication Errors Panel. Testimony provided during the meeting included statements that a big problem is that

patients forget what their drugs are for after taking them home and storing them with other medications. Testimony also stated concerns with medication safety for patients in assisted living facilities, which are regulated by the California Department of Social Services. Comments noted that the providers of these facilities who assist seniors with their medications are low paid staff members, and that by adding purpose to the labels on prescription containers would assist patients in such care facilities from duplicate medication therapies and prevent errors. Minutes from this meeting are available at the board's Web site that describes the discussion and deliberation by the board. The committee voted to recommend sponsorship of a proposal to amend section 4076 to include the purpose of the medicine on the prescription label.

Subsequent to the committee meeting, during the October 2008 Board Meeting, the board discussed the issue, heard testimony from the public, deliberated and voted to pursue sponsorship of the proposal as recommended by committee.

A copy of board materials and minutes can be obtained from the board's Web site.

Bill History

After submission to Leg Counsel, the original language was expanded to amend Business and Professions Code section 4040. The bill was introduced on February 26, 2009, and was amended twice. The bill was enrolled on August 27, 2009, and chaptered October 11, 2009.

Summary of Issues

Throughout the process, the board had a broad base of consumer and industry support as detailed below.

Senator Corbett accepted amendments offered by the California Medical Association (CMA) whose original position was Support if Amended.

Senator Corbett accepted amendments offered by the California Retailers Association and National Association of Chain Drug Stores whose original position was Oppose Unless Amended.

Support

California Alliance for Retired Americans

California Medical Association

California Pan Ethnic Health Network

California Retailers Association

California Society of Health-Systems Pharmacists

Kaiser Permanente

National Association of Chain Drug Stores

Pharmacy Foundation of California
UCSF School of Pharmacy

Opposition
None on file

SB 819 (Senate Business, Professions and Economic Development Committee) – Omnibus

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the board of pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Keep pharmacy law current and pursue non-controversial changes to benefit consumers, consistent with the board's consumer protection mandate.

Consumer Protection Factors

1. Ensure the continuity of care for patients requiring prescription medications.
2. Clarify the board's requirements for the pharmacist-in-charge (PIC). The PIC is the pharmacist responsible for overall pharmacy operations, including ensuring adherence to pharmacy law.
3. Keep Pharmacy Law current and clear so practitioners know and can comply with legal requirements.

Background

The omnibus provisions included in SB 819 were categorized into four types of changes:

1. Omnibus provisions to correct erroneous code citations resulting from the recodification of Business and Professions Code section 4052 several years before.
2. General omnibus provisions.
3. Authorization to use mobile pharmacies in disaster response activities or during renovation or reconstruction of a damaged pharmacy.

4. Changes resulting from a comprehensive legal review by board staff and counsel on the legal requirements surrounding the pharmacist-in-charge and designated representative-in-charge.

Provisions Contained Within the Proposal

Omnibus Provisions Resulting from Recodification of Business and Professions Code §4052

In 2006 Business and Professions Code section 4052 was recodified into four sections. As a result, the following references in the Business and Professions Code and Health and Safety Code to §4052 required technical amendments.

The sections affected are:

- §733 – Dispensing Prescription Drugs and Devices
- §4027 – Skilled Nursing Facility; Intermediate Care Facility; Other Health Care Facilities
- §4040 – Prescription; Content Requirements
- §4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- §4060 – Controlled Substances – Prescription Required, Exceptions
- §4076 – Prescription Container – Requirements for Labeling
- §4111 – Restrictions on Prescriber Ownership
- §4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC §11150 – Persons Authorized to Write or Issue a Prescription

General Omnibus Provisions

The following provisions are a miscellaneous aggregation of general modifications to the identified code sections.

Amend §4059.5 - Who May Order Dangerous Drugs or Devices, Exceptions.

This section was amended to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

Amend §4081 – Records of Dangerous Drugs or Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

This section replaced the term “representative-in-charge” with the correct “designated representative-in-charge” as a result of changes in SB 1307 (Chapter 857, Statutes of 2006).

Amend §4126.5 – Furnishing Dangerous Drugs by Pharmacy

This section was amended to clarify who in the supply chain may receive dangerous drugs furnished by a pharmacy.

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

This section was amended to authorize the board to inactivate a pharmacist license when a pharmacist who certifies completion of the required 30 units of continuing education as part of a renewal fails to provide proof of completion of these credits either when audited or when investigated by the board.

Amend §4301 – Unprofessional Conduct

This section was amended to reference the definition of a long-term care facility to the Health and Safety Code section 1418.

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

This section was amended to require that a clinic that dispenses Schedule III and Schedule IV controlled substances must report this information to the CURES system, consistent with the reporting requirements for pharmacies, hospitals, and others that dispense controlled drug to patients.

Use of Mobile Pharmacies

Amend §4062 Furnishing Dangerous Drugs During an Emergency

This section was amended to allow the use of a mobile pharmacy in the event of a declared natural disaster, if certain criteria are met.

Amend §4110 License Required, Temporary Permit Upon Transfer of Ownership

This section was amended to allow the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed, damaged or otherwise under repair.

Pharmacist-in-Charge and Designated Representative-in-Charge

In 2007 board staff and counsel completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge as well that of a designated representative-in-charge. A designated representative-in-charge is the non-pharmacist who is specially licensed by the board to oversee operations in a drug wholesaler. As a result of this review, several changes were recommended including technical changes as well as refining the definitions of the pharmacist-in-charge and designated representative-in-charge, and clarifying the reporting requirements to the board when a change in either occurs.

Amend §4022.5 – Designated Representative; Designated Representative-in-Charge

This section was amended to clarify the definition of “designated representative-in-charge” as well as the responsibilities of a licensee serving as such.

Add §4036.5 – Pharmacist-in-Charge

This section was added to define the term “pharmacist-in-charge” as well as the responsibilities of a pharmacist serving as such.

Amend §4161 – Non-Resident Wholesaler; Requirements

This section was amended to clarify the duties that constitute a business operating as a non-resident wholesaler. This definition is already provided in B&PC § 4043, but was needed here to provide clarity to non-resident wholesaler requirements.

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

This section was amended to specify that failure to meet notification requirements to the board about when a PIC quits serving as a PIC will constitute grounds for disciplinary action.

Amend §4329 – Non-pharmacists; Prohibited Acts

This section was amended to prohibit a non-pharmacist from acting as a supervisor or pharmacist-in-charge.

Amend §4330 – Proprietors; Prohibited Acts

This section was amended to specify that any pharmacy owner that subverts or intends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

Research and Approval Timeline

These changes were approved by the board in 2007 and many were incorporated in SB 1779 (2008) as omnibus provisions. This bill was vetoed by the Governor at the end of the 2008 session for reasons unrelated to the contents of the bill.

At the October 2008 Board Meeting, the board voted to again pursue all of the omnibus provisions approved for sponsorship in 2008.

Bill History

This bill was introduced on March 10, 2009 and was amended nine times. The bill was enrolled on September 15, 2009 and chaptered on October 11, 2009.

Summary of Issues

This bill also contained provisions for several of the healing arts boards within the DCA. This board is unaware of any concerns with the board's provisions. As a condition of being in an omnibus bill, any opposition to a provision must be removed or the provision is removed from the bill.

SB 821 (Senate Business, Professions and Economic Development Committee) – Omnibus

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Keep pharmacy law current and pursue non-controversial changes to benefit consumers, consistent with the board's consumer protection mandate.

Consumer Protection Factors

1. Provide a safe and legal manner for Californians to dispose of used sharps.
2. Clarify the board's requirements for the pharmacist-in-charge (PIC) and designated representative-in-charge (DRIC). The PIC is the pharmacist responsible for overall pharmacy operations including ensuring adherence to pharmacy law. The DRIC is a licensee responsible for overall operations of a wholesaler.
3. Provide for an efficient and quick method of communication to notify board-licensed facilities of alerts and other messages from the board.

Background

These proposals were identified over the course of 2008 and were brought to the board for consideration as legislative proposals in October 2008. Several proposals were identified from legal counsel advice to remedy questions on the interpretation of pharmacy law; however, two provisions had specific triggering events detailed below.

1. During the early months of 2008, five separate recalls of heparin were issued by for various manufacturers to remove potentially dangerous heparin from the marketplace. Heparin is a widely used drug in hospitals for anticoagulation therapy. By April 2008, tainted heparin had been

linked to 81 deaths in the US. Board staff sent out a series of e-mail alerts regarding the recalls. However, board staff, conducting specialized inspections of a sample of hospitals, discovered recalled heparin in 40 percent of hospitals initially inspected.

As a result, the board immediately began inspections of all 533 hospitals in the state to ensure that all recalled heparin was removed from patient care areas and had either been returned to the manufacturer or was properly quarantined. By the end of June 2009, the board identified 94 hospitals where recalled heparin had been found by the board at least two months following the last recall (18 percent of California's hospitals).

A recommendation resulting from this series of events was the need to develop a quick and efficient method to contact all board-licensed facilities. As a result, a provision was created that all board-licensed facilities need to join the board's subscriber alert system by July 1, 2010.

2. SB 1305 (Figueroa, Chapter 64, Statutes of 2006) prohibited any person after September 1, 2008 to knowingly place home-generated sharps in residential or commercial waste or recycle containers. This made disposal of used sharps a bit more complex, but pharmacies were not authorized to accept used sharps back from patients. The board drafted a new section to the Business and Professions Code (as section 4146) to allow pharmacies to accept back used sharps in appropriate containers from patients to ensure appropriate disposal and reduce a very serious public health risk.

Provisions Contained Within Bill

Add §4013 – Subscriber Alert

This section added a requirement that all board-licensed facilities must join the board's e-mail notification list. Such a requirement will allow the board to quickly disseminate information to board licensees at minimal cost. The board will also use this system to distribute its biannual newsletter.

Add §4146 – Disposal of Returned Sharps by a Pharmacy

This section was added to authorize a pharmacy to accept returned sharps containers from consumers for disposal.

Amend §4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.

This section was amended to clarify about when a pharmacist-in-charge or designated representative-in-charge must notify the board that he or she has ceased to serve in such a capacity.

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

This section was amended to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the board.

Amend §4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications

This section was amended to clarify 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.

Amend §4160 – Wholesaler Licenses

This section was amended 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.

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

This section was amended 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.

Research and Approval Timeline

At the October 2008 Board Meeting, the board voted to pursue these several new omnibus provisions, which were introduced in SB 821 in 2009.

Bill History

This bill was introduced on March 1, 2009 and was amended six times. The bill was enrolled on September 4, 2009 and chaptered on October 11, 2009.

Summary of Issues

This bill contains provisions for several of the healing arts boards within the DCA. We are unaware of any concerns in any of the board's provisions. As a provision in an omnibus bill, any opposition must be resolved or the provision will be removed from the bill.

2010 Legislation Sponsored by the Board of Pharmacy:

Omnibus Provisions for Sponsorship in 2010

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the board of pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Keep pharmacy law current and pursue non-controversial changes to benefit consumers, consistent with the board's consumer protection mandate.

Consumer Protection Factors

Keep pharmacy law current.

Background

The omnibus provisions for sponsorship in 2010 are categorized into two types of changes:

1. Amendments to update references to the California Department of Public Health and California Department of Health Care Services (formerly known as the Department of Health Services) and one amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California).
2. General omnibus provisions.

Provisions Contained Within Proposal

Effective July 1, 2007, pursuant to the California Public Health Act of 2006 (Chapter 241, Statutes of 2006), the Department of Health Services was split into two agencies: the Department of Public Health and the Department of Health Care Services. Several sections within the Business and Professions Code require amendment to correctly reference the appropriate agency as a result of this change.

The sections affected are:

- §4017 – Authorized Officers of the Law
- §4027 – Skilled Nursing Facilities – Intermediate Care Facilities – Other Health Care Facilities
- §4028 – Licensed Hospital
- §4037 – Pharmacy
- §4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations
- §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- §4072 – Oral or Electronic Transmission of Prescriptions – Health Care Facility
- §4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
- §4127.1 – License to Compound Injectable Sterile Drug Products Required
- §4169 – Prohibited Acts
- §4181 -- License Requirements; Policies and Procedures; Who May Dispense
- §4191 -- Compliance with California Department of Public Health; Who May Dispense Drugs
- §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring
- §4426 – California Department of Health Care Services to Study Reimbursement Rates

General Omnibus Provisions

Amend Section §4196(e) – Veterinary Food Animal Drug Retailer; Designated Representative in Charge

At its October 2008 Board Meeting, the board approved provisions to be included in the 2009 Omnibus Bill (Senate Business, Professions and Economic Development Committee, SB 821). However, the chaptered version of SB 821 contained a drafting error and the section requires correction.

§4200.1 – Retaking Examinations; Limits; Requirements (North American Pharmacist Licensure Examination (NAPLEX) and California Practice Standards and Jurisprudence Examination (CPJE) Four-time Failure)

Since 1998, the Business and Professions Code has required that pharmacist applicants who fail either the CPJE four times or the NAPLEX four times must take 16 semester hours in a school of pharmacy before retaking the examination failed four times.

In October 2008, the board approved a proposal to eliminate a sunset date of January 1, 2010 within §4200.1 that had been extended several times but not repealed. Though the Senate Business, Professions and Economic Development Committee did approve the proposal for inclusion in the 2009 omnibus bill, the proposed text was not printed in any omnibus measure. As a result, the provisions in §4200.1 were repealed.

This amendment to restore §4200.1 has been proposed to the Senate BP&ED Committee for inclusion in the 2010 Omnibus bill.

Research and Approval Timeline

During the January 2010 Board Meeting, the board voted to pursue the omnibus changes.

Bill History

These provisions are not yet contained in legislation.

Summary of Issues

We are unaware of any concerns with the board's provisions, as the provision has been law for 12 years. However, as a condition of being in an omnibus bill, any opposition to a provision must be removed or the provision is removed from the bill.

Consumer Protection Enforcement Initiative – Board of Pharmacy Specific Provisions

Bill Originator

Department of Consumer Affairs
California State Board of Pharmacy

Strategic Plan Reference

Goal 1: Exercise oversight on all pharmacy activities

Outcome: Improve consumer protection.

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the board of pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Improved consumer protection

Consumer Protection Factors

1. Reduce time to complete investigations.
2. Ensure licensees providing pharmacy related services to Californians do not have a revoked license.

Background

Over the prior year, the Department of Consumer Affairs has initiated a number of initiatives aimed at strengthening the enforcement activities of the health care boards. These changes were initiated following problems identified at the Board of Registered Nursing by the *Los Angeles Times*.

The first major change was prioritization of fingerprinting of all licensees. Fingerprinting allows a board to obtain federal and state background checks of applicants with respect to arrests and convictions entered into federal and state data bases by the courts and law enforcement agencies. It also enables boards to obtain “subsequent” arrest and conviction information if a licensee is arrested or convicted in California.

The second major problem reported in the *LA Times* was the time it was taking the Board of Registered Nursing to investigate complaints and complete enforcement actions, which exceeded 3.5 years. The BRN uses the department's Division of Investigation to investigate its complaints, and problems with recruitment and retention of investigators there has been a problem. This delayed investigations. Additionally the time it takes to secure complete work by the Attorney General's Office and Office of Administrative Hearings further added delays.

The DCA has responded with a series of proposals to strengthen the BRN's enforcement program as well as that of other health care boards.

In addition to the efforts of the department, board staff developed provisions to enhance the board's enforcement activities.

Provisions Contained Within Proposal

Amend §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

Amend this section to specify that upon request of a board inspector, an owner, corporation officer or manager shall provide requested records within 72 hours unless an extension by the board is granted.

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

Amend this section to clarify that a pharmacy shall provide the board, within 14 days, evidence of a licensee's theft of drugs or impairment. The amendment would also require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.

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

Amend this section to require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, from providing pharmacist-related services to Californians.

Research and Approval Timeline

At the October 2009 Board Meeting, the board voted to pursue these provisions and seek that they are included in the department's enforcement enhancement proposals.

During the January 2010 Board Meeting, the board reaffirmed sponsorship of these proposed changes.

Bill History

These provisions are not yet contained in legislation.

Summary of Issues

The board has requested that these provisions be included in the DCA health care boards' enforcement program enhancement legislation.

Reverse Distributor Provisions for Sponsorship in 2010

Bill Originator

California State Board of Pharmacy

Strategic Plan Reference

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Overall Legislative Intent

Specify the operations of reverse distributors, and differentiate these duties from the scope of practice authorized to a California licensed integrated waste hauler.

Consumer Protection Factors

1. Provide a safe and effective method for consumers to dispose of unwanted medicine, besides flushing it down the toilet or throwing it into the trash.

Background

For over two years, the board has been working with state and some local agencies to develop model guidelines for the take back of unwanted prescription drugs from patients. In February 2009, the California Integrated Waste Management Board finalized these guidelines, which were developed pursuant to SB 966 (Simitian, Chapter 542, Statutes of 2007). The guidelines provide components for three types of drug take back programs: 1) in pharmacies or other stationary locations, 2) at one-time or periodic community events, and 3) return via mail back to a licensed integrated waste hauler.

In 2008 while working with the California Integrated Waste Management Board and the California Department of Public Health on guidelines regarding what types of businesses could pick up aggregated pharmaceutical waste returned by patients, there appeared potential clarity issues about what a reverse drug distributor (licensed by the Board of Pharmacy) and a licensed integrated waste hauler (licensed by the California Department of Public Health) could do. The board began working on provisions to provide clearer delineation for what a reverse distributor could do, and when a reverse distributor desired to perform the duties of an integrated waste hauler, the company would need to be licensed by the CDPH as well.

The California Board of Pharmacy recently disciplined two pharmacies and the pharmacists involved in fraud involving a reverse distributor who submitted claims on behalf of the pharmacies for refunds for the return of drugs to manufacturers where the pharmacies claimed they were returning the drugs from their unused inventory. However, the reverse distributor had actually obtained the drugs from other sources.

Provisions Contained Within Proposal

Amend section 4040.5 – Reverse Distributor

Specifies that a reverse distributor may not accept previously dispensed medicine returned by patients, and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler (it is already classified in the Health and Safety Code as aggregated pharmaceutical waste). A reverse distributor may handle drugs that have never been dispensed by a pharmacy. This provision was approved by the board in January 2009, and later refined by staff after the meeting. It was not approved for sponsorship until January 2010.

Amend section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

Specifies minimum requirements for reverse distributors to document the return of drugs from a pharmacy to include the quantity or weight of the drugs being returned, the date returned and the company to which the drugs were provided. This provision was approved by the board in January 2009, and later refined by staff after the meeting. It was not approved for sponsorship until January 2010.

Amend section 4126.5 – Furnishing Dangerous Drugs by a Pharmacy

Authorizes a pharmacy to provide drugs returned from patients in a take back program to a licensed integrated waste hauler. The provisions will need additional refinement to authorize a pharmacy to accept returned product from a consumer in the event of a product recall. This provision was not previously considered by the board.

Research and Approval Timeline

During the January 2010 Board Meeting, the board voted to sponsor a bill containing to specify the operations of reverse distributors.

Bill History

These provisions are not yet contained in legislation, and will likely not be pursued until 2011.

Summary of Issues

The board did not seek a sponsor for these provisions for a 2010 introduction.