



LICENSING COMMITTEE REPORT

Stan Weisser, Licensee Member, Chairperson
Lavanza Butler, Licensee Member, Vice-Chairperson
Ryan Brooks, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member
Albert Wong, Licensee Member

Report of the committee meeting held on January 16, 2018.

a. Discussion and Consideration of Proposed Creation of an Advanced Hospital Technician (AHT) Licensing Program including Licensure Requirements, Authorized Duties and Changes to the Inpatient Pharmacy Operations

Attachment 1

Background

At several meetings, the committee has discussed the creation of an advance pharmacy technician. Most recently, both the committee and subsequently the board voted to create separate license types for community pharmacy and hospital pharmacy. During the meeting, the board also voted to pursue statutory changes to establish the requirements for the advanced community pharmacy technician.

Committee Discussion

During the meeting, members reviewed and discussed a proposal to create the advanced hospital pharmacy technician licensing program. The committee noted that the proposal is similar to the proposal developed and approved by the board for the advanced community pharmacy technician licensing program.

The committee reviewed the draft statutory proposal including a definition, licensing requirements as well as authorized duties which is summarized below.

Definition

“Advanced Hospital Pharmacy Technician” means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.7.

Licensing Requirements

- Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing
- Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
- Has obtained a minimum of an associate’s degree in pharmacy technology, obtained a bachelor’s degree, or higher or completed a board approved training program.

- Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a hospital pharmacy.
- Has passed an advanced pharmacy technician examination.

In lieu of the requirements above, an individual that has graduated from a school of pharmacy recognized by the board would also be eligible for an AHT license.

Renewal Requirements

Completion of 20 hours of continuing education each renewal cycle.

Proposed Duties

In addition to the licensure requirements, the proposal establishes authorized duties an AHT could perform under the general direction of a pharmacist in a health care setting including:

- Packaging emergency supplies.
- Sealing emergency containers.
- Preparing and sealing drug kits.
- Performing unit inspections of drug supplies, as specified.
- Other duties deemed appropriate by the board.

Requirements for Hospital

As a condition of using AHT personnel in a hospital, the proposal establishes obligations for the hospital, including:

- Policies and procedures that detail the duties that will be performed under the general direction of a pharmacist.
- PIC responsibility in the ongoing evaluation of the accuracy of the duties performed by the AHT.
- An electronic record that identifies AHT personnel responsible for performing the authorized duties.

As part of its deliberations, the committee reconsidered if the board should be creating a single advanced pharmacy technician licensing program which could be used in either the community or inpatient setting. The committee also consider if some of the advanced duties that could be performed in an inpatient setting would be also be appropriate for an advanced community pharmacy technician working in a closed-door pharmacy.

Committee Recommendation (Motion): Approve the draft language with the addition of language that would allow the board to modify the technical tasks via regulation and language that clarifies that the pharmacist is to be redirected to provide clinical services.

Attachment 1 includes the proposal as recommended by the committee.

b. Discussion and Consideration of Regulations Pursuant to AB 401 (Chapter 548, Statutes of

2017) Relating to Pharmacy Technicians Working in A Remote Dispensing Site Pharmacy

Attachment 2

Background

Last year the governor signed AB 401, which among other changes, created a remote dispensing site pharmacy (RDSP) licensing program under the board's jurisdiction. As part of the regulatory framework established by the legislation, the board is required to develop regulations that shall apply to pharmacy technicians working at an RDSP [BPC 4132(a)].

Committee Discussion

During the meeting, the committee discussed the basic framework that could be used to establish the regulation requirements a pharmacy technician must satisfy to work in a remote dispensing site pharmacy.

As part of its discussion the committee noted that the policy on the creation of an RDSP has already been decided and that now the board's obligation is to implement the provisions as required. The committee discussed the approved duties for the technicians working at the remote dispensing pharmacy which include performing order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

Under the new provisions of an RDSP, dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician at the remote site. However, a controlled substance signed for by a pharmacy technician must be stored separately from existing inventory until the controlled substance is reviewed and countersigned by a pharmacist. Further, any receipt and storage of a controlled substance by a pharmacy technician must be captured on video and maintained by the remote dispensing site pharmacy for 120 days.

The committee initially considered a proposal that would have established requirements similar to that the proposed advanced community pharmacy technician, but determined that given the scope of duties and supervision of a pharmacist, the regulation requirements could be lessened.

Committee Recommendation (Motion): Direct staff to develop draft regulation language for a pharmacy technician working in a remote dispensing site pharmacy to include the following requirements:

1. Have a pharmacy technician license that is in good standing.
 2. Possess and maintain a certification issued by a pharmacy technician certifying program.
 3. Possesses a minimum of an AA degree pharmacy technology, bachelor's degree (or higher), or has completed a board approved training program.
 4. Complete 1,000 hours of pharmacy technician experience within the last three years.
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Should the board agree with the committee's recommendation, the following motion could be used to initiate the rulemaking process.

Motion: Approve the proposed addition to Title 16 CCR Section 1793.9 and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

Attachment 2 includes a copy of BPC Section 4132 as well as the draft proposed regulation language establishing the requirements.

c. **Discussion and Consideration of the Title 16, California Code of Regulations, Section 1706.2, Related to Abandonment of Application Files**

Attachment 3

Background

CCR Section 1706.2 establishes the provisions under which the board may determine an application is abandoned. Without this regulatory section, applicants would not understand the criteria used by board staff to deem an application abandoned, which results in an application being withdrawn.

Committee Discussion and Action

The committee noted that as the board's regulatory jurisdiction continues to grow, this regulation requires frequent amendments to incorporate each newly created licensing program. In its current form, the regulation specifically mentions each license type (i.e., pharmacist, pharmacy technician, wholesaler, pharmacy, etc.).

The committee considered a recommendation offered by board staff to simplify the language to consolidate licenses issued to a premises as well as the licenses issued to individuals. **Note:** The abandonment criteria for the pharmacist licensure exam application and the intern pharmacist application will still be listed individually in the regulation language.

The committee discussed that such an approach will ensure that all applicants have appropriate notice about the requirements for abandoning an application, while reducing the administrative workload associated with frequent amendments to the regulation.

Committee Recommendation (Motion): Approve the language as provided in Attachment 3 to amend CCR Section 1706.2.

Should the board agree with the committee's recommendation, the following motion could be used to initiate the rulemaking process.

Motion: Approve the proposed amendment to Title 16 CCR Section 1706.2 and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board’s policy direction upon recommendations of the control agencies.

Attachment 3 includes the draft regulatory proposal consistent with the direction by the committee.

d. Discussion and Consideration of Patient Consultation Requirements for Mail Order Pharmacies or Nonresident Pharmacies

Attachment 4

Relevant Law

BPC Section 4112 establishes the licensing requirements for a nonresident pharmacy. Further, as part of this section, Subdivision (h) requires the board to adopt regulations that apply the same requirements for oral consultation for medications dispensed for such pharmacies.

CCR Section 1707.2 establishes the duty of a pharmacist to provide oral consultations to his or her patient in all care settings under specified conditions.

Background

At the July 2017 Board Meeting, the board discussed patient consultation provided by nonresident pharmacies. Minutes from this portion of the meeting are attached in **Attachment 4**.

Committee Discussion

The committee discussed consultation requirements for nonresident pharmacies and other mail order pharmacies. As part of its discussion the committee considered:

- Are the current requirements for mail order and nonresident pharmacies sufficient to ensure patients have access to a pharmacist for consultation?
- How can mail order and nonresident patients be advised that they have the right to translation services? Are existing requirements sufficient?
- Are patients of mail order and nonresident pharmacies receiving appropriate consultation?
- Does the board need to treat mail order pharmacies and nonresident pharmacies differently if they both ship medication to patients?
- Should the board promulgate regulations for nonresident pharmacies consistent with the provisions of Business and Professions Code section 4112(h)

The committee discussed the number of complaints the board receives each year involving mail order pharmacies and how patients are advised of their right to have translation services available. The committee also heard from representatives of mail order pharmacies that detailed their business models and how their respective companies provide oral consultation.

Committee Recommendation (Motion): Direct staff to amend CCR Section 1707.2(b)(1) and 1707.2(b)(2)(B) as follows:

...

1707.2(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent ~~in any care setting in which the patient or agent is present:~~

...

1707.2 (b)(2)(B) a telephone number shall be provided to the patient from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record. Pharmacists shall be available to speak to the patient at least six days per week, and for a minimum of 40 hours per week. The call shall be answered by a pharmacist within two minutes.;

Further, direct staff to draft proposed language requirements for patient notification of the availability of translation services and patient notification of how to file a complaint with the board of pharmacy.

Attachment 4 includes copies of the relevant laws and relevant portion of the prior board meeting discussion on this item.

e. Update on Implementation of Board-Provided Law and Ethics Continuing Education Courses

Attachment 5

Relevant Law

CCR Section 1732.5 establishes the renewal requirements for pharmacists including a provision that requires, effective July 1, 2019, all pharmacists renewing their licenses to have obtained at least two hours of continuing education on pharmacy law and ethics.

Committee Discussion

The committee was advised of the efforts underway to develop a webinar that pharmacists can complete to comply with section 1732.5(b). The webinar will highlight new pharmacy laws taking effect 1/1/18. The course will include a brief introduction by the board president and the executive officer will provide the presentation of new laws and ethics. The committee was advised that the webinar should be completed by the end of March for deployment.

Attachment 5 includes a copy of the relevant law. A copy of the PowerPoint that will be used to create the content of the webinar is also included.

f. Future Committee Meeting Dates

Provided below are Licensing Committee meeting dates through the remainder of 2018:

- April 19, 2018
- June 26, 2018
- September 26, 2018

Attachment 1

Proposal to Add BPC Sections:

Proposed BPC 4038.6

“Advanced Hospital Pharmacy Technician” means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.7.

Proposed 4115.7

- (a) In a hospital pharmacy, licensed advanced hospital pharmacy technician may perform the nondiscretionary tasks authorized in Section 4115 in addition to the following technical tasks under the general direction of a pharmacist:
- (1) Package emergency supplies for use in the health care facility.
 - (2) Seal emergency containers for use in health care facility.
 - (3) Prepare and seal drug kits for use in the health care facility.
 - (4) Perform unit inspections of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health facility in accordance with the health care facility’s policies and procedures.
 - (5) Verify the accuracy of a pharmacy technician’s filling of floor and ward stock and unit dose distribution systems for hospital orders that have been previously reviewed and approved by a licensed pharmacist.
 - (6) Other technical tasks deemed appropriate by the board.
- (b) A hospital pharmacy may use the services of an advanced hospital pharmacy technician if all of the following conditions are met:
- (1) The duties authorized in (a) are performed under general direction of a pharmacist and are specified in the hospital pharmacy’s policies and procedures
 - (2) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a).
 - (3) Pharmacists are deployed to the inpatient care setting to provide clinical services.

Proposed BCP 4211.1

- (a) The board may issue an advanced hospital pharmacy technician license to an individual who meets all the following requirements:
- (1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing,
 - (2) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
 - (3) Has obtained a minimum of an associate’s degree in pharmacy technology, obtained a bachelor’s degree, or higher or completed a board-approved training program.
 - (4) Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a hospital pharmacy.
 - (5) Has passed an advanced pharmacy technician examination.
- (b) As an alternative to the requirements in subdivision (a), the applicant has graduated from a school of pharmacy recognized by the board.
- (a) A license issued pursuant to this section shall be valid for two years.
- (b) Each person, upon application for licensure, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

Proposed BPC 4234.5

An advanced hospital pharmacy technician shall complete 20 hours of continuing education each renewal cycle. A licensee must also maintain certification as specified in Section 4211.1 (a)(2).

Proposal to Amend BPC 4400

...

(z) This section shall become operative on July 1, 2017. The fee for the advanced hospital pharmacy technician application and examination shall be \$260 dollars and may be increased to \$285. The fee for initial licensure and biennial renewal of as an advanced hospital pharmacy technician shall be \$140 and may be increased to \$195.

Attachment 2

Add section 1793.9 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.9 Pharmacy Technician in a Remote Dispensing Site Pharmacy

A pharmacy technician must satisfy each of the following requirements before working in a remote dispensing site pharmacy:

- (a) Possess a pharmacy technician license that is in good standing.
- (b) Possess and maintain a certification issued by an approved pharmacy technician certifying program.
- (c) (1) Possess a minimum of an associate's degree in pharmacy technology or a bachelor's degree in any subject, or (2) complete a board approved training program.
- (d) Complete 1,000 hours of experience working as a pharmacy technician within the three years prior to first working in the remote dispensing site pharmacy.

Authority: Section 4005 and 4132, Business and Professions Code

Reference: 4005, 4026.5, 4044.3, 4052.1, 4115, 4132, and 4202, Business and Professions Code

Business and Professions Code Section 4132(a)

4132(a) In addition to the requirements of Section 4202, a pharmacy technician working at a remote dispensing site pharmacy shall meet the qualifications promulgated by the board. The regulations developed by the board shall only apply to pharmacy technicians working at remote dispensing sites.

Attachment 3

Proposal to Amend Title 16, California Code of Regulations as follows:

§ 1706.2. Abandonment of Application

(a) An applicant for a premises license ~~to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, clinic, veterinary food animal drug retailer, or to furnish hypodermic needles and syringes~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.

~~(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.~~

~~(be)~~ An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

~~(cd)~~ An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

~~(de)~~ An applicant for an intern pharmacist license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

~~(e) An applicant for an individual license not included in subdivision (b), (c), or (d), who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4034, 4034.5, 4037, 4041, 4042, 4043, 4044.3, 4045, 4053, 4110, 4112, 4115, 4120, 4127.1, 4127.5, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4202.5, 4203, 4203.5, 4204, 4205, and 4208, and 4210, Business and Professions Code.

Attachment 4

16 CCR 1707.2.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

- (1) upon request; or
- (2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

- (A) whenever the prescription drug has not previously been dispensed to a patient; or
- (B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

- (A) of his or her right to request consultation; and
- (B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

- (1) directions for use and storage and the importance of compliance with directions; and
- (2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

- (1) the name and description of the medication;
- (2) the route of administration, dosage form, dosage, and duration of drug therapy;
- (3) any special directions for use and storage;
- (4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
- (5) prescription refill information;
- (6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
- (7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code.
Reference: Sections 4005, 4076 and 4122, Business and Professions Code.

State of California

BUSINESS AND PROFESSIONS CODE

Section 4112

4112. (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California.

(h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section

and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

(j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

(k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

(Amended by Stats. 2011, Ch. 646, Sec. 3. (SB 431) Effective January 1, 2012.)

Excerpt from the July 2017 Board Meeting Minutes

Discussion and Consideration of Pharmacist Consultation in Various Pharmacy Settings

Chairperson Weisser explained that CCR Section 1707.2 establishes the requirements for patient consultation including the conditions when such consultation must occur. Further, this section provides that when a patient or a patient's agent is not present in a pharmacy to receive consultation, the patient shall receive written notice of the patient's right to request consultation and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

Chairperson Weisser stated that CCR Section 1713 provides the authority for a pharmacy to use an automated drug delivery system (ADDS) under specified condition and subsection (d)(5) establishes the requirement for such a pharmacy using an automated drug delivery system to provide an immediate consultation with a pharmacist, either in-person or via telephone, upon the require of a patient.

Chairperson Weisser explained that BPC Section 4112(h) requires the board to adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that dispenses medications to Californians consistent with the consultation requirements established for mail order pharmacies located within California. He noted that the board does not currently have such regulations.

Chairperson Weisser stated that the board has frequently discussed the benefits of patient consultation as an important component of consumer protection and has expressed some frustration with what appears to be a lack of consultation.

Chairperson Weisser reported that during the April 2017 Pharmacy Technician Summit, the committee discussed changes in duties performed by pharmacy technicians in various settings. The committee discussed whether expanding pharmacy technician duties to include more responsibilities while under the supervision of a pharmacist would allow pharmacists to provide more patient care services, including drug utilization review, patient profile review and patient consultation. He added that as part of the discussion, the committee considered various settings including traditional community pharmacy, mail order and closed door pharmacy, inpatient, and other specialty pharmacy settings.

Chairperson Weisser stated that the committee was provided a summary of the workflow in Iowa's tech-check-tech pilot, where the pharmacist is involved at the first level interaction with the patient, performing the data and review prior to printing the label, and providing the final consultation. The committee was also presented with the pharmacist involvement for call-in prescriptions in Idaho. It was explained that in Idaho, the pharmacist would be at the DUR and PU1 station verifying the data entry. Chairperson Weisser added that in regard to patient consultation there is a toll-free number that patients may call.

Chairperson Weisser reported that the committee also discusses mail order pharmacies and staff suggested the need to broaden consultation requirements for mail order pharmacies, noting that consumer complaints surrounding mail order pharmacies involve allegations of delays in therapies because the patient is unable to reach a pharmacist. The committee also heard that medication reconciliation is performed in the mail order pharmacy setting by the pharmacy benefit managers

who have access to patient records and would highlight if there was duplication in therapy. Chairperson Weisser reported that during its meeting the committee noted that currently pharmacies are often structured and staffed so that the pharmacist is in the back of the pharmacy, and at the front of the pharmacy, interacting with patients, are the pharmacy technicians and cashiers. This is efficient for the cashiering functions, but it interrupts the flow of the pharmacy with respect to patient consultation. Chairperson Weisser explained that this service, and the important drug utilization review, must be performed by the pharmacist and are critical for patient care.

Chairperson Weisser stated that the committee discussed the idea that if pharmacy technicians were to be trained and/or qualified to perform tech-check-tech, to handle insurance functions and perhaps function under a somewhat different ratio, the pharmacist could move forward within the pharmacy to provide more interaction with and services directly to patients. This would also allow pharmacists to perform patient-care functions authorized by protocol (immunizations, naloxone, etc.) or under protocol with primary care providers either as a pharmacist or advanced practice pharmacist. Chairperson Weisser noted that cashiering functions could still be performed by non-pharmacist staff, but the actual handling of the medication could occur by the pharmacist following DUR and during consultation. Chairperson Weisser stated that not all pharmacists may prefer to organize their pharmacies under such a model, but it would permit a pharmacist who does so to focus on the duties he or she is most qualified to perform. Chairperson Weisser also stated that it could also foster the board's long-term goal of increased rates of patient consultation.

Chairperson Weisser reported that as part of its discussion, the committee considered the following questions:

1. Are the requirements currently established in CCR 1707.2 appropriate or is revision necessary?
2. Should changes at the transactional level be considered to ensure pharmacist engagement with patients in the dispensing process?
3. Is the current requirement for a mail order pharmacy sufficient to ensure patients have access to a pharmacist for consultation?
4. Should the board promulgate regulations for nonresident pharmacies consistent with the provisions of BPC 4112?
5. Are the current requirements for the use of an ADDS system sufficient to ensure patients have access to a pharmacist for patient consultation?
6. Do patients discharged from a hospital given sufficient information about their medication by either a pharmacist or registered nurse?

Chairperson Weisser reported that the committee requested that board staff evaluate the committee's discussion and bring this item back for further discussion including how best to incorporate the purpose of the medication and improve access to patient consultation for patients receiving their medication through mail order pharmacies.

Board member Wong asked if labeling requirements are same for mail order pharmacies are retail pharmacies. Ms. Herold responded that all prescriptions written for California patients must follow the patient-center labeling requirements. She added that the board may need to discuss how mail order patients are notified that they have the right to request translations.

Board member Lippe asked why mail order prescriptions are often offered at a cheaper price. President Gutierrez stated that mail order pharmacies can use large scale automation and purchase

their drugs in bulk at a cheaper price.

Dr. Wong stated that the Communication and Public Education Committee should discuss how mail order patients can be notified that they have the right to translation services.

Laura Freedman, DCA legal counsel, recommended that the board consider agendaing this discussion for a future meeting.

A pharmacist commented that mail order patients often do not receive appropriate consultations which can result in serious health problems.

Dennis McAllister, representing Express Scripts, recommended that the board work with stakeholders to address concerns with mail order pharmacies. He added that Express Scripts handles approximately 100 million prescriptions per year. Mr. McAllister explained that one of the benefits of mail order pharmacies through Express Scripts is that pharmacists are available to speak with patients 24/7. Mr. McAllister stated that they meet all state laws for translation services. He also stated that studies have shown that mail order patients have lower emergency room admission rates. Ms. McAllister stated that there may be bad mail order pharmacies, but the board should handle them rather than make requirements that apply to all mail order pharmacies.

Chairperson Weisser stated that the board has seen that many California patients do not have adequate access to pharmacists both in the community and mail order settings.

Mr. Law asked how many pharmacy technicians work at mail order pharmacies. Mr. McAllister stated that he did not have an answer to this question.

President Gutierrez asked if the majority of mail order prescriptions are new or refill prescriptions. Mr. McAllister responded that the majority of Express Scripts prescriptions are for refills.

Robert Stein from KGI School of Pharmacy, expressed concern that mail order patients may not know that they have the right to request translation services and encouraged the board to discuss this at a future meeting. Dr. Wong again stated that the Communication and Public Education Committee should handle this item.

A member of the public asked how expanding the role of technicians will help pharmacists provide consultations. Mr. Lippe responded that the intent is to allow pharmacists to have more time to provide consultations by allowing technicians to take over some of the duties currently being performed by pharmacists, the technician would not be the one providing the consultations. The commenter stated that California technicians already are allowed to perform more duties than in other states and asked what other duties the board wanted to give technicians. Chairperson Weisser responded that expanded technician duties are currently being discussed by the Licensing Committee and encouraged the person to attend the meetings to provide input.

Attachment 5

§ 1732.5. Renewal Requirements for Pharmacists.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.

(c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

California Pharmacy Law Update 2018

Virginia Herold
Executive Officer
California State Board of Pharmacy
December 2017

Statutory Mandate

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.

CA Business and Professions Code 4001.1

Resources

- * Board Website: www.pharmacy.ca.gov
 - on the far right of the webpage: Quick Hits see
2018 legislation
Laws and Regulations
- * Join the board's subscriber alert

Major Regulations Going Into Effect

- * Compounding
- * APh roll out
- * Drug Take Back

Regulations at Final Stages

- * Medication Reconciliation
- * Modifications to Compounding

Email Addresses Must Be Reported to Board *Effective July 1, 2017*

- * Each pharmacist, intern pharmacist, pharmacy technician, designated representative-3PL shall join the board's email list within 60 days of licensure or at the time of license renewal – beginning July 2017
- * Email addresses shall updated by licensee within 30 days of a change in the email address.
- * The email address shall not be posted on the board's online license verification system.
- * Reminders placed on each renewal to report and keep current the email address with the board.

B&P Code 4013

Pharmacy Licensure on Hospital Campuses

- * Expands the board's ability to license hospital pharmacies to any physical plant of a hospital campus.
- * Allows the board to issue licenses to hospital satellite compounding pharmacies in another physical plant on the CDPH GACH license
 - may only perform sterile compounding for administration to patients of the hospital receiving care in the same physical plant

Hospital Satellite Compounding Pharmacies

Satellite pharmacies must purchase, procure or obtain all components through the licensed hospital pharmacy

Report to the board any adverse effects or recalls within 12 hours if compounded in a hospital satellite pharmacy

Origin: SB 351, Roth

This was board sponsored

Expanded Options for Replenishment of EMS Emergency Drug Supplies

- * Allows the establishment of drug storage and replenishment supplies in dispensing machines located in fire stations and EMS agencies:
 1. Requires licensure of the machine with the Board of Pharmacy (called EMSADDS)
 2. Medical director, pharmacist or “designated paramedic” must be in charge of the EMSADDS

Replenishment of Ambulances

3. EMSADDS must collect data on who replenished, what medications, when
4. May be restocked by medical director, pharmacist, designated paramedic
5. “Restocker” cannot store medications in vehicles or home: appropriate storage required
6. Paramedics, pharmacists, medical directors may access EMSADDS to replenish ambulances
7. dual signatures required for removals from EMSADDS

Replenishment of Ambulances

- * Monthly inventories and reconciliation required
- * Losses reported to board within 7 days

Origin: SB 443 (Hernandez)

This was board sponsored

Update of Sterile Compounding Provisions

Repeals outdated provisions in pharmacy law that provided requirements for sterile compounding. Gone are provisions that provided:

- * An ISO Class 5 laminator airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas
- * An ISO class 5 cleanroom
- * A barrier isolator that provides an ISO class environment

Origin: SB 510, Stone This was board sponsored

Reverse Distributors' Designated Representatives

- * Establishment of a specialized route of qualification for designated representatives (individuals who are charge of drug distributors) wherein the individuals have specialized experience working in the destruction of medication or pharmaceutical waste
- * Titled "Designated Representatives – reverse distributor"

Origin: SB 752 (Stone)

This was board sponsored

Retaking the Pharmacist Licensure Exams

- * Applicants who fail the NAPLEX or CPJE may retake the examination in 45 days

Origin: SB 752 (Stone)

This provision was board sponsored

Telepharmacy

- * Defined as a system that is used by a supervising pharmacy to monitor the dispensing of prescription drugs by a remote site and provides related pharmacy services including consultation by an electronic method, using audio, visual, still image capture and store and forward technology.

Telepharmacy

- * A telepharmacy system
 - * Shall be located in a medically underserved area -- “a location that does not have a pharmacy that serves the general public within 10 road miles of the remote site”
 - * If a pharmacy is later established within 10 miles, the remote pharmacy can continue to operate
 - * Remote pharmacy shall be staffed ONLY by pharmacists or pharmacy technicians
 - * Cannot be operated by the state or in a state facility

Telepharmacy

- * If a remote site dispenses more than 225 prescriptions a day, over one year, it shall cease to be a remote dispensing site pharmacy and may become a pharmacy.
- * A supervising pharmacy may provide services to only one remote pharmacy

Telepharmacy

- * A supervising pharmacy may provide services to only one remote pharmacy
- * A supervising pharmacy must be within 150 road miles of the remote dispensing site pharmacy
- * The supervising pharmacy and remote pharmacy must be under common ownership
- * A pharmacy technician must be under direct supervision of a pharmacist whenever the remote pharmacy is open, audio and visual technology may be used to achieve supervision.

Telepharmacy

- * The PIC and the pharmacist on duty in the supervising pharmacy are responsible for sufficient staffing in both pharmacies

Telepharmacy Legislative Intent

- * The law makes a number of proclamations:
 - * Patients see their pharmacists more than any other health care provider. Making pharmacists readily available should be a top priority of the state.
 - * Over 30 percent of patients never fill their prescriptions. This number drops to 5 percent when patients have more convenient access to a pharmacy.
 - * Lack of convenient access to a pharmacy leads to over \$290 billion in avoidable medical spending.

Telepharmacy Legislative Intent

- * 76 percent of rural counties are designated as health professional shortage areas. There are 115 identified areas located in 47 counties where the closest pharmacy is more than 10 miles away
- * It is the intent of the Legislature to enact legislation that will promote policies to allow all California patients to have access to a pharmacy, thereby increasing medication adherence.

Telepharmacy

- * Creates definitions:
 - * “Remote Dispensing Pharmacy” is a pharmacy overseen by a supervising pharmacy and staffed by 1 or more pharmacy technicians.
 - * Pharmaceutical care services are remotely monitored or provided a supervising pharmacy using “telepharmacy” technology

Telepharmacy

- * A supervising pharmacy is
 - * Licensed in CA
 - * Owned and operated in majority interest by a board-licensed pharmacist and who oversees the operations of the remote pharmacy site
 - * Responsible for operations of the remote site and its employees

Telepharmacy

- * Drugs and devices may be ordered by a remote dispensing pharmacy:
 - * Received and signed for by a pharmacy technician
 - * Controlled substances accepted and signed for by a pharmacy technician in a remote site must be stored separately until reviewed and countersigned by a pharmacist.
 - * Receipt and storage of controlled substances by a technician must be captured on video and kept for 120 days

Pharmacy Technicians in Remote Dispensing Pharmacies

- * Board to develop regulations for remote dispensing pharmacy technicians
- * A remote pharmacy technician may not:
 - * Receive a prescription order from a prescriber
 - * Consult with a patient about a prescription
 - * Identify, evaluate or interpret a prescription
 - * Interpret clinical data in a patient's chart
 - * Consult with a prescriber, nurse or other provider

Telepharmacy Requires Video and Audio Systems

- * Video and audio systems are required to ensure communication between the supervising pharmacy and remote pharmacy
 - * To ensure supervision
 - * To provide patient consultation, which must be provided on ALL prescriptions dispensed by the remote pharmacy.

Telepharmacy Audio and Video Systems

- * The systems must be able to identify:
 - * The pharmacy technician preparing each prescription and the supervising pharmacist
 - * The pharmacist who reviewed the prescription with the data entry record
- The remote pharmacy must:
 - * Perform barcode reading before dispensing of the stock bottle and prescription container,
 - * Ensure pharmacist review before dispensing

Telepharmacy

- * A pharmacist must perform a monthly inspection of the remote pharmacy using a board-designed form.
- * Controlled substances
 - * Locked separately
 - * Perpetual inventory required
 - * Supervising pharmacy must inventory and reconcile

Suspicious Orders of Controlled Drugs

- * Wholesalers must report to the board all suspicious orders of controlled drugs made by other wholesalers or pharmacies.
- * Suspicious orders include: orders deviating substantially from a normal pattern, and orders of unusual frequency

Origin: AB 401 (Aguiar-Curry)

This provision was board sponsored

Shared Office Space for Clinics

- * Two independently owned and licensed nonprofit clinics may share office space provided:
 - * A co-located license is obtained
 - * Each clinic maintains physically separate and locked drug stocks.
 - * Records of medication acquisition and disposition are kept separate
 - * There is no sharing of medication

Origin: AB 401 (Aguiar-Curry)

Sales of Non-Prescription Diabetes Test Strips and Meters

- * Requires the board to post a list of authorized distributors of nonprescription diabetes test strips
- * Requires a pharmacy to retain records of acquisition and disposition for nonprescription diabetes test devices
- * Makes purchasing from an unauthorized distributor unprofessional conduct for a pharmacy
- * Allows the board to embargo product for cause

Origin: AB 602 (Bonta)

Access to CURES data

- * Allows access to the CURES systems through a health information technology system in addition to the current CURES online portal.
- * The DOJ is developing the system connection and will require a memorandum of understanding
- * Urgency provision -- in effect now, but DOJ is not yet

Origin: AB 40 (Santiago)

Partial Filling of Controlled Substances

- * Authorizes partial filling of Schedule II controlled drugs if requested by the patient or prescriber
- * Allows multiple fills, provided each partial filling is recorded on the prescription
- * The full prescription may be filled up to 30 days from the initial partial fill.
- * The prescription is no longer valid on the 31st day
- * Pharmacist may charge a dispensing fee for each partial fill

Partial Filling of Controlled Substances

- * Note each partial filling in CURES
- * Allow prorated dispensing fees for a health care service plan
- * Provisions effective 7/1/18

Origin: AB 1048 Arambula

Questions?

Thank you

Virginia Herold

www.pharmacy.ca.gov

Virginia.herold@dca.ca.gov

(916) 574-7911