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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
MINUTES

DATE: January 10, 2017

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Stanley Weisser, Chairperson
Debbie Veale, Vice-Chairperson
Albert Wong, Licensee Member
Lavanza Butler, Licensee Member
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel

Note: The committee took some agenda items out of order. For ease of use, the minutes reflect the discussion of the committee in the order the items were included on the agenda.

1. Call to Order and Establishment of Quorum

Chairperson Weisser called the meeting to order at 9:07 a.m. Roll call was taken with the following members present: Lavanza Butler, Stan Weisser, Debbie Veale and Ricardo Sanchez. (Member Albert Wong joined the meeting around 9:15.)

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Fred Meyer, PPSI, provided the committee with informational articles (attached at the end of the minutes) and asked what the committee about board efforts to address workload issues in pharmacies. He expressed concern as a consumer advocate given the expanded scope of practice of a pharmacist that pharmacists do not have more time to fulfill these roles. Mr. Meyer noted that pharmacists are filling inordinate amount prescriptions and requested that the board discuss this issue. On a separate topic he

noted that APhA recommends that pharmacist consult about medical marijuana and discussed an upcoming education event that would cover the topic.

3. Certification Programs Developed to Satisfy Requirements for Licensure as an Advanced Practice Pharmacist Pursuant to Title 16, California Code of Regulations (CCR) Section 1730.2

Chairperson Weisser noted that since the passage of SB 493 the board has been working on implementation of the various provisions, including developing regulations to establish the parameters for acceptable certification programs that can be used as one of the qualifications for licensure as an Advanced Practice Pharmacist.

Mr. Weisser noted that CCR section 1730.2 established the parameters for certification programs in general clinical pharmacy practice and highlighted the program requirements.

The committee heard a presentation from Jon Roth and Soua Vang from the California Pharmacists Association (CPHA) regarding an advanced practice pharmacist certificate training program developed in collaboration NACDS. Mr. Roth noted that this collaboration was focused not only on California requirements, but also included efforts happening on the national level which could allow for one set of parameters for employers that operate in other states as well.

Mr. Roth advised members that the advisory board established included both independent and chain drug store representatives. The program developers (SMEs) consisted of faculty from schools of pharmacy both within and outside of California.

Mr. Roth and Ms. Vang detailed how their program complies with the regulation requirements established in regulation, noting that CPhA is an approved ACPE provider and that the program includes 38 contact hours.

The committee was advised that the course includes online self-paced learning including 30 hours covering five modules. The modules include instruction, knowledge and application and must be completed in chronological order. The program requires completion of the online self-paced learning before an individual can participate in the in person skills seminar which is 8 hours.

When questioned about remediation, the committee was advised that if a person fails a module twice, then a review is required based on the module they failed. Additionally, the person must demonstrate additional training was completed before the person is eligible to take it again. The committee was also advised that if a person fails the in-person seminar, the participant must wait and take the entire course again.

The committee was advised that part of the remediation process includes a discussion with a SME who possesses more skill in the remediated area to provide more assistance to the person.

When the committee questioned about the target audience for this program, the committee was advised that participants in this program will most likely be pharmacists working under a collaborative practice agreement with a physician for about a year and are using the certification program in lieu of the

residency pathway to licensure.

The committee was advised that 30 participants completed the initial program.

The committee saw an example of the online self-study system and was advised that a video is given to a participant as part of the program modules.

Presenters advised the committee that the in-person seminar includes: overview and background, skills assessment and demonstrations, ordering and interpreting tests, patient referral, drug therapy management, documentation and conclusion which is a small group process that is facilitated by an expert in the field - either trained trainers or educators.

The committee was advised that the final exam in completed after the in-person seminar. An individual is given two attempts to pass the exam. Participants may not receive the same exam because the questions are pulled from a bank of questions. The committee was advised about the methodology used to develop the final exam that included a job analysis survey.

The committee was advised that the first public certification program will be February 2017 for people that have already completed the 30 hours of online course of study. When questioned, the committee was advised that 25 individuals are registered for the in-person seminar.

The presenters noted that the cost of the program is $799 for members and $1,499 for individuals that are not members of CPhA.

The committee also heard a presentation on a program developed by the California Society of Health Systems Pharmacists (CSPH) and Touro University from Lori DeMartini, Dr. Keith Yoshizuka and Kethen So. As part of the presentation, the committee was provided with program details the demonstrated compliance with the regulations.

Included with the meeting materials the committee was provided with detailed program information including detailed information about the modules and CVs for faculty. As part of the presentation, presenters highlighted certain elements including that all instructors are professors for Touro University. The program is ACPE accredited and meets the sequential modules requirement of the regulation. The committee was provided with an overview of the online modules and the one day in-person component. When queried, presenters advised members that their target market is pharmacist that have been working in a hospital doing performing clinical duties, but did not complete a residency.

The committee asked about how the program handles a participant that does not pass a module assessment and was advised a participant can take the assessment to four times after which an individual must start the entire program.

The committee inquired about the ratio of participants to SMEs during the in-person component and was advised the ratio would be 5:1. The committee was advised that the program has not yet started, but CSHP believe the cost of the program could be between $700 - $800 for member of the association.

When questioned about the validation of the exam, the committee was advised that exams were developed by faculty that work in the specialty areas.

CSHP noted that it is estimated that the program will start later this year with the first in-person portion taking place in May of 2017.

At the conclusion of the presentations Chairperson Weisser noted that the committee does not need to approve these programs but will report to the board about the programs.

4. Discussion and Consideration of Possible Revisions to the Licensure Requirements for a Designated Representative in a Reverse Distributor

Chairperson Weisser reviewed relevant statutes applicable to the discussion in Business and Professions Code (BPC) section 4040.5 provides a definition for a reverse distributor to include every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous drugs.

Mr. Weisser also referenced BPC section 4043 that provides a definition for a wholesaler as a person who sells for resale, or negotiates for distribution, or takes possession of, any drug or device, noting that under this section, a reverse distributor is considered a wholesaler. Chairperson Weisser also highlighted that BPC 4053 provides the board with the authority to issue a license to a designated representative. Mr. Weisser also detailed the applications requirements for a designated representative.

As part of its discussion the committee noted that by law, for a wholesaler to operate, it must have at least one designated representative or a pharmacist on the premises at all times when the wholesaler is open for business (B&PC 4160 (c)(1). A wholesaler must also have a designated representative-in-charge who shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers (B&PC 4160(d).

The committee heard a presentation from Bob Shaw and Terry Shane representing Medical Waste Services. The committee was advised that their company has received approval to dispose of pharmaceutical waste using a high heat technology that is more environmentally friendly that incineration. As part of the company's approval process from various state and federal regulator the company was advised that it must also be licensed by the board as a reverse distributor (a DEA requirement). The committee was advised of the challenges Medical Waste Services has in finding individuals that meet the licensing requirements as a designated representative because of the year of experience requirement.

The committee discussed the current licensing requirements for a reverse distributor as well as the current licensing requirements for a designated representative that works in reverse distributor and current impediments to meeting those requirements.

The committee reviewed a draft proposal to establish separate licensing requirements for a designated representative working in a reverse distributor.

MOTION: Pursue statutory changes to develop licensing requirements for a designated representative-reverse distributor including proposed addition of Business and Professions Code (B&PC) sections 4022.6 and 4053.2 and proposed amendment to B&PC 4400 with amendment to the one year of experience

requirement specified proposed section B&PC 4053.2 (b)(1)(A).

Proposed Addition of B&PC 4022.6

4022.6. Designated Representative Reverse Distributor

"Designated representative reverse distributor" means an individual to whom a license has been granted pursuant to Section 4053.2. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative reverse distributor.

Proposed Addition to B&PC 4053.2

4053.2. Designated Representative Reverse Distributor

(a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a designated representative reverse distributor to provide sufficient and qualified supervision of a licensed wholesaler who only acts as a reverse distributor as defined in Section 4040.5. The designated representative reverse distributor shall protect the public health and safety in the handling, storage, warehousing and destruction of outdated or nonsaleable dangerous drugs and pharmaceutical waste.

(b) An individual who is at least 18 years of age may apply for a designated representative reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.

(2) He or she shall meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with licensed wholesaler, third party logistics provider or pharmacy performing duties related to the distribution, dispensing or destruction of dangerous drugs or dangerous devices.

(B) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(iii) Knowledge and understand of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.

(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a designated representative reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A reverse distributor shall not operate without at least one designated representative or designated representative reverse distributor present at each of its licensed places of business as required under Section 4160.

Proposed Amendment to B&PC 4400

…(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, ~~or as~~ a designated representative-3PL pursuant to Section 4053.1, or as a designated representative reverse distributor pursuant to Section 4053.2 shall be three hundred thirty dollars ($330) and may be decreased to no less than two hundred fifty-five dollars ($255).
(2) The fee for the annual renewal of a license as a designated representative, ~~or~~ designated representative-3PL, or designated representative reverse distributor shall be one hundred ninety-five dollars ($195) and may be decreased to no less than one hundred fifty dollars ($150)…

M/S: Veale/Wong

Support: 5 Oppose: 0 Abstain: 0

5. Discussion and Consideration of a Statutory Proposal to Establish a Satellite Compounding Pharmacy Licensure Category

Chairperson Weisser provided an overview of the item as well as detailed relevant laws. Mr. Weisser noted that BPC section 4029(a) provides the definition of a hospital pharmacy and BPC section 4029(b) establishes the authority for a hospital to obtain a second hospital pharmacy license under specific conditions. Chairperson Weisser also noted that BPC section 4127.1 generally establishes the requirements for licensure for a pharmacy that compounds sterile drug products and that as part of these requirements a license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy.

The committee was advised that as the board implemented the expanded sterile compounding licensure program both hospitals and board staff have experienced challenges in applying appropriate licensing requirements. Part of the challenge results from the board's requirements and regulation while considering the regulations that a hospital must also comply with under CDPH requirements.

Mr. Weisser noted that to address some of these challenges board staff met internally as well as consulted with CDPH staff and counsel. The intent of these meetings was to gain a better understanding of the overlay between the two regulators, understand the expectations for patient care as well as determine what changes, if any, staff would recommend to ensure safe and appropriate pharmaceutical services within a hospital.

The committee was also advised that board staff was approached by a large health system that is seeking clarification on the board's authority to issue more than one hospital pharmacy license. The request was made noting that a CDPH hospital license includes more than just the physical hospital building, but also includes other "approved services" that may be located off the premises. The concern expressed was about both the logistics of the main hospital pharmacy provided medications in a safe and secure manner to such facilities that are located off site and if there was an opportunity to provide for better drug control at some of these other locations.

As part of its discussion the committee review proposed statutory changes designed to address some of these challenges as well as create additional options for hospitals. The proposed changes would:

1. Allow a hospital to secure a second hospital pharmacy license from the board to be located within

an “approved service” area that is not part of the hospital’s physical plant.

2. Establishes the authority to issue a satellite sterile compounding pharmacy license to a location separate from the hospital’s physical plant under specified conditions.

MOTION: Pursue statutory changes to approve amended language in 4029, adding 4127.15 and secure these changes via legislation.

Amend 4029.

(a) “Hospital pharmacy” means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital in another physical plant that is regulated under a hospital’s ~~consolidated~~ license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) A hospital satellite compounding pharmacy may be separately licensed by the board that compounds sterile drug products located outside of the hospital in another physical plant that is regulated under a hospital’s license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, a hospital satellite compounding pharmacy shall only dispense compounded sterile drug products for administration to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located. The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant.

Add 4127.15

(a) A hospital satellite compounding pharmacy license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(b) A hospital satellite compounding pharmacy license shall not be issued or renewed until the board does all of the following:

1. Reviews a current copy of the hospital satellite compounding pharmacy’s policies and procedures for sterile compounding.
2. Reviews the hospital satellite compounding pharmacy’s completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.
3. Receives a list of all sterile drug products compounded by the hospital satellite compounding pharmacy since the last license renewal.

(c) A hospital satellite compounding pharmacy shall do all of the following:

1. Purchase, procure, or otherwise obtain all components through the license of the hospital pharmacy, as defined in 4029(a).
2. Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty as required by Section 1793.7(f) of Title 16 of the California Code of Regulations.

3. Ensure immediate supervision, as defined in Title 22, California Code of Regulations section 70065, by a pharmacist of licensed ancillary staff involved in sterile compounding.
4. Provide to the board, within 12 hours, any recall notice issued by the hospital satellite compounding pharmacy for sterile drug products it has compounded.
5. Report to the board, within 12 hours, adverse effects reported or potentially attributable to the sterile drug products compounded by the hospital satellite compounding pharmacy. Adverse effects must also be immediately reported to the MedWatch program of the federal Food and Drug Administration.

M/S: Veale/Butler
Support: 5 Oppose: 0 Abstain: 0

6. Discussion and Consideration of a Statutory Proposal to Establish Authority for County Emergency Medical Services Providers to Use Automated Drug Delivery Systems for Purposes of Restocking Ambulances

The committee was reminded that during the December 2016 Board Meeting, members were advised that board staff have been meeting periodically with the Los Angeles County Fire Department headquarters staff on a proposal to allow the fire department to establish automated drug delivery systems in certain fire stations from which the department's ambulances can restock their ambulances. This system would supplement other methods already in place that permit the restocking of ambulances.

Chairperson Weisser indicated that the general provisions would be that medications would be owned by the county fire station, and initially purchased and stored centrally in a licensed wholesaler premises licensed by the board that is owned and operated by the fire department.

Mr. Weisser noted that a fire station with an automated drug delivery system would be licensed (requiring a new license type) and that restocking of the automated drug delivery systems would be under the supervision of a pharmacist. The automated dispensing machine would then be available for access by ambulance staff, where the tracking system for the automated drug delivery system would track the signatures of the two staff who removed medications from the automated drug delivery system to replenish the stock of medications on the ambulance.

Mr. Weisser referenced a draft statutory proposal included in the meeting materials and advised the committee that the draft was developed based on the board's discussion as well as review of California's Emergency Medical Services Personnel Programs provided by the Emergency Medical Services Authority (EMSA).

As part of its discussion the committee noted that while the issue was initially brought forward by LA County, the proposal should not be developed for a single county, but rather needed to work for all counties that wished to use the system.

The committee provided direction to staff to update the proposal to reflect changes based on its discussion.

MOTION: Pursue statutory changes to secure addition of B&PC 4032 and amendment to B&PC 4119.

Proposed Addition of Section 4034

4034. Emergency Medical Services Automated Drug Delivery System

An emergency medical services automated drug delivery system is a mechanical system that performs operations or activities relative to the storage and distribution of drugs for the sole purpose of restocking a secured emergency pharmaceutical supplies container that is used by an emergency medical services agency to provide emergency trauma medical services. The automated drug delivery system shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for security, accuracy and accountability purposes.

Proposed Amendment to Section 4119

4119. Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

(a) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to 24.

(b) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.
(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency. Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years. The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances Act.
(c) Notwithstanding any other provision of law, a pharmacy or wholesaler may furnish dangerous drugs and or dangerous devices into a emergency medical services automated drug delivery system located within a county owned fire department. Dangerous drugs and devices distributed by an emergency medical services automated drug delivery system shall be for sole purpose of restocking a secured emergency pharmaceutical supplies container and may only be used if all of the following conditions are met.
(1) The county fire department obtains licensure from the board to maintain the emergency medical services automated drug delivery system on the premises of any of its fire stations. As part of the application, the county must provide the address of each fire station, the name of the county medical director responsible for overseeing the emergency medical services system, the name of a designated consultant pharmacist responsible for monthly review, the copy of the policies and procedures detailing the provisions under which the emergency medical services automated drug delivery system will operate, and the name and license number of the pharmacy or wholesaler that is furnishing the dangerous drugs and dangerous devices to the emergency medical services automated drug delivery system. A separate license shall be required for each location.
(2) Stocking and inventory controls of dangerous drugs and devices in the emergency medical services automated drug delivery system is completed by a pharmacist.
(3) Monthly review of the emergency medical services automated drug delivery system is completed by a designated consulting pharmacist who shall be responsible for reviewing compliance with inventory controls specified in the policies and procedures. The medical director and designated consulting pharmacist shall be jointly responsible for the monthly review of the county fire department's training, storage and security of dangerous drugs and dangerous devices, and the dispensing and administration procedures which shall include a review of the use of emergency medical services automated drug delivery systems to ensure safeguards are in place allowing only authorized staff, as defined in this section, to have the ability to access and remove dangerous drugs and dangerous devices from the emergency medical services automated drug delivery systems.
(4) County fire department access to the emergency medical services automated drug delivery system shall be limited to only employees of the county that are licensed by the state as a paramedic or the county medical director.

(5) A record of each access to the emergency medical services automated drug delivery system must be maintained for at least three years in a readily retrievable form. The records must include the identity of the licensed paramedic and medical director accessing the system as well as the drug, dosage form and quantity obtained.
(6) Violations of the provisions in subdivision (c)(1)-(5) shall constitute unprofessional conduct and shall provide the board the authority to take action against the County Fire Department's licensure of the emergency medical services automated drug delivery systems.

M/S: Veale/ Wong
Support: 4 Oppose: 0 Abstain: 0

(Member Sanchez was not present for the vote on this item.)

7. Licensing Statistics

Chairperson Weisser provided an overview of the licensing statistics including receipt of 40 applications for the new Advanced Practice Pharmacists license. The committee also discussed general processing times for specific license types below:

Site Application Type	Number of Days
Pharmacy	10
Nonresident Pharmacy	14
Sterile Compounding	4
Nonresident Sterile Compounding	Current
Hospital	4
Clinic	14
Wholesaler	21
Nonresident Wholesaler	22
Third-Party Logistics Provider	Current
Nonresident Third-Party Logistics Provider	Current

The committee noted the improvement in the board's processing times.

8. Future Committee Meeting Dates

The committee reviewed meeting dates for 2017 including:

- April 4, 2017 (Pharmacy Technician Summit)
- June 29, 2017
- September 19, 2017