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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

SENATE BILL 493 IMPLEMENTATION COMMITTEE
CHAIR REPORT

Stan Weisser, RPh, Committee Chair
Amy Gutierrez, Pharm D, Board President
Debbie Veale, RPh
Victor Law, RPh

There has been no meeting of this committee since April 13, 2015.

Background:
SB 493 creates a number of new opportunities for pharmacists to provide direct care to patients. There are essentially two levels of additional services authorized – one for all pharmacists, the second to create a new licensure category of advanced practice pharmacist to provide additional duties.

The board has formed this committee to implement the multiple requirements of SB 493. This committee, called simply the Senate Bill 493 Implementation Committee, will work on components to implement the multiple provisions of this bill. The meetings where these deliberations will occur are public, and will be listed on the board's website. We invite interested individuals to attend. The recent enactment of AB 1535 (Bloom) has directed the board to develop a naloxone protocol through an emergency rulemaking process. For expediency, this task has been added to the agenda of this committee.

Copies of the minutes from the April 21 and 22 Board Meeting where certain items below were discussed are provided in this board packet under agenda item III.

a. Regulations Detailing Licensure Requirements for Advanced Practice Pharmacists

At the April 2015 Board Meeting, the board approved and moved to initiate a regulation rulemaking on proposed text that specifies the ways and supporting documentation needed to qualify for registration as an advance practice pharmacist. Additionally a fee of $300 was selected as the application and renewal fee for this license.

At the April board meeting, the board made several modifications in the text and referred the matter to the next SB 493 committee meeting. However, there has been no meeting of the committee and the following items are being brought to the board for discussion and action at this meeting. The board will vote on these proposed changes during this board meeting.

At the April Board Meeting, the board motioned to initiate a rulemaking of sections 1730 and 1730.1, with a direction to staff to clarify the experience gained under protocol in 1730.1(c).

The following text is being brought back to the board for its review and approval. The additional text is indicated in red and double underscore.

Staff is recommending that once the board finalizes the text for the first iteration of advance practice pharmacist licensure requirements, that the board direct staff to initiate a rulemaking and release the text for the 45- day comment period, and to return to the board with any negative comments, or otherwise prepare and submit the rulemaking file for approval by the Office of Administrative Law.

Article 3.5
Advanced Practice Pharmacist
1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are certified by the National Commission for Certification Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

(a) Documentation of possession of a current certification as specified in California Business and Professions Code section 4210(a)(2)(A) shall be via:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or
(2) A letter from the certification program attesting **(or confirming)** the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Documentation of completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or
(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

(c) Experience earned under a collaborative practice agreement or protocol must have been earned within 10 years of the time of application for APP licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours **of experience providing clinical services to patients,** earned over a period of no longer than four years. **If the qualifying experience was earned under a protocol, the experience must include initiating, adjusting or discontinuing drug therapy of a patient as authorized by law. The applicant shall demonstrate possession of such experience by providing both:** ~~The documentation of this experience that shall be provided to the board shall include both:~~

(1) ~~An attestation~~ **A written statement** from the applicant pharmacist attesting under penalty of perjury that he or she has earned this experience **within the appropriate time frames,** and:
(2) ~~An attestation or letter~~ **A written statement** from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant pharmacist has completed at least one year of experience providing clinical services to patients.

As a reminder, at the April Board Meeting, the board also approved proposed amendments to section 1749 (board fees) as follows:

(f)**(1)** The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300*). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.*

(g)**(1)** The fee for the biennial renewal of a pharmacist's license is one hundred ninety-five dollars ($195). The penalty fee for failure to renew is ninety-seven dollars and fifty cents ($97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). *The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.*

Board staff will include section 1749 as part of the advanced practice pharmacists licensure requirement text as part of the rulemaking.

Future Qualifying Methods for APP Licensure

Very recently, CPhA and NACDS provided the board with text that would establish a new process under which pharmacists could qualify for APP licensure. This text is provided below.

1730 Acceptable Certification Programs

(a) In addition to certification programs recognized by the Accreditation Council for Pharmacy Education (ACPE) as described in Section 4210(a)(2)(A), the ~~The~~ board recognizes the pharmacy patient care certification programs that are certified by the National Commission for Certification Agencies (NCCA) for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

(b) For purposes of this section and Business and Professions Code Section 4210(a)(2)(A), a "certification program" means a program that meets one of the following criteria:
(1) The certification is granted to an individual to designate to the public that the individual has attained the requisite level of knowledge, skill, and/or experience in a well-defined area of pharmacy.
(2) The certification is issued to an individual after the successful achievement of performance in an accredited education or training program.

(c) Further, certification programs recognized under this definition must meet all of the following criteria:
(1) Is aligned with the services permitted to be provided by an advanced practice pharmacist
(2) Is designed to measure advanced knowledge and skills in one or more areas of pharmacy practice through the use of written or practical knowledge assessments or examinations.
(3) Is developed and directed by recognized educational or pharmacy experts.

This will be the first opportunity for the board to discuss this language. The board can work on this proposal over the coming weeks, and when ready, pursue as an additional route for qualification as an APP.

b. Regulations to Implement the Non-Emergency Protocol for Pharmacists Who Furnish Naloxone, Including Labeling Requirements

Attachment 1

On April 10, the board's naloxone protocol became effective under emergency provisions that will last 180 days. The board used a subscriber email alert to advise pharmacists and others that pharmacists who possess the one hour of training could provide naloxone to anyone requesting it. A fact sheet was also released that provides patient information about naloxone. These items are also highlighted on the board's web page.

The board now has until early October to notice and promulgate a naloxone protocol regulation to replace the emergency adoption version of the protocol. We are proceeding on a schedule that should permit the timely completion of this rulemaking.

At the April Board Meeting, the board approved the non-emergency version of the naloxone protocol. On May 8, the Medical Board approved the same version of the protocol. Next week, on May 30, the new protocol will be released as part of a rulemaking, which initiates

with notice for comments for 45 days. Comments will be due back in time for the board's review at the July board meeting.

A copy of the finalized version of the protocol is provided in **Attachment 1.**

Meanwhile, staff is working to complete sample labels for display on the board's website. These labels will include labels to establish a "kit" of two dosage units, and then labels for each dosage unit.

Board staff is also working to secure translations for the consumer fact sheet provided on the board's website.

In addition to the consumer fact sheet, a fact sheet for pharmacists has also been identified that will be added to the website for reference.

c. Requirements for Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices

Under Business and Professions Code section 4052.8, immunizations may be provided by pharmacists who possess the required training to provide immunizations. Specifically, to initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC,
- be certified in basic life support,
- comply with all state and federal recordkeeping requirements,
- provide information to the patient's primary care physician and into the appropriate immunization registry designated by the immunization branch of the CDPH.

During the February and April committee meetings, the committee discussed certain issues involving immunizations. Based on the discussions during the February meeting, staff drafted language to establish parameters for those pharmacists who provide immunizations.

One requirement is to mandate required reporting into an immunization registry. Initially, the committee discussed a 15-day reporting period for reporting immunizations into the registry. The language was then drafted for reporting to the registry with 90 days. Board staff has heard comments that 90 days is too long.

Staff is recommending that once the board finalizes the proposed regulation regarding immunizations, that the board direct staff to initiate a rulemaking and release the text for the 45- day comment period, and to return to the board with any negative comments, or otherwise prepare and submit the rulemaking file for approval by the Office of Administrative Law.

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§1746.4 Pharmacists Initiating and Administering Vaccines

(a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:
(1) Completion of an approved immunization training program, and
(2) Basic life support certification.
This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 3 months of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 3 months of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours.
A pharmacist shall provide the patient with a vaccine administration record, which fully documents the initiation and administration of any vaccine. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Authority and Reference: Sections 4052(a)(11), 4052.8, Business and Professions Code.

d. Development of Proposed Requirements for Pharmacists to Provide Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

At both the February and April meetings, the committee discussed the parameters for travel medications in response to the committee's interest in establishing regulations for some of the travel medication components.

At the April committee meeting, the committee reviewed a draft regulation establishing requirements for items the committee has discussed in the past.

Staff is recommending that once the board finalizes the proposed regulation regarding furnishing travel medicaitons, that the board direct staff to initiate a rulemaking and release the text for the 45- day comment period, and to return to the board with any negative comments, or otherwise prepare and submit the rulemaking file for approval by the Office of Administrative Law.

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§1746.5 Pharmacists Furnishing Travel Medications

(a) For purposes of section 4052(a)(10)(A)(3), "not requiring a diagnosis" means either:
(1) A self-diagnosable and self-treatable condition under the federal Centers for Disease Control and Prevention's (CDC) Health Information for International Travel (commonly called the Yellow Book), or
(2) A prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to Section 4052(a)(10) of the Business and Professions Code shall follow the requirements specified in subdivisions (c) through (f) of this section.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of:
(1) Completion of an approved travel medicine training program, which must consist of at least 20 hours and cover the International Society of Travel Medicine's body of knowledge,
(2) Completion of the CDC Yellow Fever Vaccine Course, and
(3) Basic life support certification.
This documentation shall be kept on site and available for inspection.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history form using a destination-specific travel database. The travel history form must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history form is available on the Board of Pharmacy's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 3 months of the date of dispense, or enter the appropriate information in a patient record system shared

with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code, and title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.
A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel plan. An example of an appropriate and comprehensive progress note is available on the Board of Pharmacy's website.

Authority and Reference: Sections 4052(a)(10)(A)(3), 4052(a)(10)(B), Business and Professions Code.

Attachment 1

Title 16. Board of Pharmacy. Adopt §1746.3 as follows:

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

A pharmacist furnishing naloxone hydrochloride pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:
(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.
(2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride. Before providing naloxone hydrochloride, the pharmacist shall:

(1) Screen the potential recipient by asking the following questions:
(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids? (If the recipient answers yes, the pharmacist may skip screening question B.);
(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. If the recipient answers yes, the pharmacist may continue.
(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. If the recipient answers yes, the pharmacist may not provide the naloxone. If the recipient responds no, the pharmacist may continue.
These screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:
(A) The pharmacist shall provide the recipient with appropriate counseling

and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: A pharmacist shall advise the recipient to how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA approved product form. The pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(5) Labeling: A pharmacist shall label the naloxone hydrochloride consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Authority: Section 4052.01, Business and Professions Code
Reference: Section 4052.01, Business and Professions Code

For the Board of Pharmacy's website:

Naloxone
Suggested Labeling (by route of administration):

Intramuscular	Intranasal	Auto-Injector
Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1. Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration. Should contain 2 vials and 2 syringes.	Naloxone needleless prefilled syringe (1mg/1ml concentration) 2ml, # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Should contain 2 prefilled needleless syringes and 2 atomizers.	Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1. Commercially available as a twin pack with directions for administration included.