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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

LICENSING COMMITTEE REPORT

Debbie Veale, Licensee Member, Chairperson
Lavanza Butler, Licensee Member, Vice-Chairperson
Allen Schaad, Licensee Member
Albert Wong, Licensee Member

The Licensing Committee met on December 12, 2019, and January 9, 2020. During the meetings the following items were discussed.

a. Discussion and Consideration of Implementation for Recently Enacted Legislation Impacting the Practice of Pharmacy SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis, including Possible Adoption of Emergency Regulations and Initiation of Regular Rulemaking Related to Development of Training Program

Background

As part of the November 2019 Board Meeting, the board discussed the provisions of SB 159 including the statutory provisions requiring the board to adopt emergency regulations by July 1, 2020. The board referred development of these regulations to the Licensing Committee.

As provided in the legislation, prior to a pharmacist furnishing preexposure or postexposure prophylaxis, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of the preexposure or postexposure prophylaxis. Further, the statute specifies specific areas that must be covered in the training program including information about financial assistance programs.

Subsequent to the board meeting, initially board staff had the opportunity to attend a meeting with experts from the Office of Aids, Department of Health Care Services, and other experts. Participants in the meetings provided foundational information as well as expressed interest in assisting the board in development of regulations. Additionally, some experts offered to assist the board in development of a training program.

The committee has discussed the measure, including development of regulations and training programs on two occasions, December 12, 2019, and January 9. These meetings provided the committee with an opportunity to discuss the essential elements of training program and to consider public input from stakeholders.

For the committee and stakeholders consideration, meeting materials included background materials including a copy of the underlying measure, the CDC Guidelines referenced in the statute, resources provided by the Office of AIDS and a sample of fact sheets.

Committee Discussion and Action

During its meetings, the committee discussed the basic tenets of a training program and the regulation components necessary to ensure pharmacists have the requisite knowledge to safely furnish PrEP and PEP as authorized in the statute. Ultimately after consideration of information provided, including public comments, the committee determined that a single training course that covered both types of prophylaxis is appropriate.

Although there was a variance of opinion regarding the duration of training that would be sufficient, the committee ultimately determined that a minimum 1.5 hours of training is sufficient to cover all of the required topics. The committee did note that this would be a minimum number of hours and that both pharmacists and training providers could exceed the number of hours.

Further the committee reached consensus on the basic elements of the training course which must include the following:

- Preexposure and postexposure prophylaxis pharmacology.
- Legal requirements contained in BPC sections 4052.02 and 4052.03.
- Patient counseling information and techniques, including counseling on sexually transmitted diseases and sexual health.
- Patient referral and supplemental resources.
- Clinical eligibility requirements.

The committee also determined that passing an assessment with a score of 70% or higher was appropriate and documentation of completion should be maintained for a period of four years. More detailed information on the committee and public discussion is included in the draft meeting minutes included as an attachment.

Committee Recommendation (Motion): Update the regulation text as discussed in the six policy areas. Recommend the board's adoption of the proposed emergency regulations and delegate to the Interim Executive Officer the authority to make changes consistent with the policy.

Recent Update

Subsequent to the meeting, staff updated the regulation proposal consistent with the committee's motion. The proposal included in these materials incorporates those changes.

Following the meeting, one additional policy consideration was identified related to ongoing continuing education. Specifically, should the board also require ongoing continuing education for pharmacists similar to the requirement for pharmacists that furnish nicotine replacement products?

Should the board determine that ongoing continuing education is necessary, the following language could be used to create the requirement.

> A pharmacist performing the services authorized in BPC section 4052.02 and section 4052.03 must complete one hour of continuing education focused on preexposure and postexposure prophylaxis therapy biennially for each subsequent renewal cycle following the completion of the training program established in this section.

As this was not discussed by the committee, the full board will need to consider the language.

Emergency Rulemaking Process

Under the provisions of the Administrative Procedures Act, an agency may adopt an emergency regulation, however the regulation remains in effect for 180 days unless the Office of Administrative Law approves a readoption for an additional 90 days.

It is recommended that the board make a declaration of emergency consistent with the statutory requirements. Provided below is language that could be used to facilitate such action.

> **Suggested Motion**: The finding of emergency based on the statutory provisions contained with Senate Bill 159 (Weiner, Statutes of 2019) that mandates the board to adopt emergency regulations by July 1, 2020 for the immediate preservation of the public peace, health, safety, or general welfare.

As such, the board must also pursue the change through the regular rulemaking process. It is recommended that the board, if deemed appropriate, separately vote on concurrent initiation of the regular rulemaking process. Provided below is language that could be used to facilitate such action.

> **Additional Suggested Motion:** Approve the proposed addition to Title 16 CCR section 1747, Independent HIV Preexposure and Postexposure Prophylaxis Furnishing. Initiate the regular rulemaking process. 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 1 includes the regulation proposal incorporating the changes made during the stakeholder meeting, Senate Bill 159 and written comments received.

Additional Resources

The prior meeting materials can be accessed on the board's website:
https://www.pharmacy.ca.gov/meetings/agendas/2019/19_dec_lic_mat.pdf

The Office of AIDS consolidates many resources on its website:
https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA_prev_PrEP.aspx.

The CDC guidelines for PEP:
https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf

The CDC guidelines for PrEP:
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

b. Discussion and Consideration of Board's Proposal to Establish New Licensing Programs Related to Advanced Pharmacy Technician Requirements and Functions

Background

In response to changes in pharmacy practice and the expanded roles of pharmacists, the committee and board completed development of a statutory proposal to create new licensing programs for advanced pharmacy technicians. Ultimately the committee and board focused on proposed changes that would benefit consumers including making pharmacists more available to engage in more direct patient care activities.

Committee Discussion

In response to comments and feedback received on the board's proposal, the committee determined it appropriate to reassess some of the basic tenets of the proposal. Provided below is a brief summary of the basic provisions and noted recommendations considered by the committee.

1. When initially drafted, the proposal included two separate advanced pharmacy technician licenses – Advanced Pharmacy Technician (outpatient setting) and Advance Hospital Pharmacy Technician (inpatient setting).

   Recommendation: Given the similarity in application requirements, a single license type appears appropriate.

2. As the proposals developed, the pathways to licensure expanded. There is concern that the minimum licensing requirements exceed what is necessary for minimum competence to perform the authorized duties, resulting in a barrier to licensure for this advanced license.

   Recommendation:

   - Current and active license as a pharmacy technician.
   - 3,000 hours of experience performing the duties of a licensed pharmacy technician or pharmacy intern.
   - **And** one the following:
     a. Current certification by a pharmacy technician certification program.
     b. Completion of an AA degree in pharmacy technology.
     c. Completion of a bachelor's degree.

3. The board's initial proposal included specified authorized functions for community pharmacies and separate authorized functions for inpatient pharmacies.

Recommendation: As the practice site models have evolved, it appears appropriate to consolidate authorized functions of an advanced pharmacy technician as well as consolidate the conditions under which pharmacy may employ such an individual.

The committee received significant public comment on the proposal. The discussion included a focus on the primary difference between a pharmacy technician and the proposed advanced pharmacy technician, most notably the level of autonomy.

In general, there was support for the revised proposal, although some expressed concern that in its current form, the proposal was silent as to the ratio. The committee requested submission of outstanding question from the public to allow for research prior to response. Further, the committee suggested that the public may wish to suggestion additional services or conditions for which a pharmacy may use an APT. After discussion and consideration, the committee determined the issue of the ratio should be discussed with the full board. More detailed information on the committee and public discussion is included in the draft meeting minutes included as an attachment.

Committee Recommendation (Motion): Move the proposal to the board with the discussed changes (removing the provision related to verifying the accuracy on new prescription labels, incorporate a training requirement for APTs technical task of administering an immunization, correct the fee provision to remove reference to the hospital), and provide authority for the chair of the committee to work with staff and counsel to refine the language, and seek guidance from the board on how to address the ratio issue.

<u>Recent Update</u>
Subsequent to the meeting, the proposal was updated consistent with the committee's motion. Further, counsel refined the proposal, restructured some of the proposal, and provided clarifying language regarding the supervision requirements. The proposal included in the materials incorporates those changes.

Further, to help facilitate the discussion of the ratio, the following language is offered by the chair for the board's consideration:

Proposed 4115.7 (Conditions for Use)
…
(f) No more than two (2) advanced pharmacy technicians are on duty at a time in the pharmacy, although the board may allow a pharmacy to petition for additional advanced pharmacy technicians to be on-duty, provided that it is not to allow an advanced pharmacy technician to engage in direct patient services.

Attachment 2 includes the revised statutory proposal for the board's consideration.

c. Review of Licensing Statistics

Licensing statistics for July 1, 2019 through December 31, 2019, are provided in **Attachment 3**.

As of December 31, 2019, the board has received 7,579 initial applications, including:

- 1,601 intern pharmacists
- 497 pharmacist exam applications
- 114 advanced practice pharmacists
- 2,417 pharmacy technicians
- 196 community pharmacy license applications
- 66 sterile compounding pharmacy license applications
- 59 nonresident pharmacy license applications
- 17 hospital pharmacy license applications
- 223 automated drug delivery system applications

As of December 31, 2019, the board has received 263 requests for temporary site license applications, including:

- 129 community pharmacy license applications
- 27 sterile compounding pharmacy license applications
- 41 nonresident pharmacy license applications
- 18 hospital pharmacy license applications

As of December 31, 2019, the board has issued 7,171 licenses, renewed 33,631 licenses and has 141,691 active licenses, including:

- 7,171 intern pharmacists
- 47,670 pharmacists
- 624 advanced practice pharmacists
- 69,796 pharmacy technicians
- 6,519 community pharmacies
- 469 hospital pharmacies
- 952 automated drug delivery systems

Processing Times

The general application and deficiency mail processing times by license type are provided below reflecting data current as of January 10, 2020. The data reflects the time from when an application or deficiency response is received by the board through to the time it is processed by licensing staff.

The standard performance processing time is within 30 days for initial applications and is within 10 days for deficiency mail. The board is currently outside of the standard performance processing times for some of its types of applications. The board continues to be challenged with four vacant positions in licensing, which impacts meeting the standard performance processing times. Management is continuing to redirect workload to address the outstanding performance times.

Premises Application Types	Application Processing Times as of 1/10/2020	Application Processing Times as of 1/10/2020
Pharmacy	28	39
Nonresident Pharmacy	32	60
Sterile Compounding	Current	52
Nonresident Sterile Compounding	Current	22
Outsourcing	Current	Current
Nonresident Outsourcing	Current	3
Hospital Satellite Compounding Pharmacy	Current	Current
Hospital	Current	Current
Clinic	32	Current
Wholesaler	23	Current
Nonresident Wholesaler	22	7
Third-Party Logistics Provider	Current	Current
Nonresident Third-Party Logistics Provider	Current	2
Automated Drug Delivery System	1	Current
Automated Patient Dispensing System	0	Current
Emergency Medical Services Automated Drug Delivery System	0	Current

Individual Application Type	Application Processing Times as of 1/10/2020	Application Processing Times as of 1/10/2020
Exam Pharmacist	15	Current
Pharmacist Initial Licensure	Current	N/A
Advanced Practice Pharmacist	15	Current
Intern Pharmacist	28	Current
Pharmacy Technician	30	8
Designated Representative	23	24
Designated Represenatives-3PL	11	24
Designated Representatives-Reverse Distributor	Current	Current

d. Future Committee Meeting Dates

The next Licensing Committee meetings are scheduled for the following dates in 2020:

- May 6, 2020
- July 8, 2020
- October 27, 2020

Attachment 4 includes copies of the draft minutes from the December 12, 2019, and January 9, 2020 meetings.

Attachment 1

Proposal to Add Section 1747 to Title 16 of the California Code of Regulations, to read as follows:

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board or provided by a provider accredited by an approved accreditation agency. To be approved or accredited, the training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:

(1) Preexposure and postexposure prophylaxis pharmacology.

(2) Requirements for independently initiating and furnishing preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.

(3) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.

(4) Patient referral resources and supplemental resources for pharmacists.

(5) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (Prep-AP).

(6) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).

(b) The training program shall require the passing of an assessment with a score of 70% or higher to receive documentation of successful completion of the training program.

(c) A pharmacist who independently initiates or furnishes preexposure or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and/or 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

DRAFT

STATE OF CALIFORNIA
LEGISLATIVE COUNSEL BUREAU
AUTHENTICATED
ELECTRONIC LEGAL MATERIAL

Senate Bill No. 159

CHAPTER 532

An act to amend Section 4052 of, and to add Sections 4052.02 and 4052.03 to, the Business and Professions Code, to add Section 1342.74 to the Health and Safety Code, to add Section 10123.1933 to the Insurance Code, and to amend Section 14132.968 of the Welfare and Institutions Code, relating to HIV prevention.

[Approved by Governor October 7, 2019. Filed with Secretary of State October 7, 2019.]

LEGISLATIVE COUNSEL'S DIGEST

SB 159, Wiener. HIV: preexposure and postexposure prophylaxis.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of these requirements a crime. Existing law generally authorizes a pharmacist to dispense or furnish drugs only pursuant to a valid prescription, except as provided, such as furnishing emergency contraceptives, hormonal contraceptives, and naloxone hydrochloride, pursuant to standardized procedures.

This bill would authorize a pharmacist to furnish preexposure prophylaxis and postexposure prophylaxis in specified amounts and would require a pharmacist to furnish those drugs if certain conditions are met, including that the pharmacist determines the patient meets the clinical criteria for preexposure prophylaxis or postexposure prophylaxis consistent with federal guidelines. The bill would require a pharmacist, before furnishing preexposure prophylaxis or postexposure prophylaxis, to complete a training program approved by the board. Because a violation of these requirements would be a crime, this bill would impose a state-mandated local program.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services pursuant to a schedule of benefits, including pharmacist services, which are subject to approval by the federal Centers for Medicare and Medicaid Services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions.

This bill would expand the Medi-Cal schedule of benefits to include preexposure prophylaxis and postexposure prophylaxis as pharmacist services, as specified.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers

by the Department of Insurance. Existing law authorizes health care service plans and health insurers that cover prescription drugs to utilize reasonable medical management practices, including prior authorization and step therapy, consistent with applicable law. For combination antiretroviral drug treatments medically necessary for the prevention of AIDS/HIV, existing law prohibits plans and insurers, until January 1, 2023, from having utilization management policies or procedures that rely on a multitablet drug regimen instead of a single-tablet drug regimen, except as specified.

This bill would additionally prohibit plans and insurers from subjecting antiretroviral drugs, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except that if the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, the bill would instead require the plan or insurer to cover at least one of the therapeutically equivalent versions without prior authorization or step therapy. The bill would also prohibit plans and insurers from prohibiting, or allowing a pharmacy benefit manager to prohibit, a pharmacy provider from providing preexposure prophylaxis or postexposure prophylaxis, except as specified. The bill would prohibit plans and insurers from covering preexposure prophylaxis that has been furnished by a pharmacist in excess of specified amounts. Because a willful violation of these provisions by a health care service plan would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer drugs and biological products that have been ordered by a prescriber.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the

enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Perform procedures or functions as authorized by Section 4052.6.

(7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

(A) (i) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

(ii) Nicotine replacement products, as authorized by Section 4052.9.

(iii) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.

(iv) HIV preexposure prophylaxis, as authorized by Section 4052.02.

(v) HIV postexposure prophylaxis, as authorized by Section 4052.03.

(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(11) Administer immunizations pursuant to a protocol with a prescriber.

(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

SEC. 2. Section 4052.02 is added to the Business and Professions Code, to read:

4052.02. (a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.

(b) For purposes of this section, "preexposure prophylaxis" means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, "CDC guidelines" means the "2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish at least a 30-day supply, and up to a 60-day supply, of preexposure prophylaxis if all of the following conditions are met:

(1) The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.

(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.

(3) The patient does not report taking any contraindicated medications.

(4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity.

The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 60-day supply of preexposure prophylaxis to a single patient more than once every two years.

(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.

(6) The pharmacist does not furnish more than a 60-day supply of preexposure prophylaxis to a single patient more than once every two years, unless directed otherwise by a prescriber.

(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.

(f) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

SEC. 3. Section 4052.03 is added to the Business and Professions Code, to read:

4052.03. (a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.

(b) For purposes of this section, "postexposure prophylaxis" means any of the following:

(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.

(2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.

(3) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, "CDC guidelines" means the "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV–United States, 2016," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation

with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish a complete course of postexposure prophylaxis if all of the following conditions are met:

(1) The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines.

(2) The pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.

(3) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV.

(4) The pharmacist notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding followup care for postexposure prophylaxis.

(f) A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

SEC. 4. Section 1342.74 is added to the Health and Safety Code, immediately following Section 1342.73, to read:

1342.74. (a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs that are medically necessary for

the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) A health care service plan shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

(d) This section does not require a health care service plan to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit.

SEC. 5. Section 10123.1933 is added to the Insurance Code, immediately following Section 10123.1932, to read:

10123.1933. (a) (1) Notwithstanding Section 10123.201, a health insurer shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health insurer to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) Notwithstanding subdivision (b), a health insurer shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

SEC. 6. Section 14132.968 of the Welfare and Institutions Code is amended to read:

14132.968. (a) (1) Pharmacist services are a benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare and Medicaid Services.

(2) The department shall establish a fee schedule for the list of pharmacist services.

(3) The rate of reimbursement for pharmacist services shall be at 85 percent of the fee schedule for physician services under the Medi-Cal program.

(b) (1) The following services are covered pharmacist services that may be provided to a Medi-Cal beneficiary:

(A) Furnishing travel medications, as authorized in clause (3) of subparagraph (A) of paragraph (10) of subdivision (a) of Section 4052 of the Business and Professions Code.

(B) Furnishing naloxone hydrochloride, as authorized in Section 4052.01 of the Business and Professions Code.

(C) Furnishing self-administered hormonal contraception, as authorized in subdivision (a) of Section 4052.3 of the Business and Professions Code.

(D) Initiating and administering immunizations, as authorized in Section 4052.8 of the Business and Professions Code.

(E) Providing tobacco cessation counseling and furnishing nicotine replacement therapy, as authorized in Section 4052.9 of the Business and Professions Code.

(F) Initiating and furnishing preexposure prophylaxis, as authorized in Section 4052.02 of the Business and Professions Code, limited to no more than a 60-day supply of preexposure prophylaxis to a single patient once every two years.

(G) Initiating and furnishing postexposure prophylaxis, as authorized in Section 4052.03 of the Business and Professions Code.

(2) Covered pharmacist services shall be subject to department protocols and utilization controls.

(c) A pharmacist shall be enrolled as an ordering, referring, and prescribing provider under the Medi-Cal program prior to rendering a pharmacist service that is submitted by a Medi-Cal pharmacy provider for reimbursement pursuant to this section.

(d) (1) The director shall seek any necessary federal approvals to implement this section. This section shall not be implemented until the necessary federal approvals are obtained and shall be implemented only to the extent that federal financial participation is available.

(2) This section neither restricts nor prohibits any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter, or the Medicaid state plan.

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2021, the department shall adopt regulations

in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing July 1, 2017, the department shall provide a status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CSHP | CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

December 20, 2019

RECEIVED
JAN 06 2020
California State Board of Pharmacy

Deborah Veale, Licensing Committee Chairperson
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Esteemed Colleagues of the Licensing Committee, California Board of Pharmacy,

We would like to thank you for an interesting and informative committee meeting on December 12, 2019. We found it very informative and enlightening with regards to the Board of Pharmacy's perspective in this matter. In light of this, the California Society of Health-Systems Pharmacists (CSHP) and the CSHP Foundation would like to propose an agenda (with timelines) for a training program that should appropriately prepare pharmacists to meet the requirements of SB 159 and be prepared to meet the intent of the bill. We agree that the intent of the bill is to be an access point for HIV prevention medications, and not to provide ongoing primary care for people at risk for acquiring HIV. Additionally, it addresses some of the concerns that were raised regarding the need to have a better understanding of the aspects of patient counseling (with regard to sexual health histories, STD prevention and adherence to the preventative HIV medications) that are beyond the scope of most pharmacists. We submit this on the understanding that (#1), this would be the minimum training required for a licensed pharmacist to participate in the activities allowed for in the legislation, and (#2), the Board of Pharmacy allows external providers to offer educational programs that meet these minimum standards, but may also go above and beyond to provide interested pharmacists more advanced training in the area should they feel it would be helpful to them.

We would be more than happy to discuss this proposal with any member(s) of the Licensing Committee, or the full Committee that attends the January 9th, 2020, meeting.

Program:
Basics of HIV: 10min
ARVs 101: 10min
Patient counseling
- Adherence (facts and processes): 15 min
- STI & Sexual Health counseling: 15min

Guidelines for PEP: 15 min
- Who/risk factors
- What
- Duration
- Follow-up

Guidelines for PrEP: 15 min
- Who/risk factors
- What
- Duration
- Follow-up/referral

Financial Assistance for PEP/PrEP: 5 min
Resources: 5 min

Respectfully submitted,

James D. Scott, PharmD, FCSHP, FASHP, FCCP, AAHIVP
Professor and Associate Dean, Western University College of Pharmacy
Board of Directors, CSHP and CSHP Foundation

Jerika Lam, PharmD, AAHIVP, FCSHP
Associate Professor, Chapman University
Board of Directors, CSHP

Don Kishi, PharmD
Professor, UCSF
President CSHP Foundation

Lisa Gunther-Lum, PharmD
Medication Safety Pharmacist, Adventist Health, Glendale
President, CSHP

Loriann De Martini, PharmD, BCGP
Chief Executive Officer, CSHP and CSHP Foundation

cc: Gregory N. Lippe, President, California State Board of Pharmacy

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

January 8, 2019

Chairperson Debbie Veale and Members
Licensing Committee
California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento CA 95833

RE: *Training Program for Pharmacist Furnishing Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) Therapies*

Dear Chairperson Veale and Members of the Licensing Committee:

On behalf of the National Association of Chain Drug Stores' (NACDS) the twenty-one member companies operating more than 4,300 pharmacies throughout the State of California, we want to provide our perspective on a training program for pharmacist furnishing pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) therapies that the California Board of Pharmacy's Licensing Committee will be discussing on Thursday, January 9th.

As the healthcare community moves toward value-based care, the role of community pharmacists has expanded to include additional facets of direct patient care. Noted as the most accessible and trusted member of the healthcare team, pharmacists are well-positioned and able to play a role in the delivery of health care services and impact overall public health. In October 2019, California made major strides by authorizing pharmacists to prescribe and dispense pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) without a physician prescription. NACDS applauds California for their efforts to include pharmacists in the call to increase awareness and access to essential HIV prevention medications and provides the following insight regarding pharmacists' training to provide this clinical service.

Training: The Board recommends a one- to two-hour online course, of which, NACDS believes that all the pertinent information can be accurately and appropriately relayed within a one-hour, online refresher course.

- ***Employer Choice***: NACDS supports the Board's idea for a one-hour online training while maintaining employer flexibility to develop their own training should they choose. Employers should have the ability to develop and select the program appropriate for their employees, which will be approved by the Board as required by statute. With numerous variations of workflow and different expectations between pharmacies, employers are in the best position to tailor the program to their employees' needs.

- ***Focus Areas for Board-developed program***: Pharmacists already undergo extensive pharmacotherapy education and training in order to receive their PharmD degree. Incorporation of the financial assistance programs is essential (as required by statute); however, additional topics should be determined by the entity developing the program. Specific to the Board-developed program, recommended topics created by the Board and their stakeholders are appropriate so long as the refresher training can be achieved in a one-hour time frame. Topics listed below (except item one) are preferred but not required:
    - Financial Assistance programs for PrEP/PEP (HIV prevention program)- *required by statute*

- Legal requirements
- Operational issues: Reimbursement, Recordkeeping requirements
- Pharmacist resources
- Patient referral resources
- Appropriate clinical counseling techniques
- PrEP Pharmacology

- ***Brief Knowledge***: The Board and their stakeholders recommended that the training program include an examination prior to completion. A brief knowledge check may be conducted with approximately 4-5 questions for the one- hour educational program; however, NACDS does not believe that a formal examination is necessary. Pharmacists are already required to complete and pass a national exam as well additional state-specific exams in order to be recognized as a fully licensed pharmacist.

- ***Continuing Education (CE) Requirements***: The Board has suggested that online CE is the preferred method to receive additional training. NACDS believes that it should be determined by the entity developing the program to place CE requirements related to HIV prevention and PrEP/PEP therapies.

Licensure to Conduct HIV prevention services: While Pharmacists should be licensed in the State of California, they should not also be required to receive any additional degree, certification, or examination.

- Pharmacists are well-positioned and have the necessary foundational knowledge to provide this specific clinical service. Pharmacists receive extensive education and training in various clinical disease states. Entry-level pharmacists receive a minimum of six years of advanced education as part of the Doctor of Pharmacy degree (PharmD).
- Pharmacists are also required to pass a national, comprehensive and standardized board exam (North American Pharmacist Licensure Examination (NAPLEX)) and are subject to state licensure requirements. The training of pharmacists emphasizes patient-- centered care as a medication expert, which involves interpreting evidence, formulating patient assessments and recommendations, implementing, monitoring and adjusting patient care plans, and documenting activities.[1]

We ask that the Licensing Committee accept our suggestions for a training program for pharmacist furnishing pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). NACDS thanks the Board for considering our comments on this issue. If you have any questions, please contact Mary Staples at mstaples@nacds.org or 817-442-1155.

Sincerely,

Steven C. Anderson, IOM, CAE
President and Chief Executive Officer

cc: Anne Sodergren

[1] Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree. Accreditation Council for Pharmacy Education. Feb 2015. https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf

Attachment 2

Proposed BPC 4038.5 (Definition)
"Advanced Pharmacy Technician" means an individual licensed by the board who is authorized to perform all the duties permitted by section 4115, and technical pharmacy tasks as authorized in Section 4115.6 under the indirect supervision of a pharmacist. For the purposes of this section, "indirect supervision" means that a pharmacist is on the premises at all times and is generally aware of all activities performed by the advanced pharmacy technician, but the advanced pharmacy technician may, if permitted by the pharmacist, perform authorized tasks without direction from the pharmacist.

Proposed 4115.6 (Specified Duties)
(a) A licensed advanced pharmacy technician may perform these technical tasks to allow the pharmacist to engage in more direct patient services:
(1) Verify the accuracy of the filling of a prescription container by confirming that the medication and quantity reflected on the label is accurately reflects the container's contents for refill drug orders.
(2) Accept new prescriptions from a prescriber's office unless the prescription requires the professional judgment of a pharmacist.
(3) Inquire about the intended purpose or indication for prescribed medication on verbal orders received from a prescriber's office.
(4) Accept refill authorizations from a prescriber's office unless the authorization requires the professional judgment of a pharmacist.
(5) Transfer a prescription to another pharmacy.
(6) Receive the transfer of a prescription from another pharmacy.
(7) Provide the technical task of administration of an immunization if appropriate training has been completed.
(8) Initiate post discharge contact with a patient or patient's agent for a patient recently discharged from a health facility.
(9) Provide medication guidance and referral services for pharmacy services post discharge from a health facility.
(10) Develop medication dosing schedules for discharge medications.
(11) Initiate post discharge contact with a patient or patient's agents.
(b) Other than as permitted by this section, an advanced pharmacy technician may not engage in direct patient services.

Proposed 4115.7 (Conditions for Use)
A pharmacy may use the services of an advanced pharmacy technician if all of the following conditions are met:
(a) The duties authorized in section 4115.6 are performed as specified in the pharmacy's policies and procedures.
(b) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a) of section 4115.6.

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(c) A pharmacist personally provides all new prescription medications and controlled substances medications directly to the patient or patient's agent, and provides patient information consistent with the provisions of Section 4052 (a) (8).
(d) A record is created identifying the personnel responsible for the preparing and dispensing of the prescription medication.
(e) Initiate and provide post discharge follow-up for a patient recently discharged from a health care facility consistent with the provisions of Section 4052(a)(8). Such discharge follow-up must be provided by a pharmacist at the request of the patient or patient's agent unless the patient is discharged to another health care facility.

Proposed BCP 4211 (Licensing Requirement)
(a) The board may issue an advanced pharmacy technician license to an individual who meets all the following requirements:
(1) Holds a pharmacy technician license issued pursuant to this chapter that has been active and in good standing for at least 1 year immediately preceding filing an application.
(2) Has obtained 2,050 hours of experience performing the duties of a licensed pharmacy technician or pharmacist intern in a pharmacy within the three (3) years immediately preceding filing an application.
(3) Satisfies at least one of the following requirements:
(A) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
(B) Has obtained a minimum of an associate degree in pharmacy technology.
(C) Has obtained a bachelor's degree.
(b) A license issued pursuant to this section, if not renewed, shall expire two years after issuance.

Proposed BPC 4234 (CE/Renewal Requirement)
As a condition of renewal, an advanced pharmacy technician shall complete 20 hours of continuing education each renewal cycle, including a minimum of two hours of education in medication error prevention and two hours of board sponsored law and ethics education.

Amendment to BPC 4400 (Fee)
…
(z) ~~This section shall become operative on July 1, 2017.~~ The fee for the advanced 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 pharmacy technician shall be $140 and may be increased to $195.

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Attachment 3

Licensing Statistics

A hard copy of this document will be made available at the meeting or upon request. Requests may be made to Jennifer Niklas at jennifer.niklas@dca.ca.gov.

Attachment 4

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

LICENSING COMMITTEE
DRAFT MEETING MINUTES

DATE:	December 12, 2019
LOCATION:	California State Board of Pharmacy 2720 Gateway Oaks Dr., 1st Floor Hearing Room Sacramento, CA 95833
BOARD MEMBERS PRESENT:	Deborah Veale, Licensee Member, Chair Albert Wong, Licensee Member Allen Schaad, Licensee Member
BOARD MEMBERS NOT PRESENT:	Lavanza Butler, Licensee Member, Vice Chair
STAFF PRESENT:	Anne Sodergren, Interim Executive Officer Jennifer Niklas, Senior Administrative and Policy Manager Norine Marks, DCA Staff Counsel Kristina Jarvis, Deputy Attorney General Debbie Damoth, Administration Manager

1. Call to Order and Establishment of Quorum

Chairperson Veale called the meeting to order at 12:00 p.m.

Committee members present: Allen Schaad, Deborah Veale, and Albert Wong. Quorum was established.

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

Ramin Hojati representing DxTreat, a company that creates medical software has a proposal regarding a PEP tool to help support implementation of SB 159. Mr. Hojati would like his company's proposal to build a tool to collect patient information that identifies if the patient is eligible for PEP to be considered for a future meeting. Ms. Anne Sodergren asked the proposal to be sent to her so that she could work with the Committee Chairperson to determine if it would be appropriate.

3. Discussion and Consideration of Implementation for Recently Enacted Legislation Impacting the Practice of Pharmacy SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

Chairperson Veale provided that as part of the November 2019 Board Meeting, the board discussed the provisions of SB 159 included the statutory provisions requiring the board to adopt emergency regulations by July 1, 2020. The board referred development of these regulations to the Licensing Committee.

Ms. Veale noted as provided in the legislation, prior to a pharmacist furnishing preexposure or postexposure prophylaxis, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of the PrEP (preexposure) or PEP (postexposure) prophylaxis. The statute specifies areas that must be covered in the training program including information about financial assistance programs.

Ms. Veale explained subsequent to the committee meeting, the interim executive officer had the opportunity to attend a meeting with experts from the Office of AIDS, Department of Health Care Services, and the Pacific AIDS Education and Training Center and a separate meeting with an expert from San Francisco.

Ms. Veale reviewed the meeting materials including a study conducted in 2017 which assessed pharmacists' perceived knowledge on the use of PrEP, and attitudes towards PrEP, and identified training needs around HIV PrEP. Ms. Veale highlighted the educational resources that are available through the CDC, Office of AIDS, and other organizations referred to in the meeting materials.

Ms. Veale added that based on stakeholder input from the Office of AIDS, Department of Health Care Services, and the Pacific AIDS Education and Training Center, the following areas were identified as appropriate for inclusion in any training program:

- Overview of the legal requirements.
- Appropriate clinical counseling techniques.
- Operational issues including reimbursement and recordkeeping requirements.
- Patient referral resources including local health jurisdictions.
- Pharmacists resources.
- Financial assistance programs for PEP and PrEP, including the HIV prevention program.

Ms. Veale added the training program should include an examination prior to completion. Based upon the study results, it may be appropriate include online CE is the preferred method to receive additional training on PrEP for HIV prevention.

Ms. Veale provided as the committee considers the regulation, it appears the training could be accomplished in one or two hours and continuing education is appropriate.

Ms. Veale noted as required by the statute, development of the training programs must be done in consultation with the Medical Board. Staff will be working with the Medical Board to facilitate

the process and will include review by a member of the Medical Board and their chief medical consultant. At this point, the committee is interested in hearing feedback from the stakeholders on how to implement SB 159.

Mr. Schaad commented on how in-depth the education will have to be.

Danny Martinez stated that CPhA was a main co-sponsor of SB 159 and noted that they agree on most of the items proposed by the board. Mr. Martinez commented on the board staff recommendation of a board provided training program. Mr. Martinez expressed concern of confusing pharmacists on what is required and would like to be consistent with SB 493 where training is board approved. Mr. Martinez stated board provided training programs would be a barrier to expanding PrEP and PEP.

Ms. Sodergren clarified that the board's approach will include developing regulations for others to be able to offer training in addition to the board providing training.

Mr. Martinez stated in talking internally with co-sponsors and advocates, CPhA does not consider one to two hours of training to be enough for this training. Mr. Martinez stated in addition to areas covered in the meeting materials, additional areas that need to be part of the training include education on HIV disease which is not generally provided in specificity in pharmacy schools.

Further, representatives from CPhA noted that cultural training should a component of the training and noted that PEP is not currently part of the curriculum on pharmacy school. Further it was suggested that the training should include information on Hepatis B and Hepatis C vaccinations, information on ordering and interpreting lab results, and that the required training course should be five to seven hours.

The committee received additional comments from Dr. Scott, CSHP, who agreed with the comments offered by CPhA representatives indicating the need for pharmacists to catch up on background information, especially if they have not been providing such services historically. Further, it was suggested that a two-hour training may be too limiting and noted the need to incorporate training on STIs especially given that STIS increase the risk of contracting HIV.

The committee expressed concern that some comments from stakeholders may go beyond what is necessary for pharmacists to initiate PrEP and PEP, and the proposal needs to reflect the statutory goals to improve access to these medications while balancing consumer protection. The committee noted the importance of striking the correct balance. The committee expressed concern that an eight-hour training would exceed the knowledge requirements to perform the services authorized in the measure and would result in barriers to access.

Other stakeholders noted that a five to seven-hour training would become a barrier to access noting the minimum training is appropriate and trusting the professional to seek out additional training if he or she determines it necessary.

Representatives from the Office of AIDS suggested that the training should incorporate information on HIV, STI diagnosis, and the legal provisions of the underlying statute, while also focusing on cultural awareness issues and the appropriate ways to take a medical history. Further, suggesting that a comprehensive training program may be necessary for some pharmacists, but development of general training for all pharmacists and making such training available is important. It was noted that practitioners report that as continue to provide such services, their comfort in doing so increases, again emphasizing the need to increase access points. Further, it was noted that barriers to access exist in both urban and rural areas.

The committee briefly discussed reimbursement for services and noted that the measure established reimbursement provisions for Medi-Cal, noting that the medication will be a fee for service and clinical services reimbursement rates are set in statute.

The committee was reminded about challenges related to naloxone distribution and barriers to access. The board put considerable effort into establishing a training program, but access remains low. The committee was cautioned to balance training program requirements, noting that access points in community pharmacies are critical to save lives and reduce the spread of HIV. The committee was reminded that it is essential to get medication started, and in the case of PEP, within the necessary window of exposure.

The committee also received testimony from an expert working in San Francisco who provided information about a program operated in San Francisco where pharmacists are providing similar, but expanded services, under a collaborative practice agreement. As part of that program, pharmacists would ideally be receiving 10 hours of training, but that the level of training may vary based on a pharmacist's background. The committee was advised that requirements for HIV testing and risk reduction strategies would be important components of a training program and expressed concern that a pharmacist may not be appropriate trained with two-hour training course. Further, the committee was advised about the importance of a pharmacist demonstrating competency.

As part of its discussion, it was noted that PEP can be a streamlined process, but PrEP is more complicated. The committee noted the expanding roles of pharmacists and indicated the need for pharmacists to gain more knowledge but not too overregulate.

The committee determined that an additional committee meeting focused on stakeholder input would be appropriate to further develop the regulations and training program.

4. Discussion and Consideration of Board's Proposal to Establish New Licensing Programs Related to Advanced Pharmacy Technician Requirements and Functions

Ms. Veale reported that in response to changes in pharmacy practice and the expanded roles of pharmacists, the committee and board completed development of a statutory proposal to create new licensing programs for advanced pharmacy technicians. Ultimately the committee and board focused on proposed changes that would benefit consumers, including making pharmacists more available to engage in more direct patient care activities.

Ms. Veale noted that the board was unsuccessful securing an author to implement the proposal and that it could be due in part to concerns raised by stakeholders that were not addressed. Ms. Veale noted the goal is to refine the proposal to make it more workable and ultimately to secure enactment.

Ms. Veale highlighted the suggested changes to the proposal. When initially drafted, the proposal included two separate advanced pharmacy technician licenses – Advanced Pharmacy Technician (outpatient setting) and Advance Hospital Pharmacy Technician (inpatient setting). Ms. Veale noted that given the similarity in application requirements, a single license type appears appropriate.

Further, Ms. Veale note that as the proposals developed, the pathways to licensure expanded. There is concern that the minimum licensing requirements exceeded what is necessary for minimum competence to perform the authorized duties, resulting in a barrier to licensure for this advanced license. Ms. Veale offered changes including requiring that the individual be currently licensed as a pharmacy technician for a minimum of one year. Further the experience requirement recommendation is reduced from 3,000 hours to 2,050 hours of experience of a licensed pharmacy technician or intern, within past three years. In addition, one of the following pathways must be satisfied, 1) currently certified by a pharmacy technician certification program or 2) completion of an AA degree in pharmacy, or 3) a bachelor's degree. Ms. Veale noted that as proposed an education component is incorporated into the pathways to licensure, but that an individual could qualify as an APT without education because not everyone attends college. Ms. Veale noted that the requirement to take an examination is being removed under the recommendation. Further, as recommended, an advanced pharmacy technician would not be required to maintain a pharmacy technician certification as the proposal includes a continuing education requirement. Requiring an individual to also maintain a certification could create a financial hardship.

Ms. Veale noted that as the practice site models have evolved, it appears appropriate to consolidate authorized functions of an advanced pharmacy technician as well as consolidate the conditions under which a pharmacy may employ such an individual. Ms. Veale commented that the streamlined proposal maintains the policy goals of the board while also providing license portability within the practice settings.

The committee indicated general support for the revised proposal. The committee noted that there is no requirement on a pharmacy to use an advanced practice pharmacist, rather it is up to the judgement of the pharmacist to determine if the advanced duties could be performed.

Public comment suggested that it may be appropriate to establish a requirement for APTs to complete appropriate immunization training.

A representative from CSHP also suggested that things have changed since the board developed its original proposal. Further, the comments noted that verification of accuracy on new prescriptions prior to final check by a pharmacist is a function already performed by technicians,

that APTs should not be taking phone calls to accept new prescriptions and suggested that such language should be modified to limit the allowance and suggested that the oral transferring of a prescription is problematic. CSHP expressed concern with an APT developing medication dosing schedules for discharge medications and offered to host a pharmacy technician taskforce meeting.

The committee discussed the significant difference in the level of autonomy an APT has versus a pharmacist technician. Specifically, it was noted that a pharmacy technician must perform under the direct supervision and control of a pharmacist, however the APT performs under general supervision and not under the control of a pharmacist.

The committee discussed that the proposal does not include a ratio as the policy of the board when developing the proposal was for the APT to act independently, noting that the existing ratio for pharmacist to pharmacy technician remains unchanged.

The committee received comments in support of the proposal from other stakeholders.

The committee was advised that CPhA thanked the committee for its work and advised the committee that its house of delegates supports the concept however expressed concern with the issue of ratios and requested additional deliberations on the ratio issue. CPhA noted that its support for the proposal is to assist pharmacists in their expanded roles, not to replace them.

The committee requested submission of outstanding questions from the public to allow for research prior to response. Further, the committee suggested that commenters may wish to suggest additional services or conditions for which a pharmacy may use an APT.

The committee determined it appropriate to remove the provision that would authorize an APT to verify the accuracy on new prescriptions labels. The committee determined that appropriate training should be included as part of the administering immunization. The committee noted that the issue of ratio needs be addressed and suggested that it may be appropriate discussion for the full board.

Motion: Move the proposal to the board with the discussed changes (removing the provision related to verifying the accuracy on new prescription labels, incorporate a training requirement for APTs technical task of administering an immunization, correct the fee provision to remove reference to the hospital), and provide authority for the chair of the committee to work with staff and counsel to refine the language, and seek guidance from the board on how to address the ratio issue.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

5. Review of Licensing Statistics

The committee noted that licensing statistics for July 1, 2019 through November 30, 2019, were provided in the materials and that summary data covering the above time period, indicates that the board had issued over 812 pharmacist licenses following release of examination results for the CPJE examination administered November 16-17, 2019. The committee was advised of a new online process for pharmacist's applicants to submit licensure payments on line as well as the automated notifications individuals receive upon issuance of their pharmacist license.

The committee reviewed the statistics provided including the number of applications received, licenses issued, and licenses renewed.

In addition, the committee reviewed application processing times noted that some processing times are outside of the performance measures but that the data reflects overall improvement.

The committee did not take action on this item.

6. Adjournment

Meeting adjourned 2:54 pm

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
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Phone: (916) 515-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

LICENSING COMMITTEE
SENATE BILL 159 STAKEHOLDER
MEETING MINUTES
DRAFT

DATE: January 9, 2020

LOCATION: Department of Consumer Affairs
1625 N. Market Blvd., 1st Floor Hearing Room
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Debbie Veale, Licensee Member, Chairperson
Allen Schaad, Licensee Member
Albert Wong, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Lavanza Butler, Licensee Member, Vice-Chairperson

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Norine Marks, DCA Staff Counsel
Jennifer Niklas, Senior Administrative and Policy Manager
MaryJo Tobola, Senior Enforcement Manager

1. **Call to Order and Establishment of Quorum**

   Chairperson Veale called the meeting to order at 9:12 a.m. Board members present: Allen Schaad, Albert Wong, and Debbie Veale. A quorum was established.

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

   There were no comments from the committee or the public.

3. **Discussion and Consideration of Implementation for Recently Enacted Legislation Impacting the Practice of Pharmacy Senate Bill (SB) 159 (Wiener, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis, including Development of Training Program and Regulations**

   Chairperson Veale provided background on SB 159 stating that as part of the November 2019 Board Meeting, the board discussed SB 159 including the statutory provisions requiring the board to adopt emergency regulations by July 1, 2020. The board referred development of these regulations to the Licensing Committee.

Ms. Veale provided that included in the meeting materials were proposed regulation she developed with DCA Counsel, Norine Marks and Interim Executive Officer, Anne Sodergren. Chairperson Veale invited the committee and stakeholders to discuss the proposal. She noted that parts of the proposal that are non-negotiable as they are part of the statue: CCR section 1747(a)(6) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' HIV prevention program; and (a)(7) Clinical eligibility recommendations provided in the CDC guidelines defined in Business and Professions Code section 4052.02(c).

Ms. Veale reiterated that the intent of SB 159 is to reduce barriers to accessing prophylaxis. As such, it is recommended that the board allow the training program to be certified by the ACPE or approved by the board. She noted that this would allow the board to develop its own course in the future, perhaps in a format similar to the continuing education webinars.

Lindsay Goldburn representing NACDS stated that they submitted a letter of support and urged the committee to consider a one-hour online refresher course that contains all the necessary components. Ms. Goldburn reiterated the need for access and stated that a one-hour online refresher course is in line with that goal. Ms. Goldburn stated that NACDS does not believe that a formal exam after the training is necessary, and instead recommended a four- to five-question "knowledge check." She noted that pharmacists already receive extensive training and must pass a comprehensive national exam.

Ms. Veale asked the NACDS representative if the one-hour course should be considered continuing education. The representative stated that whether it should be considered continuing education should be left up to those developing the training.

Ms. Veale also inquired how the "knowledge check" differs from an exam. The representative stated it was more like four or five questions just to make sure that the person taking the online course has the knowledge. Ms. Veale inquired if the proposed regulation at 1747(b) should be reworded to use the term "knowledge check" instead of exam. Ms. Goldburn stated that the language should be reworded, and she would have to get back to the board with potential wording for that section. Ms. Veale clarified that the training is one hour for both PEP and PrEP.

Jim Scott from CSHP Foundation stated his organization also submitted a letter to the committee. CSHP believes a longer training time may be needed, possibly 90 minutes. He also stated that the training should include counseling techniques and information on new medications available. Dr. Scott also suggested that the training course include an assessment with some level of achievement, as is stated in the proposed regulations. The committee members spoke in support of CSHP's proposed training guidelines included in the letter.

Severiano Christian, the Senate consultant to the LGBTQ Caucus, spoke on behalf of Senator Weiner's office. Mr. Christian thanked the board for its work on the bill and for serving as an access point to preventative care. Mr. Christian also stated, based on an email received from the Senator's office, he would like to see the training short but comprehensive, possibly one to two hours but no more than four hours. Mr. Christian stated that ensuring the course is comprehensive and succinct will encourage pharmacists to participate.

Tami Martin of Equality California and a co-sponsor of the SB 159 also stated they would like to see a short, comprehensive training and thanked the board for its attention to this bill.

Ms. Veale asked Mr. Christian and Ms. Martin if one to two hours of training would be sufficient. Mr. Christian deferred to those pharmacists in the field but agreed that, based on prior discussion, more training may be needed on the HIV preventative care.

Ms. Veale stated that the training was originally set up in two sections – PEP and PrEP – so that a pharmacist could choose which to take. Ms. Sodergren explained that the bill identified training in both PEP and PrEP and asked Mr. Christian if the statute envisioned a single training to address both forms of prophylaxis. Mr. Christian stated the intent of the bill was to be as concise as possible.

Keith Yoshizuka on behalf of Touro University spoke regarding the education requirements and requested something similar to what is stated in SB 493 (CCR 1746.2(b)(8)), "…an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy." He stated he would modify the sentence to read "…an equivalent curriculum-based training program completed on or after [2021] in an accredited California school of pharmacy." Dr. Yoshizuka stated that PEP and PrEP is taught in the schools currently. However, until the requirements for education have been developed, they may have to tailor what they are teaching.

Ms. Veale clarified that both PEP and PrEP are currently taught but also inquired if Dr. Yoshizuka thought that a current pharmacist could complete the training within the one to two hours. Dr. Yoshizuka stated that the training for a pharmacy student for PEP and PrEP from beginning to end would be about six hours, so he believes the training could be accomplished in a lesser amount of time because of the extensive knowledge licensed pharmacists already have.

Ms. Sodergren inquired how the board could confirm a student has completed the training for enforcement purposed. Dr. Yoshizuka stated that after SB 493, the deans of all the pharmacy schools signed an attestation stating students at those institutions were completing the training. Ms. Sodergren stated that if this is the way the committee would like to go, staff can work with counsel to develop language to include in the proposed regulation.

Philip Peters, Medical Officer with the California Department of Public Health, Office of AIDS, also spoke in support of having the trainings for both PEP and PrEP combined, unless statutorily mandated otherwise. Dr. Peters also stated that having the training available online is necessary, especially for those providing this service in remote locations. Ms. Sodergren stated that if the training is combined into one, BPC sections 4052.02 and 4052.03 could be cited.

Dr. Peters suggested two topics for consideration in the training: interpretation of HIV test results and highlighting the importance of being tested for sexually transmitted infections (STI).

Dr. Peters also stated the program name in proposed regulation CCR 1747(a)(6) needed to be changed to the "Office of AIDS PrEP Assistance Program (PrEP-AP)" instead of the "Office of AIDS HIV prevention program."

Danny Martinez representing California Pharmacists Association (CPhA) agreed with Mr. Peter's comments regarding the STI testing and interpretation of HIV lab test results. CPhA also supported one training for both PEP and PrEP and did not want variation in trainings.

Mr. Martinez stated the CPhA believe the counseling is a core component for quality training and would like the following added to the end of CCR section 1747(a)(3), "…for the prevention of HIV, including counseling for unique populations who may be at higher risk, importance of STI testing and treatment." CPhA is in support of a three- to four-hour training at a minimum to cover PEP and PrEP.

Mr. Martinez suggested that (a)(2) and (a)(7) may be duplicative and that the subsections could be combined into one requirement. Mr. Martinez also suggested adding requirements to the training to include information on recommended vaccines for hepatitis B and hepatitis C and could be added to (a)(4).

Mr. Martinez proposed a 70 percent passing rate for the exam as opposed to the 80 percent by adding more questions to the exam.

The committee recessed for a break at 10:17 a.m. and resumed at 10:41 a.m.

Clint Hopkins from Pucci's Pharmacy in Sacramento spoke on behalf of community pharmacies and how this legislation will be implemented and impact the community. Dr. Hopkins stated his pharmacy is currently part of a collaborative practice agreement (CPA) and is providing PEP, PrEP, and HIV treatment. Dr. Hopkins is concerned that this new bill does not introduce any new barriers to access. Mr. Hopkins discussed how PEP and PrEP currently works in his pharmacy under the CPA and noted that the initial HIV test must include the patient's identity. The pharmacist must also confirm the patient's hepatitis B status, check for any other treatments for STIs, check the renal function, determine the pregnancy status of the patient, and notify the primary care physician (PCP). If the patient does not have a PCP, one will be assigned based on the CPA. For those patients who have not completed an HIV test, a pharmacist with a Clinical Laboratory Improvement Amendments (CLIA) waiver will need to provide a test. The pharmacists also need to know how to counsel a patient if the results return HIV positive. Dr. Hopkins also stated another barrier is the cost of the HIV testing.

Committee member Wong inquired how long the pharmacist spends with a new patient. Dr. Hopkins stated that from start to finish it takes approximately one hour.

Dr. Hopkins concluded that he was in support of the proposals and comments provided by Mr. Martinez (CPhA).

Ms. Veale noted that the committee will work with the Public Education Committee on outreach for the implementation of the bill.

Ms. Veale stated that the committee needed to make determinations on six policy points in order to meet the goal of providing proposed regulations to the full board at the January 2020 meeting.

The first policy decision Ms. Veale proposed was to decide between one or two training programs. All committee members confirmed that there should be one training for both PEP and PrEP.

Ms. Veale stated the second decision point is the minimum number of hours required for the training. Below is a summary of the comments from stakeholders.

- CPhA believes a minimum of three hours should be required based on the amount of knowledge that is required.
- Mark Johnston, representing CVS pharmacies, stated they can operationalize 1.5 hours of training.
- Dr. Chang, representing 24 pharmacies in community health clinics, said less training is preferable. Dr. Chang suggested focusing on access and suggested 1.5 hours of training is appropriate.
- Dr. Scott from CHSP noted this is an access issue and not about a continuation of care.
- Jignesh Patel, representing Safeway and Albertsons, spoke in support of the 1.5 hours of training. Dr. Patel also stated they could provide pharmacists with additional resources to improve their training.

After hearing stakeholder comments, the committee determined the duration of the training should be a minimum of 1.5 hours.

Ms. Veale proposed the third policy decision as whether the training should be ACPE or board approved. The committee decided that there will be two avenues for approval of the training, ACPE and board approved.

Ms. Veale stated the fourth policy decision was to consider the consultation requirements in (a)(3), including those considered in the statute such as STI and sexual health. Dr. Wong stated that counseling should be included in the regulation, while Allen Schaad stated he believed the regulation was fine the way it is currently written. CPhA and CHSP both spoke in support of including counseling on STIs in the regulation.

The committee concluded that the regulation should incorporate counseling on STIs and sexual health.

Chairperson Veale and Ms. Sodergren expanded that the requirements in (a)(2) will focus on the legal requirement of 4052.02 and 4052.03 and the language will be reflected as such.

Ms. Veale explained that the fifth policy decision was regarding how long the pharmacist must keep the documentation of course completion. Bob Dávila, Board of Pharmacy staff, stated that consistent with other continuing education requirements the pharmacist must keep the documentation for four years.

Ms. Veale concluded the sixth policy decision was the potential removal of the operation requirements as stated in (a)(4). Mr. Martinez stated that the language is duplicative and should be provided as part of the education. Dr. James Gasper noted training will be essential on how to operationalize this practice, especially without being part of a collaborative practice. The committee decided it would be best to remove (a)(4) from the proposed regulations.

Ms. Veale proposed replacing the term “exam” with “assessment” and replacing the 80 percent passing score with a 70 percent passing score.

There was no additional public comment.

Motion: Update regulation text as discussed in the six policy areas. Recommend the board's adoption of the proposed emergency regulations and delegate to the interim executive officer the authority to make changes consistent with the policy.

M/S: Wong/Schaad

Support: 3 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Veale	x			
Schaad	x			
Wong	x			
Butler				x

4. Adjournment

Chairperson Veale adjourned the meeting at 11:30 a.m.