

# California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833

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



# LICENSING COMMITTEE REPORT December 12, 2019

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

- 1. Call to Order and Establishment of Quorum
- 2. Public Comment for Items Not on the Agenda, Matters for Future Meetings

\*(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).)

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

### 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 PrEP (preexposure) or PEP (postexposure) prophylaxis. Further, the statute specifies areas that must be covered in the training program including information about financial assistance programs.

Subsequent to the board meeting, board staff 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. 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.

Further, a study conducted in 2017 assessed pharmacists' perceived knowledge on the use of PrEP, and attitudes towards PrEP, and identified training needs around HIV PrEP. The study included survey responses from community pharmacists in Minnesota.

### For Committee Discussion

During the meeting members will have an opportunity to discuss possible areas for regulations, including development of training program parameters. In addition, board staff recommends the committee consider development of a board provided training program.

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.

The training program should include an examination prior to completion.

Based upon the study results, it may be appropriate include PrEP pharmacology. The results also support the inclusion of effective counseling and education. The study also indicates that online CE is the preferred method to receive additional training on PrEP for HIV prevention.

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

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.

Significant educational resources are available through the CDC, Office of AIDS, and other organizations. Office of AIDS consolidates many resources on its website - - <a href="https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA\_prev\_Prep.aspx">https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA\_prev\_Prep.aspx</a>. The CDC posts its guidelines for PEP [https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf] and Prep [https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf] and fact sheets.

**Attachment 1** includes a copy of SB 159 as well as a sample of fact sheets available that could serve as a foundation for some elements of the training program as well as the PrEP study previously noted.

# 4. 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.

# For Committee Discussion

In response to comments and feedback received on the board's proposal, it appears appropriate to reassess some of the basic tenets of the proposal.

- 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). 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. The following is offered as an alternative:
  - Current and active license in good standing as a pharmacy technician for a minimum of 1 year.
  - 2,050 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.

[Note the board's original proposal required all of the above conditions as well as an examination. Further, it required 3,000 hours of experience.]

3. 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.

Provided in **Attachment 2** is a revised proposal that incorporates the changes detailed above.

The streamlined proposal maintains the policy goals of the board while also providing license portability within the practice settings. Should the committee agree with these changes, it would be appropriate to recommend approval by the full board during its January 2020 Board Meeting.

# 5. Review of Licensing Statistics

Licensing statistics for July 1, 2019 through November 30, 2019, are provided in **Attachment 3**. In addition to the below summary data covering the above time period, the board has issued

over 600 pharmacist licenses during the week of December 2, following release of examination results for the CPJE examination administered November 16-17, 2019.

As of November 30, 2019, the board has received 5,961 <u>initial</u> applications, including:

- 1,571 intern pharmacists
- 455 pharmacist exam applications
- 91 advanced practice pharmacists
- 2,014 pharmacy technicians
- 162 community pharmacy license applications
- 59 sterile compounding pharmacy license applications
- 43 nonresident pharmacy license applications
- 10 hospital pharmacy license applications
- 211 automated drug delivery system applications

As of November 30, 2019, the board has received 199 requests for <u>temporary</u> site license applications, including:

- 106 community pharmacy license applications
- 21 sterile compounding pharmacy license applications
- 24 nonresident pharmacy license applications
- 11 hospital pharmacy license applications

As of November 30, 2019, the board has issued 5,354 licenses, renewed 28,551 licenses and has 141,525 active licenses, including:

- 7,885 intern pharmacists
- 46,868 pharmacists
- 601 advanced practice pharmacists
- 69,831 pharmacy technicians
- 6,538 community pharmacies
- 470 hospital pharmacies
- 913 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 November 27, 2019. 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.

Premises Application Types	Application Processing Times as of 11/27/2019	Deficiency Mail Processing Times as of 11/27/2019
Pharmacy	30	37
Nonresident Pharmacy	49	40
Sterile Compounding	41	50
Nonresident Sterile Compounding	41	49
Outsourcing	Current	Current
Nonresident Outsourcing	14	Current
Hospital Satellite Compounding Pharmacy	26	Current
Hospital	15	Current
Clinic	9	2
Wholesaler	19	2
Nonresident Wholesaler	21	2
Third-Party Logistics Provider	Current	Current
Nonresident Third-Party Logistics Provider	14	Current
Automated Drug Delivery System	Current	Current
Automated Patient Dispensing System	Current	Current
Emergency Medical Services Automated Drug Delivery System	Current	Current

Individual Application Type	Application Processing Times as of 11/27/2019	Deficiency Mail Processing Times as of 11/27/2019
Pharmacist Examination	12	21
Pharmacist Initial Licensure	Current	N/A

Individual Application Type	Application Processing Times as of 11/27/2019	Deficiency Mail Processing Times as of 11/27/2019
Advanced Practice Pharmacist	42	41
Intern Pharmacist	9	5
Pharmacy Technician	34	47
Designated Representative	23	Current
Designated Represenative-3PL	21	Current

# 6. Future Committee Meeting Dates

As part of the meeting, the committee may wish to establish another meeting date in advance of the January 2020 Board Meeting. Members will be surveyed for their availability if necessary.

# 7. Adjournment

# Attachment 1

• SB 159 (Weiner, Chapter 532, Statutes of 2019)

A copy of the following documents will be made available for public inspection at the meeting and are available upon request:

- Pacific AETC Quick Clinical Guide: HIV PrEP Pre-Exposure Prophylaxis
- Office of AIDS Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP)
- Research: HIV pre-exposure prophylaxis: Exploring the potential for expanding the role of pharmacists in public health (Okoro, Olihe; Hillman, Lisa; Journal of the American Pharmacist Association, Volume 58, 2018, pp. 412-420)

Requests may be emailed to: debbie.damoth@dca.ca.gov.



#### 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

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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

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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:

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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.

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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

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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

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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:

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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

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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.

# **Attachment 2**

# Proposed BPC 4038.5 (Definition)

"Advanced Pharmacy Technician" means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.6. Such an individual may also perform nondiscretionary tasks as specified in Section 4115.

# Proposed 4115.6 (Specified Duties)

- (a) A licensed advanced pharmacy technician may perform these technical tasks:
  - (1) Verify the accuracy on new prescription labels before the final check by a pharmacist.
  - (2) 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.
  - (3) Accept new prescriptions from a prescriber's office unless the prescription requires the professional judgment of a pharmacist.
  - (4) Inquire about the intended purpose or indication for prescribed medication on verbal orders received from a prescriber's office.
  - (5) Accept refill authorizations from a prescriber's office unless the authorization requires the professional judgment of a pharmacist.
  - (6) Transfer a prescription to another pharmacy.
  - (7) Receive the transfer of a prescription from another pharmacy.
  - (8) Provide the technical task of administration of an immunization.
  - (9) Initiate post discharge contact with a patient or patient's agent for a patient recently discharged.
  - (10) Provide medication guidance and referral services for post discharge pharmacy services.
  - (11) Develop medication dosing schedules for discharge medications.
  - (12) Initiate post discharge contact with a patient or patient's agents.

## Proposed 4115.7 (Conditions for Use)

- (a) A pharmacy, may use the services of an advanced pharmacy technician if all of the following conditions are met:
  - (1) The duties authorized in subdivision (a) are performed under the supervision of a pharmacist and are specified in the pharmacy's policies and procedures.
  - (2) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a).
  - (3) A pharmacist shall personally provide all new prescription medications and controlled substances medications directly to the patient or patient's agent, and must provide patient information consistent with the provisions of Section 4052 (a) (8).
  - (4) A record is created identifying the personnel responsible for the preparing and dispensing of the prescription medication.
  - (5) 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)**

The board may issue an advanced pharmacy technician license to an individual who meets all the following requirements:

- (a) (1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing for at least 1 year.
  - (2) Has obtained 2,050 hours of experience performing the duties of a licensed pharmacy technician or pharmacist intern in a pharmacy.
  - (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 shall be valid for two years.

# Proposed BPC 4234 (CE/Renewal Requirement)

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. A licensee must also maintain certification as specified in Section 4211 (a)(3)(A)).

# Amendment to BPC 4400 (Fee)

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(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 hospital pharmacy technician shall be \$140 and may be increased to \$195.

# **Attachment 3**

Licensing Statistics for FY 2019/2020

A copy of these documents will be made available for public inspection at the meeting and are available upon request.

Requests may be emailed to: debbie.damoth@dca.ca.gov.