



**California State Board of Pharmacy**  
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Business, Consumer Services and Housing Agency  
Department of Consumer Affairs  
Gavin Newsom, Governor



## **LICENSING COMMITTEE REPORT**

### **September 4, 2024**

Seung Oh, PharmD, Licensee Member, Chairperson  
Trevor Chandler, Public Member, Vice-Chairperson  
Renee Barker, PharmD, Licensee Member  
Jessica Crowley, PharmD, Licensee Member  
Satinder Sandhu, PharmD, Licensee Member  
Jason Weisz, Public Member

- I. Call to Order and Establishment of Quorum**
- II. Public Comment on Items Not on the Agenda/Agenda Items for Future Meetings**

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

- III. Discussion and Consideration of Proposed Amendments to Pharmacy Law to Transition to a More Robust Standard of Care Model for Some Pharmacist-Provided Patient Care Services**

#### Relevant Law

Former BPC section 4301.3 required the Board to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy, and to make recommendations to the Legislature about the outcome of its discussions through a report submitted to the Legislature on or before July 1, 2023.

[BPC sections 4052 – 4052.10](#) generally establish the scope of practice for pharmacists.

[BPC section 4301](#), subdivisions (v) and (w) establish as unprofessional conduct, actions or conduct that would subvert the efforts of a pharmacist or pharmacist-in-charge, to comply with laws and regulations, or exercise professional judgment, including creating or allowing conditions that may

interfere with a pharmacist's ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care.

[BPC section 4306.5](#) establishes as unprofessional conduct acts or omissions that involve, in whole or in part, the inappropriate exercise of a pharmacist's education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the Board. The section further establishes as unprofessional conduct failure of a pharmacist to exercise or implement their best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services. Also, the section provides that the failure to consult appropriate patient, prescription, or other records pertaining to the performance of any pharmacy function is unprofessional conduct, as is the failure to maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

#### Background

Consistent with the legislative mandate of former BPC section 4301.3, the Board established an ad hoc committee to evaluate the issue and submitted its [report](#) as required. The Board's final recommendations included that the hybrid enforcement model used by the Board remains appropriate for the practice of pharmacy for consumer protection. The Board also noted that, based on the information received and considered, California patients would benefit from pharmacists gaining additional independent authority to provide patient care services, not limited to the traditional dispensing tasks performed at licensed facilities, consistent with their respective education, training, and experience.

The Board further recommended revisions to certain provisions detailing a pharmacist's authorized scope of practice for specified clinical patient care services and transition to a standard of care model for provisions of specified patient care services where sufficient safeguards are in place to ensure pharmacists retain autonomy to utilize professional judgment in making patient care decisions. The Board concluded that under those conditions, transitioning to greater use of a standard of care model in the provision of specified patient care services could benefit patients by providing expanded and timely access to patient care from suitably educated, trained, and experienced health care providers.

More recently, during the April 2024 meeting, members considered draft statutory language. Provided below are highlights of the proposed changes and the relevant sections of law.

BPC section 4052: Consolidates various provisions of Pharmacy Law into this section and simplifies the language. Further, would make the following changes:

1. Would expand provisions for pharmacists to perform CLIA waived tests, beyond those currently allowed in BPC section 4052.4.
2. Would allow a pharmacist to perform a therapeutic interchange under specified conditions.
3. Would establish authority for pharmacists to furnish FDA approved or authorized medication that is preventative or does not require a diagnosis under specified conditions.
4. Would expand upon pharmacists' current authority to administer biologics and would allow a pharmacist to furnish an FDA approved or authorized noncontrolled medication for the treatment of minor, non-chronic health conditions or for which a CLIA waived test provides diagnosis and the treatment is limited in duration.
5. Would expand current authority for pharmacists to complete missing information on a noncontrolled medication if there is evidence to support the change.
6. Would expand authority for pharmacists to substitute medications that are generally considered interchangeable (*i.e.*, if insurance will only cover one medication but an interchangeable medication was prescribed).
7. Would allow for medication therapy management and adjust treatments to manage chronic conditions diagnosed by a prescriber to optimize drug therapy (*i.e.*, adjusting medication dosing in response to laboratory results such as for warfarin, or medication to better control diabetes).

As part of its prior discussion, members noted that the transition to a more robust standard of care model for pharmacists should be included as part of the Board's sunset report. As previously noted, the draft proposed language does not remove specific authorities for pharmacists that currently exist, but rather, expands the language and removes some of the prescriptive authorities that currently exist. Members noted that the transition to the standard of care as proposed provided for more patient-focused care with individual pharmacists making the decision how to care for a patient. Members generally agreed that pharmacists need more flexibility to take care of patients with some concern noted that pharmacists in some environments may not have sufficient autonomy to use their professional judgment or

access to necessary medical information to make appropriate patient care decisions.

In prior discussions, members of the public spoke generally in support of the proposal and also noted the need to make conforming changes in other areas of California law, including provisions in the Health and Safety Code.

More recently during the July 2024 Committee meeting, members were advised that staff are seeking information on [California's Dx/F Data Sharing Agreement](#), which is the first-ever, required statewide data sharing agreement in California, which may allow for use of an existing platform to facilitate coordination of care envisioned in the proposal.

In preparation for the Board's upcoming sunset report, and to ensure sufficient time to finalize proposed statutory changes, members have considered the legislative proposal on several occasions further refining the language. Changes previously made to the language were made to address some of the concerns raised by members including liability issues and access to patient medical records.

More recently, as part of the July 2024 Committee Meeting, members continued discussion of the proposal and considered both public comment received during the meeting and written comments received in advance of the meeting. Members noted agreement with some of the comments made and requested that staff make updates to the language consistent with the Committee's comments.

#### For Committee Consideration and Discussion

In preparation for the meeting, staff coordinated with President Oh to update the language to incorporate discussion from the committee. Changes made to the language include the following:

1. Nonsubstantive changes
2. Restructuring to include the provisions for coordination of care into a standalone provision (see BPC 4052(e))
3. Incorporating ACIP recommendation to provisions related to immunization authority (see BPC 4052(a)(16))
4. Explicit language regarding the Board's autonomous authority to define or interpret Pharmacy law (see BPC 4052(d))
5. Language defining "standard of care" (see BPC 4051(b)(4))

**Attachment 1** includes a copy of the updated draft statutory proposal that is being provided to assist with the Committee's discussion. Changes to the proposal are illustrated with yellow highlighting.

**IV. Future Committee Meeting Dates**

October 17, 2024

**V. Adjournment**

# **Attachment 1**

## **Proposal to Amend Business and Professions Code Section 4052.**

(a) Notwithstanding any other law, a pharmacist may do all of the following:

- (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. Initiate and perform routine patient assessment procedures including skin puncture and clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration as authorized by section 12 06.5 or section 12 06. 6. A pharmacist exercising these authorities must do so in collaboration with a patient's primary care provider or diagnosing prescriber, if applicable.~~
- (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 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. Upon patient consent, perform therapeutic interchanges unless the prescriber has indicated "Do not substitute" "Do not alter" or similar words or the medical literature does not support such a change. Such interchanges include, but are not limited to, use of biosimilars, different dosage forms, drugs within the same drug classification, and generic substitutions intended to optimize patient care.~~
- (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. Prescribe over-the-counter medications if requested.~~
- (9) Provide professional information, including clinical or pharmacological information, advice, or consultation to patients and other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.
- (10) Furnish FDA approved or authorized medications as part of preventative health care services that do not require a diagnosis. 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. This section shall not allow a pharmacist to furnish a medication for off-label use.~~

(11) Furnish an FDA approved or authorized noncontrolled medication for the treatment of conditions that

(a) are minor, non-chronic health conditions

(b) or for which a CLIA waived test provides diagnosis and the treatment is limited in duration.

~~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 primary care provider. This section shall not allow a pharmacist to furnish a medication for off-label use.~~

(12) Order and interpret drug therapy related tests. tests for the purpose, 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.

(13) Initiate, adjust, or discontinue drug therapy for a patient under any of the following:

(A) A collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.

(B) Pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the entity providing health care services unless a patient's treating prescriber otherwise prohibits such action.

(14) Provide medication used to treat substance use disorder-assisted treatment pursuant to a state protocol, to the extent authorized by federal law.

(15) Complete missing information on a prescription for a noncontrolled medication if there is evidence to support the change.



(16) Initiate and administer any FDA approved or authorized immunization for persons three years of age and older consistent with Advisory Committee on Immunization Practices recommendations.

(17) Adjust prescription treatment drug regimens consistent with the current standard of care for management of medication therapy management reviews for chronic conditions. A pharmacist exercising these authorities must do so in collaboration with a patient's primary care provider or diagnosing prescriber, if applicable.

(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.

(d) Nothing in this section shall be construed as establishing an obligation on a pharmacist to perform or provide a service or function authorized by subdivision (a) where the pharmacist has made a professional determination that (1) they lack sufficient education, training, or expertise, or access to sufficient patient medical information, to perform such service or function properly or safely; or (2) performing or providing such service or function would place a patient at risk.

(e) Where applicable, 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 or electronic record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

Amend BPC 4050 as follows:

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) ~~Pharmacy~~ Pharmacist practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of patient-care activities to optimize appropriate drug use, drug-related therapy, disease management and prevention, and communication for clinical and consultative purposes. ~~Pharmacy~~ Pharmacist practice is continually evolving to include more sophisticated and comprehensive patient care activities.

(c) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

(d) No state agency other than the board may define or interpret Pharmacy Law and its regulations for those licensed pursuant to the provisions of this chapter or develop standardized procedures and protocols pursuant to this chapter, unless so authorized by this chapter, or specifically required under state or federal statute. "State agency" includes every state office, officer, department, division, bureau, board, authority and commission.

Amend BPC 4051 as follows:

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section ~~4052.1, 4052.2, 4052.3, or 4052.6~~, and otherwise provide clinical advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

(1) The clinical advice, services, information, or patient consultation is provided to a health care professional or to a patient or patient's agent.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) The pharmacist provides the service or activity consistent with accepted standard of care defined as the degree of care a prudent and reasonable pharmacist licensed pursuant to this chapter, with similar education, training, and experience would exercise in a similar situation.

Amend BPC 4036 as follows:

4036. Pharmacist "Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy ~~as authorized by this chapter~~.

Amend BPC 4040 as follows:

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, the prescriber's license classification, and the prescriber's federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.

(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, pharmacist, or naturopathic doctor licensed in this state, ~~or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.~~

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

**4052.01.**

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~~(a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:~~

~~(1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.~~

~~(2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.~~

~~(3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.~~

~~(b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.~~

~~(c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.~~

~~(d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(e) The board may adopt emergency regulations to establish the standardized procedures or protocols. 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 emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).~~

~~(Added by Stats. 2014, Ch. 326, Sec. 1. (AB 1535) Effective January 1, 2015.)~~

**4052.02.**

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~~(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 childbearing 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.~~

~~(Amended by Stats. 2020, Ch. 370, Sec. 5. (SB 1371) Effective January 1, 2021.)~~

### **4052.03.**

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~~(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.~~

~~(Added by Stats. 2019, Ch. 532, Sec. 3. (SB 159) Effective January 1, 2020.)~~

**4052.1.**

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~~(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:~~

~~(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(2) Ordering drug therapy-related laboratory tests.~~

~~(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.~~

~~(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.~~

~~(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.~~

~~(Added by Stats. 2006, Ch. 777, Sec. 5. Effective January 1, 2007.)~~

#### **4052.2.**

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~~(a) Notwithstanding any other law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional clinic, a licensed clinic in which there is 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, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):~~

~~(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(2) Ordering drug therapy-related laboratory tests.~~

~~(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.~~

~~(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the~~



~~appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.~~

~~(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.~~

~~(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:~~

~~(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.~~

~~(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.~~

~~(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.~~

~~(4) Except for procedures or functions provided by a health care facility, a licensed correctional clinic, as defined in Section 4187, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.~~

~~(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:~~

~~(1) Successfully completed clinical residency training.~~

~~(2) Demonstrated clinical experience in direct patient care delivery.~~

~~(Amended by Stats. 2019, Ch. 497, Sec. 5. (AB 991) Effective January 1, 2020.)~~

### **4052.3.**

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~~(a) (1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the~~

~~pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.~~

~~(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:~~

~~(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.~~

~~(B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(2) Prior to performing a procedure authorized under this subdivision, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.~~

~~(3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.~~

~~(4) A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision.~~

~~(c) For each emergency contraception drug therapy or self-administered hormonal contraception initiated pursuant to this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.~~

~~(Amended by Stats. 2013, Ch. 469, Sec. 7. (SB 493) Effective January 1, 2014.)~~

#### **4052.4.**

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~~(a) Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for themselves, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.~~

~~(b) A pharmacist may perform any aspect of any FDA-approved or -authorized test that is classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, under all of the following conditions:~~

~~(1) The test meets the criteria in subparagraph (A) or (B) and does not require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid.~~

~~(A) The test is used to detect or screen for any of the following illnesses, conditions, or diseases:~~

~~(i) SARS-CoV-2 or other respiratory illness, condition or disease.~~

~~(ii) Mononucleosis.~~

- ~~(iii) Sexually transmitted infection.~~
- ~~(iv) Strep throat.~~
- ~~(v) Anemia.~~
- ~~(vi) Cardiovascular health.~~
- ~~(vii) Conjunctivitis.~~
- ~~(viii) Urinary tract infection.~~
- ~~(ix) Liver and kidney function or infection.~~
- ~~(x) Thyroid function.~~
- ~~(xi) Substance use disorder.~~
- ~~(xii) Diabetes.~~

~~(B) Other tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration and approved by the board by regulation, in conjunction with the Medical Board of California and Laboratory Field Services in the State Department of Public Health.~~

~~(2) The pharmacist completes the testing in a pharmacy laboratory that is appropriately licensed in California as a laboratory pursuant to Section 1265, unless otherwise authorized in law.~~

~~(3) The pharmacist has completed necessary training as specified in the pharmacy's policies and procedures maintained pursuant to subdivision (b) of Section 4119.10, and that allows the pharmacist to demonstrate sufficient knowledge of the illness, condition, or disease being tested, as applicable.~~

~~(Amended by Stats. 2021, Ch. 604, Sec. 3. (SB 409) Effective January 1, 2022.)~~

#### **4052.5.**

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~~(a) In addition to the authority allowed under Section 4073, a pharmacist filling a prescription order for a drug product may select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy.~~

~~(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute" or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from~~

checking a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark.

~~(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.~~

~~(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.~~

~~(e) When a substitution is made pursuant to this section, the use of the different form of medication shall be communicated to the patient, and the name of the dispensed drug product shall be indicated on the prescription label, unless the prescriber orders otherwise.~~

~~(f) This section shall not permit substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients.~~

~~(Added by Stats. 2001, Ch. 631, Sec. 1. Effective January 1, 2002.)~~

#### **4052.7.**

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~~(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.~~

~~(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:~~

~~(1) All the information required by Section 4076.~~

~~(2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.~~

~~(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.~~

~~(Added by Stats. 2001, Ch. 728, Sec. 27. Effective January 1, 2002.)~~

#### **4052.8.**

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~~(a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer any vaccine that has been approved or authorized by the federal Food and Drug Administration and received a federal Advisory Committee on Immunization Practices individual vaccine~~

recommendation published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.

(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction. *(Amended by Stats. 2021, Ch. 655, Sec. 1. (AB 1064) Effective January 1, 2022.)*

#### **4052.9.**

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(a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met:

(1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.

(2) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient, or enters 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 provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice.

(3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.

(4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.

~~(b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.~~

~~(Added by Stats. 2013, Ch. 469, Sec. 10. (SB 493) Effective January 1, 2014.)~~

Amend BPC 4064 as follows:

(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

~~(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.~~

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

~~(g) During a proclaimed state of emergency, nothing in either this section or any other provision of this chapter prohibits a pharmacist, a clinic licensed under Section 4180, or a mobile pharmacy or clinic described in subdivision (c) of Section 4062 from refilling a prescription if the prescriber is unavailable, or if after a reasonable effort has been made, the pharmacist, clinic, or mobile pharmacy is unable to contact the prescriber.~~

Amend BPC 4064.5 as follows:

(a) A pharmacist may dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if all of the following requirements are satisfied:

(1) The patient has completed an initial 30-day supply of the dangerous drug.

(2) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(3) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

(4) The pharmacist is exercising his or her professional judgment.

(b) For purposes of this section, if the prescription continues the same medication as previously dispensed in a 90-day supply, the initial 30-day supply under paragraph (1) of subdivision (a) is not required.

(c) A pharmacist dispensing an increased supply of a dangerous drug pursuant to this section shall notify the prescriber of the increase in the quantity of dosage units dispensed.

~~(d) In no case shall a pharmacist dispense a greater supply of a dangerous drug pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "No change to quantity," provided that the prescriber personally initials the box or checkmark. To indicate that an increased supply shall not be dispensed pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "No change to quantity," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "No change to quantity." In either instance, it shall not be required that the prohibition on an increased supply be manually initialed by the prescriber.~~

(e) This section shall not apply to psychotropic medication or psychotropic drugs as described in subdivision (d) of Section 369.5 of the Welfare and Institutions Code.

(f) Except for the provisions of subdivision (d), this section does not apply to FDA-approved, self-administered hormonal contraceptives.

(1) A pharmacist shall furnish or dispense, at a patient's request, up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills.

~~(2) A pharmacist furnishing an FDA-approved, self-administered hormonal contraceptive pursuant to Section 4052.3 under protocols developed by the Board of Pharmacy may furnish, at the patient's request, up to a 12-month supply at one time.~~

(3) Nothing in this subdivision shall be construed to require a pharmacist to dispense or furnish a drug if it would result in a violation of Section 733.

(g) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary's plan benefit.

#### **~~4073.~~**

~~(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic~~



drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

~~(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.~~

~~(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.~~

~~(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.~~

~~(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.~~

#### **4073.5.—**

~~(a) A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:~~

~~(1) The alternative biological product is interchangeable.~~

~~(2) The prescriber does not personally indicate "Do not substitute," or words of similar meaning, in the manner provided in subdivision (d).~~

~~(b) Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists' designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry that can be~~

electronically accessed by the prescriber through one or more of the following electronic records systems:

- (1) An interoperable electronic medical records system.
- (2) An electronic prescribing technology.
- (3) A pharmacy benefit management system.
- (4) A pharmacy record.

(c) Entry into an electronic records system as described in subdivision (b) is presumed to provide notice to the prescriber.

(d) If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist's designee shall communicate the name of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply:

- (1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed.
- (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(e) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning.

(1) This subdivision shall not prohibit a prescriber from checking a box on a prescription marked "Do not substitute," provided that the prescriber personally initials the box or checkmark.

(2) To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription, as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(f) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (e). A pharmacist who selects an alternative biological product to be dispensed pursuant to this section shall assume the same responsibility for substituting the biological product as would be incurred in filling a prescription for a biological product prescribed by name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist select a biological product that meets the requirements of subdivision (a) unless the cost to the patient of the biological product selected is the same or less than the cost of the prescribed

biological product. Cost, as used in this subdivision, includes any professional fee that may be charged by the pharmacist.

~~(g) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.~~

~~(h) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.~~

~~(i) The board shall maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the federal Food and Drug Administration to be interchangeable.~~

~~(j) For purposes of this section, the following terms shall have the following meanings:~~

~~(1) "Biological product" has the same meaning that applies to that term under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262(i)).~~

~~(2) "Interchangeable" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in Section 262(k)(4) of Title 42 of the United States Code, or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.~~

~~(3) "Prescription," with respect to a biological product, means a prescription for a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).~~

~~(k) This section shall not prohibit the administration of immunizations, as permitted in Sections 4052 and 4052.8.~~

~~(l) This section shall not prohibit a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.~~