California State Assembly

BUSINESS AND PROFESSIONS

EVAN LOW
CHAIR

Chief Consultant
Robert Sumner

Deputy Chief Consultant
Vincent Chee

Consultant
Danielle Sires
Patrick Le

Committee Secretary
Ophelia Szigeti

1020 N Street, Room 379
(916) 319-3301
FAX: (916) 319-3306

AGENDA

Tuesday, July 6, 2021
9 a.m. -- State Capitol, Assembly Chamber

BILLS HEARD IN FILE ORDER

1.	SB 409	Caballero	Pharmacy practice: SARS-CoV-2 and influenza testing.
2.	SB 757	Limón	Solar energy system improvements: consumer protection.
3.	SB 362	Newman	Community pharmacies: quotas.
4.	SB 306	Pan	Sexually transmitted disease: testing.
5.	SB 263	Rubio	Real estate applicants and licensees: education requirements: fair housing and implicit bias training.
6.	SB 524	Skinner	Health care coverage: patient steering.
7.	SB 509	Wilk	Optometry: COVID-19 pandemic: temporary licenses.(Urgency)

COVID FOOTER

SUBJECT:

We encourage the public to provide written testimony before the hearing by visiting the committee website at http://abp.assembly.ca.gov/. Please note that any written testimony submitted to the committee is considered public comment and may be read into the record or reprinted.

Due to ongoing COVID-19 safety considerations, including guidance on physical distancing, seating for this hearing will be very limited for press and for the public. All are encouraged to watch the hearing from its live stream on the Assembly's website at https://www.assembly.ca.gov/todaysevents.

The Capitol will be open for attendance of this hearing, but the public is strongly encouraged to participate via the web portal, Remote Testimony Station, or phone. Any member of the public attending a hearing in the Capitol will need to wear a mask at all times while in the building. We encourage the public to monitor the committee's website for updates.

Date of Hearing: July 6, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 409 (Caballero) – As Amended July 1, 2021

SENATE VOTE: 38-0

SUBJECT: Pharmacy practice: testing

SUMMARY: Expands the types of clinical laboratory tests that a licensed pharmacist may perform to include clinical laboratory tests are classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) and that are used to detect or screen for specified conditions, establishes additional requirements for testing performed by pharmacists and the pharmacies using the pharmacists, and authorizes a pharmacist-in-charge to serve as the laboratory director.

EXISTING LAW:

1) Related to the practice of medicine:

    a) Regulates the practice of medicine under the Medical Practice Act, which establishes the Medical Board of California (MBC) to administer and enforce the act. (Business and Professions Code (BPC) §§ 2000-2529.6)

    b) Defines "diagnose" and "diagnosis" as an undertaking by any method, device, or procedure to ascertain or establish whether a person is suffering from any physical or mental disorder, including the taking of a person's blood pressure and the use of mechanical devices or machines for the purpose of making a diagnosis and providing the person any conclusion regarding their physical or mental condition, except for the use of machines or mechanical devices for measuring or ascertaining height or weight. (BPC § 2038)

    c) Authorizes the holder of a physician's and surgeon's license to use drugs or devices in or upon human beings and to sever or penetrate the tissues of human beings and to use any other methods in the treatment of diseases, injuries, deformities, and other physical and mental conditions. (BPC § 2051)

    d) Prohibits the practice of medicine without a physician's and surgeon's license issued by the MBC, including practicing, attempting to practice, or advertising as practicing, any system or mode of treating the sick or afflicted in this state or diagnosing, treating, operating for, or prescribing for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person. (BPC § 2052)

2) Related to the practice of pharmacy:

    a) Regulates and licenses the practice of pharmacy under the Pharmacy Law and establishes the California State Board of Pharmacy to administer and enforce the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000-4427.8)

b) Makes it unlawful for a person to practice pharmacy, which means to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription of a prescriber unless the person is a pharmacist licensed under the Pharmacy Law. (BPC § 4051(a))

c) Defines "pharmacist" as a natural person who has a license issued by the Board of Pharmacy who is entitled to practice pharmacy within or outside of a licensed pharmacy, as authorized by the Pharmacy Law. (BPC § 4036)

d) Defines "pharmacist-in-charge" as a pharmacist proposed by a pharmacy and approved by the Board of Pharmacy as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. (BPC § 4036.5)

e) Defined "intern pharmacist" as means a person issued a temporary license who is enrolled in a specified school of pharmacy, is a graduate of an international school, failed the pharmacy licensing exam four times and is reenrolled in a school of pharmacy, or is required by the Board of Pharmacy as part of a decision of reinstatement. (BPC §§ 4030, 4208)

f) Authorizes an intern pharmacist to perform all functions of a pharmacist at the discretion of and under the direct supervision and control of a licensed pharmacist, except a pharmacist may not supervise more than two intern pharmacists at any one time. (BPC § 4114)

g) Authorizes the following, among other things, as part of the scope of practice of a licensed pharmacist:

    i) Performing procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician. (BPC § 4052(a)(5))

    ii) Providing consultation, training, and education to patients about drug therapy, disease management, and disease prevention. (BPC § 4052(a)(8))

    iii) Ordering and interpreting tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests under this authorization is required to ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, 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. (BPC § 4052(a)(12))

3) Related to the regulation of clinical laboratory technology:

   a) Provides for the regulation, registration, and licensure of clinical laboratory technology, including laboratory facilities and clinical laboratory personnel, by the California Department of Public Health (CDPH). (BPC § 1200-1327)

   b) Defines "CLIA" as the federal Clinical Laboratory Improvement Amendments of 1988 (United States Code, title 42, § 263a; Public Law 100-578) and the regulations adopted by the federal Health Care Financing Administration (HFCA) that are effective on January 1, 1994, or later when adopted by the CDPH after being deemed equivalent to or more stringent than California laws or regulations, as specified. (BPC § 1202.5(a); BPC § 1208(b))

   c) Defines "clinical laboratory test or examination" as the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual. (BPC § 1206(a)(5))

   d) Defines "clinical laboratory" as any place used or any establishment or institution organized or operated for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. (BPC § 1206(a)(8))

   e) Requires every clinical laboratory to operate under the overall operation and administration of a laboratory director. (BPC § 1206.5(a), 1206.5(b), 1206.5(c))

   f) Establishes the definition, duties, and qualifications of a "laboratory director" for purposes of clinical laboratories and testing. (BPC § 1209)

   g) Defines "laboratory director" as any person who is any of the following:

      i) A duly licensed physician and surgeon. (BPC § 1209(a)(1))

      ii) Only for purposes of a clinical laboratory test or examination classified as waived:

         (1) A licensed clinical laboratory scientist. (BPC § 1209(a)(2)(A))

         (2) A licensed limited clinical laboratory scientist. (BPC § 1209(a)(2)(B))

         (3) A licensed naturopathic doctor. (BPC § 1209(a)(2)(C))

         (4) A licensed optometrist serving as the director of a laboratory that only performs clinical laboratory test classified as waived under CLIA that include the ordering of smears, cultures, sensitivities, complete blood count, mycobacterial culture, acid fast stain, urinalysis, tear fluid analysis, and X-rays necessary for the diagnosis of conditions or diseases of the eye or adnexa. (BPC § 1209(a)(2)(D))

iii) Otherwise licensed to direct a clinical laboratory under the chapter on clinical laboratory technology. (BPC § 1209(a)(3))

iv) The pharmacist-in-charge of a pharmacy that applies for a registration with the CDPH as a community pharmacy that only performs blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA and are approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit. (BPC §§ 1206.6, 1265(k))

h) Prohibits the performance of a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by specified persons, including a pharmacist if ordering drug therapy-related laboratory tests or if performing skin puncture in the course of performing routine patient assessment procedures as specified under the Pharmacy Law. (BPC § 1206.5)

i) Excludes from the waived testing requirements a pharmacist at a community pharmacy who, upon customer request, performs only blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA and are approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, provided that the pharmacy has a federal certificate of waiver, the laboratory director is the pharmacist-in-charge, the pharmacy registers with the CDPH, and the pharmacist performs tests in the course of performing routine patient assessment procedures that a patient could, with or without a prescription, perform on their own or clinical laboratory tests that are classified as waived under CLIA. (BPC § 1206.6)

THIS BILL:

1) Authorizes a pharmacist to perform any aspect of any FDA-approved or -authorized test that is classified as waived pursuant to CLIA and either (1) approved by the Board of Pharmacy in conjunction with the Medical Board of California or (2) used to detect or screen for any of the following illnesses, conditions, or diseases:

   a) SARS-CoV-2 or other respiratory illness, condition or disease.

   b) Mononucleosis.

   c) Sexually transmitted infection.

   d) Strep throat.

   e) Anemia.

   f) Cardiovasular health.

   g) Conjunctivitis.

h) Urinary tract infection.

i) Liver and kidney function or infection.

j) Thyroid function.

k) Substance use disorder.

l) Diabetes.

2) Requires pharmacist performing those tests to meet the following:

a) The test must be performed in a laboratory that is appropriately licensed in California as a laboratory.

b) If performed in a pharmacy, the pharmacist must complete necessary training as specified in the pharmacy's policies and procedures maintained pursuant to this bill.

3) Authorizes a pharmacist-in-charge of a pharmacy to serve as the director of a laboratory that only performs tests waived pursuant to CLIA and as authorized under this bill.

4) Authorizes a pharmacy located in the state to use pharmacists to perform FDA-approved or-authorized tests that are classified as waived pursuant to CLIA, under all of the following conditions:

a) The pharmacy is appropriately licensed as a laboratory.

b) The pharmacy maintains policies and procedures that do all of the following:

i) Establish the initial training requirements, including specimen collection techniques relevant to a test being performed at the pharmacy, and ongoing training.

ii) Establish safety precautions necessary to protect pharmacy staff and consumers and to reduce the risk of transmission, consistent with Cal-OSHA and CDC requirements, including, but not limited to, provisions for the use of personal protective equipment, cleaning and sanitizing procedures, appropriate biohazard waste requirements, and space requirements for pharmacy staff and consumers.

iii) Ensure the availability of dedicated physically distanced space or other segregated space that provides for privacy during the testing process and private consultation with the pharmacist, and limits potential contamination of other consumers in the pharmacy.

iv) Establish requirements for providing test results to the patient in a nonverbal manner, complying with mandatory reporting requirements to local and state reporting systems, and notification to primary care providers if consent is provided.

v) Ensure documentation of testing equipment maintenance and calibration.

vi) Ensure appropriate storage and handling of specimens, testing reagents, and other supplies or equipment that require specialized storage or handling. Specimen collection shall not include vaginal swab, venipuncture, or the collection of seminal fluid.

c) The test is authorized to be administered by a pharmacist pursuant to the authority established by this bill in the Pharmacy Law.

d) The pharmacist-in-charge does both of the following:

i) Annually reviews the policies and procedures maintained pursuant to the requirements of this bill, assesses the pharmacy's compliance with its policies, and documents corrective actions to be taken when noncompliance is found.

ii) Maintains documentation of the annual review and assessment in a readily retrievable format for a period of three years from the date of completion.

e) The pharmacy maintains documentation related to performing tests that demonstrates compliance with this bill, which includes the name of the pharmacist performing the test, the results of the test, and communication of results to a patient's primary medical provider, and is maintained in a readily retrievable format for a period of three years from the date of creation.

FISCAL EFFECT: According to the Senate Committee on Appropriations analysis of the February 12, 2021, version of this bill, pursuant to Senate Rule 28.8, no significant state costs anticipated.

COMMENTS:

Purpose. This bill is sponsored by the *California State Board of Pharmacy*. According to the author, "The CDC has acknowledged that the flu and COVID-19 are both respiratory illnesses that are caused by different viruses that may be difficult to differentiate based on symptoms alone without testing to confirm a diagnosis. It is widely recognized that community pharmacies provide unique access for patients to obtain tests in a safe and convenient location. Pharmacists already provide certain CLIA waived tests, so in an effort to increase efficiency, [this bill] secures a more permanent solution through statutory changes that facilitate authority for pharmacists to perform CLIA-waived COVID and influenza testing in a safe manner."

Background. Existing law generally limits the use of laboratory testing because the tests are used in the diagnostic process. The purpose of CLIA and the California requirements is to minimize the risk of incorrect or unreliable results, patient harm during testing, and improper diagnoses, among other things.

CLIA. At both the federal and state level, a facility or location where people perform laboratory tests on human specimens for diagnostic or assessment purposes must be certified under CLIA. While CLIA establishes the minimum standards under federal law, it allows states to establish more stringent requirements.

In all cases, the requirements for CLIA certification vary depending on the complexity of the laboratory tests performed. Clinical laboratories or other testing sites need to know whether each test system used is waived, moderate, or high complexity. In general, the more complicated the test, the more stringent the requirements, including increased training and licensing of laboratory personnel. At a minimum, all laboratories must have a licensed clinical laboratory director.

The FDA determines the complexity of laboratory tests under CLIA. Waived tests are simple tests with a low risk for an incorrect result. They include tests listed in the CLIA regulations, tests cleared by the FDA for home use, and tests approved for a waiver by the FDA using the CLIA criteria. Tests not classified as waived are assigned a moderate or high complexity category based on seven criteria given in the CLIA regulations, including ease of use, knowledge required, and types of materials tested. For commercially available FDA-cleared or approved tests, the test complexity is determined by the FDA during the pre-market approval process.

Under federal and California law, anyone providing direct care may perform a waived test in a federally-certified laboratory or as part of a nondiagnostic health assessment program under the overall direction of a laboratory director, unless otherwise limited. In applying for a CLIA certificate of waiver, the laboratory director must list the types of analytes to be tested, the tests performed, and the test manufacturer.

Pharmacy Testing. California law defines the practice of pharmacy as "a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities." It is unlawful to practice pharmacy without a license, which includes manufacturing, compounding, furnishing, selling, or dispensing a dangerous drug or dangerous device, or dispensing or compounding a prescription.

Currently, licensed pharmacists are also authorized to assist in the care of patients in coordination with other health care professions, including the following:

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

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

3) 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 must 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.

4) Perform routine drug-therapy related patient assessment procedures and order drug therapy-related laboratory tests in specified circumstances and settings, including:

a) 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.

b) 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.

c) In a community pharmacy that has obtained a federal CLIA certificate of waiver and when the customer requests blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived and are approved by the FDA for sale to the public without a prescription in the form of an over-the-counter test kit. The pharmacist must report the results to the patient and a physician designated by the patient.

In addition, in May 2020, the Governor issued, pursuant to an executive order, a waiver of certain CLIA testing restrictions, allowing pharmacists to order SARS-CoV-2 tests and collect specimens necessary for the tests. The waiver required that: (1) the tests must be authorized by the FDA; (2) the pharmacist must be "competent and trained to collect the specimen needed for the particular test"; and (3) the specimen must be collected consistent with the provisions of an Emergency Use Authorization issued by the FDA. The waiver also authorized pharmacists to serve as qualified laboratory testing personnel—but only in an appropriately licensed or registered clinical laboratory under the direction of a laboratory director.

This bill would codify that waiver and further allow pharmacists to perform additional waived tests that (1) either test or screen for the conditions listed under this bill or are approved by the Board of Pharmacy and the Medical Board of California.

The goal of the bill is to allow pharmacists to serve as an additional entry point into the health system, providing patients an additional avenue to identify potential health risks early on. In addition, it would allow pharmacists to perform time-sensitive tests onsite. For example, pharmacists with additional training are authorized to initiate and furnish HIV preexposure prophylaxis (PrEP) and HIV postexposure prophylaxis (PEP). PrEP requires a negative HIV test within the last 7 days, and patients exposed to HIV should test for HIV and must begin PEP within 72 hours of exposure. Allowing the pharmacist to perform the waived testing may ensure patients who are reluctant to come back or see a physician receive the proper care.

Laboratory Director. According to the Centers for Medicare and Medicaid Services, a laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel. A laboratory director may delegate some responsibilities, but is ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met. It is the laboratory director's responsibility to ensure that the laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results.

Under federal law, there are no additional education or training requirements for laboratory directors other than the administrative and supervisory duties. Under California law, those who may be a laboratory director are limited to:

1) A physician and surgeon.

2) Specified licensed clinical laboratory personnel.

3) Only for purposes of a clinical laboratory test or examination classified as waived:

    a) A licensed clinical laboratory scientist.

    b) A licensed limited clinical laboratory scientist.

    c) A licensed naturopathic doctor.

    d) A licensed optometrist serving as the director of a laboratory that only performs the ordering of smears, cultures, sensitivities, complete blood count, mycobacterial culture, acid fast stain, urinalysis, tear fluid analysis, and X-rays necessary for the diagnosis of conditions or diseases of the eye or adnexa.

    e) The pharmacist-in-charge of a pharmacy that applies for a registration with the CDPH as a community pharmacy that only performs blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA and are approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit.

This bill would allow the pharmacist-in-charge to be the laboratory director of a pharmacy that performs the additional CLIA-waived tests authorized under this bill.

Current Related Legislation. AB 691 (Chau), which is pending in the Senate Appropriations Committee, expands the authority of a qualified optometrist to administer immunizations to include the administration of the SARS-CoV-2vaccine, and authorizes an optometrist to engage in specified COVID-19 testing.

AB 1328 (Irwin), which is pending in the Senate Committee on Business, Professions and Economic development, would authorize 1) a pharmacist to perform all clinical laboratory tests are classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) that can lawfully be used within the pharmacist's practice, 2) the pharmacist-in-charge of a pharmacy to be the laboratory director of a laboratory certified to perform all CLIA-waived tests, 3) additional settings in which a pharmacist may perform waived tests, and 4) a pharmacist to perform health screenings under policies, procedures, or protocols.

Prior Related Legislation. SB 1481 (Negrete McLeod), Chapter 874, Statutes of 2012 established the authority for the pharmacist-in-charge to be the laboratory director of a community pharmacy if the pharmacy only performs blood glucose, hemoglobin A1c, or cholesterol tests classified as waived under CLIA that are approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit and are performed by a pharmacist at a community pharmacy upon customer

request, provided that the pharmacy obtains a CLIA certificate of waiver and a registration from the CDPH and complies with all other requirements governing clinical laboratories, as specified.

ARGUMENTS IN SUPPORT:

The Board of Pharmacy (sponsor) writes in support of the February 12, 2021, version of this bill, "As a consumer protection agency charged with regulating the practice of pharmacy, the Board recognizes that community pharmacies provide unique access for patients to obtain tests in a safe and convenient location. The Board is sponsoring this statutory change to secure permanent authority for pharmacists to perform CLIA waived COVID and influenza testing in a safe manner as an important public health measure. Increasing testing capacity is essential not only during the immediate public health crisis, but ongoing. The CDC has acknowledged that the flu and COVID-19 are both respiratory illnesses that are caused by different viruses that may be difficult to differentiate based on symptoms alone without testing to confirm a diagnosis. Providing authority to perform both tests is essential."

The *California Pharmacists Association (CPhA)* writes in support of the February 12, 2021, version of this bill:

> CPhA is in full support of allowing pharmacists to independently perform CLIA-waived testing for [COVID-19] and flu. Since the early days of the [COVID-19] pandemic, pharmacists have demonstrated their ability to perform those tests efficiently and with great success under Governor Gavin Newsom's Executive Order N-75-20. This authority, however, is temporary and only exists during the declared state of emergency. Pharmacists are the most accessible healthcare professionals that exist for all patient populations, which is why allowing them the permanent authority in law makes sense and is good public policy.
>
> A pharmacist's training consists of 3-4 years of professional graduate level study to earn a Doctor of Pharmacy (PharmD) degree. During these years, student pharmacists are also required to complete a minimum of 1,500 hours of clinical practice experience in conjunction with their formal didactic education.
>
> Once the didactic and clinical hours are completed, pharmacist candidates must successfully pass two board exams: North American Pharmacist Licensure Examination (NAPLEX) and California Practice Standards and Jurisprudence Exam (CPJE) to be duly licensed pharmacists with the California Board of Pharmacy. Licensed pharmacists are required to complete a minimum of 30 hours of continuing pharmacy education (CE) every two years to renew their pharmacist license within the state.
>
> Pharmacists are more than capable of performing CLIA waived tests. By definition, CLIA waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." The Food and Drug Administration (FDA) determines which tests meet these criteria when it reviews manufacturer's applications for test system waiver.

> Recent studies have noted that, "pharmacies have become an increasingly important location for patients to access CLIA-waived tests in the United States, now serving as the second largest provider of CLIA-waived tests by the total number of locations. Most of this growth occurred between 2019 and 2020 due to the COVID-19 pandemic, and concentrated efforts will be necessary to sustain this momentum."

The *California Retailers Association* and *National Association of Chain Drug Stores* write in support of the February 12, 2021, version of this bill, "The current pharmacy testing and vaccine flexibilities provided during COVID-19 should extend beyond the pandemic, to allow pharmacies to best meet the healthcare needs across communities in California. By expanding the emergency waiver authority to allow pharmacists to perform CLIA-waived COVID-19 testing, as well as flu testing, [this bill] will increase the state's testing capacity utilizing pharmacists, which are trusted and experienced healthcare providers. This will aid in recovery from the COVID-19 Pandemic, save lives, and get California's economy working again."

ARGUMENTS IN OPPOSITION:

The *California Association for Medical Laboratory Technology* was opposed to the February 12, 2021, version of this bill unless it was amended to narrow the bill to waived tests that only test for SARS-CoV-2 and influenza that are available over the counter and delete the authorization to serve as laboratory directors:

> We believe our proposed amendment will achieve the objective of pharmacists, while crucially maintaining the best standard of practice for California clinical laboratory science and the highest level of patient care. Our amendment will expand the law to allow pharmacists to perform FDA-approved tests for the presence of SARS-CoV-2, the virus that causes COVID-19, or influenza that is classified as waived under the Clinical Laboratory Improvement Act "CLIA" for sale to the public without a prescription in the form of an over-the-counter test.
>
> Currently, the pharmacists' scope of practice includes laboratory testing using FDA approved over the counter "OTC" tests for glucose, hemoglobin A1c and cholesterol without a laboratory director. We do not object to adding FDA approved OTC tests for SARS-CoV-2 and influenza. If these amendments are acceptable, then there would not be a need to add pharmacists to the list of being qualified waived laboratory directors.
>
> Waived laboratory directorship is not in the interest of patient care for the following reasons:
>
> • Pharmacy school curriculum does not include sufficient instruction in biomedical laboratory sciences that would prepare them to serve as waived laboratory directors.
>
> • Pharmacists are not authorized to perform all waived tests which would not serve the essential level of patient care in California.

AMENDMENTS:

1) Because there are some forms of specimen collections that may not be safe or otherwise appropriate to perform in a pharmacy or by a pharmacist, the bill should be amended as follows:

   On page 11 of the bill, line 39:

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

2) To clarify that the Board of Pharmacy may approve additional tests if the tests are classified also as waived under CLIA and if in conjunction with the Medical Board, rather than in consultation with, the bill should be amended as follows:

   On page 12 of the bill, lines 16-17:

   (B) ~~The board, in consultation with the Medical Board of California, enacts a regulation authorizing the test to be performed.~~ *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 through regulation, in conjunction with the Medical Board of California.*

3) To clarify the parameters of the training pharmacists must complete, the bill should be amended as follows:

   On page 12 of the bill, line 25:

   (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.~~ *4119.10 and that allows the pharmacist to demonstrate sufficient knowledge of the illness, condition, or disease being tested.*

REGISTERED SUPPORT:

California State Board of Pharmacy (sponsor)
California Pharmacists Association
California Retailers Association
National Association of Chain Drug Stores

REGISTERED OPPOSITION:

California Association for Medical Laboratory Technology (unless amended)

Analysis Prepared by: Vincent Chee / B. & P. / (916) 319-3301

Date of Hearing: July 6, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 757 (Limón) – As Amended April 12, 2021

SENATE VOTE: 40-0

SUBJECT: Solar energy system improvements: consumer protection

SUMMARY: Adds the installation of solar energy systems to the definition of "home improvement"; and adds additional regulations to the laws pertaining to home improvement sales persons related to solar energy systems.

EXISTING LAW:

1) Provides for the licensure and regulation of contractors, including home improvement contractors, under the Contractors State License Law (Contractors Law) by the Contractors State License Board (CSLB or Board) within the Department of Consumer Affairs. The CSLB registrar of contractors is executive officer and secretary of the Board vested with the authority to carry out the administrative duties of the Board. (Business and Professions Code (BPC) § 7000 et seq.)

2) Defines "home improvement" to mean the repairing, remodeling, altering, converting, or modernizing of, or adding to, residential property, as well as the reconstruction, restoration, or rebuilding of a residential property that is damaged or destroyed by a natural disaster and provides that home improvement includes but is limited to, the construction, erection, replacement, or improvement of driveways, swimming pools, spas and hot tubs, terraces, patios, awnings, storm windows, landscaping, fences, porches, garages, fallout shelters, basements, and other improvements of the structures or land adjacent to a dwelling house. (BPC § 7151)

3) Defines a "home improvement contractor" including a swimming pool contractor as a licensed contractor who is engaged in the business of home improvement either full time or part time, as specified. (Business and Professions Code (BPC) § 7150.1)

4) Defines a "home improvement salesperson" as a person who is registered with the Contractors State License Board (CSLB) and engaged in the business of soliciting, selling, negotiating, or executing contracts for improvements, for the sale, installation or furnishing of home improvement goods or services or of swimming pools, spas, or hot tubs on behalf of a licensed home improvement contractor. (BPC § 7152(a))

5) Provides that, before a home improvement salesperson begins work for a home improvement contractor, that the contractor notify the registrar in writing about the employment of a registered home improvement salesperson, including the name and registration number of the home improvement salesperson who is employed by the contractor. (BPC § 7154)

6) Provides that it is misdemeanor and cause for disciplinary action for any home improvement salesperson to fail to account for or to remit to their employing contractor any payment received in connection with any home improvement transaction or any other transaction involving a work of improvement and for any person to use a contract form in connection with any home improvement transaction or any other transaction involving a work of improvement if the form fails to disclose the name of the contractor principal by whom they are employed (BPC § 7156)Requires specified information and notices to be included in a home improvement contract, such as the consumer's three day or five day right to cancel a contract, description of the project and description of significant materials to be used and equipment to be installed, approximate start and completion dates, a list of documents and notices to be incorporated into the contract, a schedule of progress payments if progress payments are to be made and series of other requirements, , as specified. (BPC § 7159)

7) Provides that home improvement contracts be in writing and include the agreed contract amount in dollars and cents and that if a down payment will be charged, the down payment is not exceed one thousand dollars or 10 percent of the contract amount, whichever is less. Further provides that except for a down payment, the contractor shall neither request nor accept payment that exceeds the value of the work performed or material delivered. Additionally, provides that violation of these provisions by a licensed home improvement contractor or an unlicensed contractor subjects the individual to license discipline or misdemeanor punishable by a fine or imprisonment (BPC § 7159.5)

8) Requires a representation made by any contractor or home improvement salesperson with respect to a trademark or brand name, quality, or size of any goods or materials in reference to certain items and systems, including, but not limited to, bathroom fixtures and paints, to be set forth in writing in the contract or specifications and include a description of the goods or materials, including any brand name, model number, or similar designation. Provides that the failure to install the specific goods or materials as represented constitutes a cause for disciplinary action. (BPC § 7162)

9) Requires the CSLB to annually compile a report documenting consumer complaints related to solar contractors, which must be available on the CSLB and the Public Utilities Commission's internet websites. (BPC § 7170(b))

10) Provides that for the purposes of solar complaint tracking and for the purposes of the solar energy system solar disclosure document, that "solar energy system" means a solar energy device to be installed on a residential building that has the primary purpose of providing for the collection and distribution of solar energy for the generation of electricity, that produces at least one kW, and not more than five MW, alternating current rated peak electricity, and that meets or exceeds the eligibility criteria established pursuant to Section 25782 of the Public Resources Code. (BPC §7167, 7170 (c))

THIS BILL:

1) Adds the existing definition of "solar energy system" currently limited to BPC 7169 and 7170 to the definition of "home improvement", thereby extending that definition to the entire Article (Article 10, Home Improvement Business) Modifies that definition by adding

"residential property" to the definition of solar energy system. Includes the word "installation" among the activities involving residential property that define "home improvement."

2) Permits a home improvement salesperson to be employed by one, or more than one, home improvement contractor; however; prior to engaging in any specified activity, a home improvement sales person must identify to the owner or tenant, the business name and license number of the contractor they are representing for the purpose of that transaction, and failure to do so is a cause for disciplinary action, as specified.

3) Adds any home improvement salesperson who assists, recommends, selects or otherwise guides an owner or tenant in the selection of a contractor for the performance or sale of home improvement goods or services if notification of employment by the home improvement contractor, as required, has not been received by the Contractors State License Board (CSLB) to the list of items that are considered a misdemeanor and a cause for disciplinary action by the CSLB.

4) Adds to the prohibition of a contractor requesting or accepting payment that exceeds the value of work performed or material delivered, except for the down payment, the advance payment in whole or part from any lender or financier for the performance or sale of home improvement goods or services.

5) Adds "solar energy system" among the goods or materials that subject to the prohibitions against failure to install specific goods or materials as represented or as described in writing, or in any representation made as to a trademark, brand name, quality, or size of goods

FISCAL EFFECT: Unknown. This bill is keyed fiscal by Legislative Counsel.

COMMENTS:

Purpose. The Sponsor of this bill is *The Delores Huerta Foundation*. According to the Author, "Roof-top home solar is an essential part of California's climate goals. Unfortunately, some solar customers have been taken advantage of by bad actors. In 2019-2020 the Contractor State Licensing Board (CSLB) received an average of 90 new complaints a month alleging misrepresentation, fraud, or abandonment. CSLB referred 122 of those cases that were substantiated and unsettled to legal action. Non-English speakers and seniors are most commonly targeted by bad actors misrepresenting these improvements as free or low cost, when they are actually significant investments.

[This bill] will give consumers more protections and transparency around solar installation. Although solar is often considered a home improvement, this bill will clarify solar consumers have contract cancellation rights, down payment security, and are not required to pay in full until the work is completed. This bill will also require the salesperson to disclose the contractors they are working with, so the consumer can make an informed decision."

Background. *CSLB and Contractors*. The CSLB is responsible for implementation and enforcement of the laws and regulations related to the licensure, practice and discipline of the

construction industry in California. All businesses and individuals who construct or alter, or offer to construct or alter, any building, highway, road, parking facility, railroad, excavation, or other structure in California must be licensed by the CSLB if the total cost (labor and materials) of one or more contracts on the project is $500 or more. The Board licenses approximately 280,000 contractors in 44 license classifications and two certifications. In addition, the CSLB registers some 19,000 home improvement salespersons who are engaged in the sale of home improvement goods and services. Only those contractors with specified license classifications are authorized to perform solar construction or installation. Those without the proper license classifications are not authorized to perform solar installation work.

Home Improvement. Individuals who sell solar systems as part of a home improvement contract must register with the CSLB as a home improvement salesperson. Any individual who solicits door-to-door or negotiates the terms of a contract is required to be a registered home improvement salesperson. This bill aims to strengthen the definition of "home improvement" to specifically include the installation of a solar energy system, which would ensure that only appropriately registered individuals are permitted to sell home improvement services, and specifically require that sales and installation of solar energy systems be subject to the requirements governing home improvement.

The current definition of "home improvement" means the repairing, remodeling, altering, converting, or modernizing of, or adding to, residential property, as well as the reconstruction, restoration, or rebuilding of a residential property that is damaged or destroyed by a natural disaster, as specified, and include, but not be limited to, the construction, erection, replacement, or improvement of driveways, swimming pools, including spas and hot tubs, terraces, patios, awnings, storm windows, landscaping, fences, porches, garages, fallout shelters, basements, and other improvements of the structures or land which is adjacent to a dwelling house. "Home improvement also means the installation of home improvement goods or the furnishing of home improvement services. However, currently, it does not include the installation of solar energy systems, which this bill will add.

Under current law, individuals who sell contracting services for the home improvement construction of real property in California must register with the CSLB as a "home improvement salesperson". As part of the home improvement laws, these sales are subject to specified laws in California, which govern the written contract, which is required for all home improvement projects over $500. A home improvement contract and any changes made to that contract must be in writing, legible, easy to understand, and inform the consumer of his/her rights to cancel or rescind the contract. Home improvement salespersons may sell those services as defined under the definition of "home improvement".

There are several specified requirements that must be contained in the home improvement contract, many of which are intended to help protect consumers from unscrupulous actors including contract cancellation rights, down payment security, or the prohibition on payment in advance of completed work and undelivered materials. By adding installation of a solar energy system to the definition of home improvement, this bill ensures that sale of a solar energy system is subject to the current requirements governing a home improvement contract.

In addition, BPC Section 7154 requires a home improvement contractor licensed by the CSLB to notify the registrar, in writing, about a home improvement salesperson who is employed by that

contractor. It is a violation of the Contractor's License Law for a licensed contractor to employ a home improvement sales person without registering with the CSLB, thereby subjecting the licensed contractor to discipline. Additionally, a contractor is required to notify the CSLB when that contractor no longer employs a home improvement salesperson. While existing law does not specifically prohibit or limit the number of contractors that a home improvement salesperson may be employed by, this bill requires the home improvement salesperson to identify to the owner or tenant, the business name and license number of the contractor they are representing for that specific transaction, and subjects the home improvement contractor to discipline for failing to do so.

Public Utilities Commission (PUC). The PUC regulates services and utilities, protects consumers, safeguards the environment, and assures Californians' access to safe and reliable utility infrastructure and services. The essential services regulated at the PUC include electric, natural gas, telecommunications, water, railroad, rail transit, and passenger transportation companies. Under the PUC's jurisdiction are the electricity providers that connect solar systems to the grid. The PUC initiated Rulemaking 14-07-002 in fall of 2020 to solicit feedback on establishing some form of restitution as proposed by this bill.

Prior Related Legislation. SB 1189 (McGuire, Chapter 364, Statutes of 2020) creates a B-2 Residential Remodeling Contractor license as a new classification of contracting business and revises the definition of home improvement.

AB 1070 (Gonzalez Fletcher, Chapter 662, Statutes of 2017) requires the Contractors State License Board (CSLB) in collaboration with the Public Utilities Commission (PUC) to develop a "solar energy system disclosure" document, as specified, which a solar energy system company will provide to a consumer prior to the sale, financing or leasing of a solar energy system; requires the CSLB to review complaints and consumer questions regarding solar companies and contractors; requires the CSLB, beginning January 1, 2019, to annually compile a report documenting consumer complaints and make it available on the CSLB and the PUC's Web Sites; and, further requires the PUC to develop standardized inputs and assumptions to be used in the calculation and presentation of electric utility bill savings, as specified.

AB 2699 (Gonzalez, 2016) would have required the CSLB to develop a disclosure form related to solar panel purchase, including information about financing, terms, rebates, risks, fees, where to file complaints, and related information. Specifies a solar energy systems company must provide the form to a consumer prior to completion of a sale, financing, or lease of a solar energy system. (Status: This bill was held in the Assembly Committee on Appropriations.)

AB 2693 (Dababneh, Chapter 618, Statutes of 2016) created the Property Assessed Clean Energy (PACE) Program Preservation and Consumer Protections Act by adding consumer protections to California's PACE Program.

ARGUMENTS IN SUPPORT: According to the *National Electrical Contractors Association*, "[This bill] will provide enhanced oversight by the Contractors State License Board (CSLB) over licensed contractors who perform residential photovoltaic installations. This is achieved by clarifying that the installation of a residential solar system is considered a home improvement, which affords homeowners enhanced protections under state law.

While many of our members responsibly perform residential photovoltaic installations, the practice of energy finance companies, aggressively targeting homeowners and not fully disclosing what the consumer will be responsible for is not a practice we endorse. Convincing customers to enter into Property Assessed Clean Energy (PACE) agreements without full disclosure that the loans to pay for these projects will be paid through increased property taxes and misleading consumers with promises of free solar and/or zero-dollar utility bills creates a blackeye for the industry overall.

Solar energy is an important tool in reaching the state's clean energy goals, but ignoring unscrupulous behavior to reach those goals is bad public policy. SB 757 provides needed oversight within the industry and for that reason we are in support of this measure."

Also writing in support is *Clean Power Alliance of Southern California (CPA),* CPA believes that customers should have a choice in how and where they get their energy, including the option to produce their own energy. CPA offers programs to support rooftop solar, including a net energy metering program, and an online Solar Marketplace to help customers make well-informed solar and battery storage decisions. While the vast majority of solar salespeople have helped customers navigate the process of installing solar, there are some bad actors that have misled customers into signing contracts for expensive or defective solar that they are unable to cancel. While all customers can fall victim, low-income, elderly, and non-native English speakers are disproportionately targeted.

This bill would create additional protections for customers by adding solar energy systems to the definition of home improvements, thereby ensuring that solar customers receive the same protections they would receive when working with a home improvement contractor. This includes contract cancellation rights, down payment security and contractor transparency. This bill helps to protect customers and the credibility of the solar industry, and we thank the author for her leadership."

REGISTERED SUPPORT:
Dolores Huerta Foundation (Sponsor)
American Subcontractors Association-California
California Community Banking Network
California State Association of Electrical Workers
Center for Community Action & Environmental Justice
Central Coast Alliance United for a Sustainable Economy
Clean Power Alliance of Southern California
Consumer Federation of California
Contractors State License Board
Dolores Huerta Foundation
National Electrical Contractors Association (NECA)

REGISTERED OPPOSITION:

None on file

Analysis Prepared by: Danielle Sires / B. & P. / (916) 319-3301

Date of Hearing: July 6, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 362 (Newman) – As Amended May 20, 2021

SENATE VOTE: 30-9

SUBJECT: Community pharmacies: quotas

SUMMARY: Prohibits a community pharmacy from establishing quotas to numerically measure or evaluate a pharmacist or pharmacy technician's performance of duties requiring a license.

EXISTING LAW:

1) Establishes the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000 *et seq.*)

2) Establishes the California State Board of Pharmacy (Board) to administer and enforce the Pharmacy Law, comprised of seven pharmacists and six public members. (BPC § 4001(a))

3) Defines "chain community pharmacy" as a chain of 75 or more stores in California under the same ownership. (BPC § 4001(c))

4) Provides that protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. (BPC § 4001.1)

5) Authorizes the Board to adopt rules and regulations as may be necessary for the protection of the public. (BPC § 4005)

6) Defines "pharmacy" as an area, place, or premises licensed by the Board in which the profession of pharmacy is practiced and where prescriptions are compounded. (BPC § 4037)

7) Declares pharmacy practice to be "a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes" and that "pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities." (BPC § 4050)

8) Authorizes a pharmacist to do all of the following, among other permissible activities, as part of their scope of practice:

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

    b) 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.

c) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies in coordination with the patient's primary care provider or diagnosing prescriber.

d) Administer immunizations pursuant to a protocol with a prescriber.

e) Furnish emergency contraception drug therapy, self-administered hormonal contraceptives, naloxone hydrochloride, HIV preexposure and postexposure prophylaxis, and nicotine replacement products, under certain conditions.

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

(BPC § 4052)

9) Prohibits a community pharmacy from requiring a pharmacist to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee is made available to assist the pharmacist at all times. (BPC § 4113.5)

10) Requires every pharmacy to establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. (BPC § 4125)

11) Imposes a maximum penalty of $2,000 for any person who knowingly violates any of the provisions of the Pharmacy Law, when no other penalty is provided, and in all other instances where a person violates the Pharmacy Law, imposes a maximum penalty of 1,000. (BPC § 4321)

12) Imposes a maximum penalty of $5,000 for any person who attempts to secure or secures licensure by making or causing to be made any false representations, or who fraudulently represents themselves to be registered. (BPC § 4322)

13) Imposes a maximum penalty of $5,000 for any person or entity who violates provisions of the Pharmacy Law governing outsourcing facilities. (BPC § 4129.5)

14) Authorizes any board to establish, by regulation, citations featuring administrative fines of no more than $5,000 for violations of the law. (BPC § 125.9)

THIS BILL:

1) Prohibits a community pharmacy from establishing a quota related to the duties for which a pharmacist or pharmacy technician license is required.

2) Prohibits a community pharmacy from communicating the existence of such quotas to pharmacists or pharmacy technicians who are employees of the community pharmacy or with whom the community pharmacy contracts, through employees, contractors, or third parties.

3) Defines "quota" as a fixed number or formula related to the duties for which a pharmacist or pharmacy technician license is required, against which the community pharmacy or its agent

measures or evaluates the pharmacist or pharmacy technician's performance of those duties in the community pharmacy.

4) Provides that "quota" includes a fixed number or formula related to any of the following:

   a) Prescriptions filled.

   b) Services rendered to patients.

   c) Programs offered to patients.

   d) Revenue obtained.

5) Exempts from the definition of "quota" any measurement communicated on an annual basis to a pharmacist or a pharmacy technician by a community pharmacy that documents the items sold, prescriptions filled, or services rendered during the preceding 12 months compared to other pharmacists and pharmacy technicians during the same period.

6) Authorizes the Board to take an enforcement action against a community pharmacy that violates the provisions of the bill unless, by clear and convincing evidence, the community pharmacy demonstrates that the violation was contrary to its policy.

7) Makes various findings and declarations regarding the practice of pharmacy within community pharmacy settings and why the establishment of quotas poses risk to patient safety and pharmacist morale.

FISCAL EFFECT: According to the Senate Committee on Appropriations, unknown, potentially significant fiscal impact to the Board of Pharmacy.

COMMENTS:

Purpose. This bill is co-sponsored by the United Food and Commercial Workers (UFCW) Western States Council and the California Pharmacists Association. According to the author:

> "SB 362 prohibits large retail chain pharmacies from imposing performance quotas on licensed pharmacists and pharmacy technicians. Imposing top-down, corporate-created work quotas on licensed pharmacists and pharmacy technicians elevates the pursuit of profits over the need to provide individualized, patient-centered care. These profit-driven quotas imperil the lives and health of Californians and pose an entirely unjustified risk to patients. They likewise impose degrading and demoralizing work conditions upon licensed healthcare professionals who we rely upon to be our last line of defense against medical errors and who are the essential and final part of ensuring that health care is delivered compassionately and effectively. SB 362 will ensure that pharmacists will be able to honor their oaths and make medical decisions based on patient needs."

Background.

In January 2021, the New York Times published an article titled "How Chaos at Chain Pharmacies Is Putting Patients at Risk." The article described how many pharmacists in large

chain pharmacies "struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients and call doctors and insurance companies, they said — all the while racing to meet corporate performance metrics that they characterized as unreasonable and unsafe in an industry squeezed to do more with less."[1] An NBC News article published in March 2021 similarly described issues relating to pharmacist burnout in chain pharmacies, largely resulting from the pressure of expectations that certain performance metrics be met. That article described one major retail pharmacy as "[giving] pharmacists a range of metrics to meet and monitors the time they spend on various tasks, from calls to patients to prescriptions filled and vaccinations given per week."[2]

In addition to creating stressful work environments for pharmacists and pharmacy technicians in chain pharmacies, there have been several articles discussing the use of numerical performance metrics at pharmacies indicate that the pressure of meeting quotas leads to increased medication errors. The potential risk to patients has led to calls for workplace reform in chain pharmacy settings where corporate employment of pharmacists may arguably result in undue financial interests overwhelming professional practice and judgment. While several major chain pharmacies have argued that they have actually reduced their use of performance metrics in recent years and that they do not impose what might be commonly understood as "quotas," there is a cogent argument to be made that expressly prohibiting numerical evaluations and measurements of pharmacy practice in chain settings would reduce risks to patient safety in busy pharmacy settings.

This bill would expressly prohibit community pharmacies—which are distinct from pharmacies in hospitals or state facilities and are commonly situated as "drug store" retailers—from establishing or communicating quotas relating to licensed services provided by pharmacists and pharmacy technicians. The bill does include exemptions from the definition of "quota" but would generally disallow any measurement or evaluation based solely on the quantification of a professional's performance of licensed services. The bill would generally authorize the Board to bring an action against a pharmacy for violating its provisions, which under current law could result in a maximum fine of $5,000.

Current Related Legislation. AB 1533 (Assembly Committee on Business and Professions) would extend the sunset date for the Board until January 1, 2026 and make additional technical changes, statutory improvements, and policy reforms in response to issues raised during the Board's sunset review oversight process. *This bill is pending in the Senate Committee on Business, Professions, and Economic Development.*

AB 1064 (Fong) would expand the authority of a pharmacist to initiate and administer immunizations to include any vaccine approved or authorized by the United States Food and Drug Administration (FDA) for persons 3 years of age and older. *This bill is pending in the Senate Committee on Business, Professions, and Economic Development.*

---

[1] https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html
[2] https://www.nbcnews.com/health/health-care/overworked-understaffed-pharmacists-say-industry-crisis-puts-patient-safety-risk-n1261151

ARGUMENTS IN SUPPORT:

The **United Food and Commercial Workers (UFCW) Western States Council** is co-sponsoring this bill. According to UFCW, "for the past decade, pharmacists have been sounding the alarm about imposed corporate benchmarks based on business metrics that create working conditions undermining their professional judgment and ability to provide care to their patients in the manner they see fit." UFCW argues that "with so many important, detail-oriented responsibilities to juggle, a pharmacist's only priority should be to provide the very best care to their patients.. Patients cannot be placed at greater risk by allowing corporations to impose performance-based quotas on highly educated, licensed healthcare professionals that have been entrusted with an ever-expanding role in California's healthcare delivery network."

The **California Pharmacists Association (CPhA)** is co-sponsoring this bill. CPhA states that "benchmarks and quotas are not conducive to the clinical practice of pharmacy and may actually inhibit a pharmacist's care for their patients. Additionally, many times it can be a patient safety issue. On top of all these quotas, pharmacists have to assist patients at drive thrus in the pharmacy, work at the register, call physicians and insurances, counsel their patients on new medications, recommend over-the-counter medications for patients, among other duties in the pharmacy."

ARGUMENTS IN OPPOSITION:

The **California Retailers Association (CRA)** and the **National Association of Chain Drug Stores (NACDS)** oppose this bill. According to the CRA and NACDS, "retail pharmacies in California are committed to the safety of their patients and employees. To safely reopen our nation, protect patients and keep Californians healthy, it is imperative that community pharmacies are permitted to utilize some form of metrics to evaluate the job performance of pharmacy team members."

AMENDMENTS:

1) Provide that a chain community pharmacy may communicate the existence of quotas that are not unlawful under the provisions of the bill.

2) Clarify the definition of "quota" to mean a fixed number or formula against which a chain community pharmacy measures or evaluates either the number of times an individual pharmacist or pharmacy technician performs tasks or provides services while on duty.

3) Revise and expand the bill's exemptions from the meaning of "quota" to exclude the following:

   A) A measurement of the revenue earned by a particular licensed chain community pharmacy not calculated in relation to or measured by the tasks performed or services provided by individual pharmacists or pharmacy technicians.

   B) Any evaluation or measurement of the competence, performance, or quality of care provided to patients of a pharmacist or pharmacy technician, so long as the evaluation does not use quotas as defined by the bill.

C) Any performance metrics required by state or federal regulators that do not use quotas as defined by the bill.

4) Expressly provide that the provisions of the bill do not prohibit a chain community pharmacy from establishing policies and procedures that assist in assessing the competency and performance of a pharmacist or pharmacy technician in providing care to patients, so long as the measurements are not or do not include quotas.

5) Add a severability clause.

REGISTERED SUPPORT:

United Food and Commercial Workers, Western States Council *(Co-Sponsor)*
California Pharmacists Association *(Co-Sponsor)*
California Alliance for Retired Americans
California Chronic Care Coalition
California Dental Association
California Labor Federation
California Medical Association
California Nurses Association
California Society of Health-System Pharmacists
California State Council of Service Employees International Union (SEIU)

REGISTERED OPPOSITION:

California Retailers Association
National Association of Chain Drug Stores

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301

Date of Hearing: July 6, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 306 (Pan) – As Amended June 23, 2021

SENATE VOTE: 31-7

SUBJECT: Sexually transmitted disease: testing

SUMMARY: Authorizes a pharmacist to dispense a drug to treat a sexually transmitted disease (STD) without the name of an individual for whom a drug is intended if the prescription includes the words "expedited partner therapy" or the letters "EPT." Provides pharmacists and health care providers immunity from civil, criminal, or administrative penalties when prescribing, dispensing, or furnishing, or rendering EPT. Requires health care professionals providing prenatal care or attending a birthing patient to provide syphilis screening and testing, as specified. Permits an HIV counselor to perform STD testing. Requires health care service plans and health insurance policies to provide coverage for home test kits for STD.

EXISTING LAW:

1) Establishes the Pharmacy Law, which governs the practice of the pharmacy profession in California. (Business and Professions Code (BPC) Section 4000 et seq.)

2) Prohibits a pharmacist from dispensing any prescription drug unless the container meets specified state and federal requirements and is correctly labeled with, among other items, the name of the patient or patients, the directions for the use of the drug, the condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription. (BPC Section 4076)

3) Permits a physician and surgeon who diagnoses a sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection in an individual patient to prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners. (Health and Safety Code (HSC) Section 120582(a))

4) Permits nurse practitioners, certified nurse-midwives, and physician assistants to dispense, furnish, or otherwise provide prescription antibiotic drugs to the sexual partner or partners of a patient with a diagnosed sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection without examination of the patient's sexual partner or partners. (HSC Section 120582(b))

5) Requires every licensed physician and surgeon engaged in prenatal care or attending at the time of delivery to obtain a blood specimen of the woman at the time of the first professional visit or within 10 days thereafter. (HSC Section 120685)

6) Authorizes an HIV counselor who meets specified requirements to perform any human immunodeficiency virus (HIV), hepatitis C virus (HCV) or combination HIV/HCV test that

is classified as waived under the federal Clinical Laboratory Improvement Act (CLIA). (HSC Section 120917(a))

7) Establishes the Department of Managed Health Care to regulate health plans and the California Department of Insurance to regulate health insurers. Requires health plans and health insurers providing health coverage in the individual and small group markets to cover, at a minimum, essential health benefits, as specified in federal and state law. (HSC Section 1341 et seq. and Insurance Code Section 10403 et seq.)

8) Establishes the Family Planning, Access, Care, and Treatment (Family PACT) program to provide "comprehensive clinical family planning services" to individuals who meet specified income requirements. (Welfare and Institutions Code Section 14105.181)

THIS BILL:

1) Names the existing practice of prescribing, dispensing, furnishing, or otherwise providing prescription antibiotic drugs to a patients' sexual partner or partners without examination of that patient's partner or partners as "expedited partner therapy", or EPT.

2) Authorizes a pharmacist to dispense a prescription drug and label the drug without the name of an individual for whom the drug is intended if the prescription includes the words "expedited partner therapy" or the letters "EPT."

3) States that if a health care provider is unable to obtain the name of a patient's sexual partner for a drug prescribed to treat an STD, the prescription shall include the words "expedited partner therapy" or the letters "EPT."

4) Declares that a pharmacists prescribing, dispensing, furnishing or rendering EPT shall not be liable nor subject to civil, criminal, or administrative action, sanction, or penalty for rendering EPT, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

5) Declares that a health care provider will not be liable in a medical malpractice action or professional disciplinary action for the use of EPT, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

6) Requires a pharmacist providing EPT to provide written notification describing the right of an individual who receives EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions.

7) States that nurse practitioners, certified nurse-midwives, and physician assistants may include EPT in their practice.

8) Mandates every health care professional engaged in providing prenatal care or attending a birthing patient at the time of delivery to provide syphilis screening and testing as outlined in the most recent guidelines published by the California Department of Public Health (CDPH).

9) Clarifies that a local health jurisdiction may provide additional recommendations or guidelines for syphilis screening and testing, and that a health care professional may follow the syphilis screening and testing recommendations or guidelines issued by local health authorities, as long as, at minimum, the health care professional complies with the testing and screening requirements established by this bill.

10) Authorizes an HIV counselor to perform CLIA-waived (rapid) STD testing.

11) Mandates HIV counselors performing any rapid HIV, HCV, or other STD testing to additionally complete a training course that has been approved by the Office of AIDS.

12) Prohibits HIV counselors from administering a rapid HIV, HCV, or STD test until they demonstrate proficiency in administering the test.

13) Requires HIV counselors certified prior to January 1, 2022, who will administer rapid STD tests, to obtain the necessary training. Prohibits HIV counselors from performing rapid STD tests until after completing the required training, unless they are also certified as a limited phlebotomist technician.

14) Defines a home test kit as a product designed, developed, and federally approved to allow individuals to collect specimens for STD testing remotely at a location outside of a clinical setting.

15) Requires every health plan contract issued, amended, renewed or delivered on or after January 1, 2022 to provide coverage for home test kits for STD, including the laboratory costs of processing the kit, that are deemed medically necessary or appropriate to and ordered directly by a clinician or furnished through a standing order for patient use based on clinical guidelines and individual health needs.

16) Requires a health insurance policy, excluding specialized health insurance policies, issued, amended, renewed or delivered on or after January 1, 2022, to provide coverage for home test kits for STD, including the laboratory costs of processing the kit, that are deemed medically necessary or appropriate to and ordered directly by a clinician or furnished through a standing order for patient use based on clinical guidelines and individual health needs.

17) Specifies that commercial health care plans are required to cover home test kits for STDs when ordered for an enrollee by an in-network provider. Further states that for Medi-Cal beneficiaries, these services shall be covered when ordered by an enrolled Medi-Cal provider.

18) Expands the scope of benefits in Medi-Cal and Family PACT to include home STD test kits for STDs, including the laboratory costs of processing the kit, that are deemed medically necessary or appropriate and ordered directly by an enrolled Medi-Cal or Family PACT clinician or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs.

19) Makes various findings and declarations regarding the impact of STDs on California communities, the health care costs associated with STDs, and the need for California to take

a comprehensive and robust approach to strengthen public health infrastructure to ensure access to STD coverage and care.

FISCAL EFFECT: According to the Senate Committee on Appropriations:

- California Department of Public Health Office of AIDS reports costs of $382,000 FY 2021-22 and $410,000 FY 2022-2023 (General Fund) for 3.0 positions to carry out the requirements of this bill if HIV test counselors are allowed to perform all CLIA-waived STI tests, including for herpes simplex virus and trichomonas.

- The Department of Managed Health Care estimates the total cost of this bill to be approximately $126,000 MCF and 0.6 PY in FY 2021-22, $217,000 MCF and 1.1 PYs in FY 2022-23, $126,000 MCF and 0.6 PY in FY 2023-24 and annually thereafter

- Medi-Cal & Family PACT reimbursement subject to appropriation. Unknown, potentially in the tens of millions General Fund and federal match

- Medi-Cal & Family Pact home tests & related costs of $30 million.

COMMENTS:

Purpose. This bill is sponsored by **APLA Health, Black Women for Wellness Action Project, Essential Access Health, Fresno Barrios Unidos, Los Angeles LGBT Center, and the San Francisco AIDS Foundation.** According to the author, "California has taken a robust approach to expanding access to health care. However, the state has lagged in enacting comprehensive policies to increase access to STD screening and treatment, and uninsured Californians lack a pathway to STD treatment. For example, while the Family PACT program includes STD services as a covered benefit, it's only for patients that are seeking family planning services.

California's EPT statute, the first in the nation, permits health care providers to treat the sex partners of patients diagnosed with STDs by providing prescriptions or medications to the patient to take to his/her partner without the health care provider first examining the partner. However, our EPT statute is underutilized because it lacks liability protections for providers who might otherwise be interested in integrating the evidence-based practice into their service delivery.

HIV Counselors, trained professionals working with some of our most vulnerable populations, can provide rapid testing for HIV and hepatitis, but cannot perform rapid tests for other common STDs.

Current law requires congenital syphilis screening in the first trimester of pregnancy, but without additional screening requirements, far too many cases go undetected.

Finally, during the pandemic, with undiagnosed cases of STDs rampant, access to home test kits, which would detect undiagnosed STDs, is limited due to coverage restrictions. The COVID-19 pandemic has exacerbated STD infection rates across the country, and this bill takes a comprehensive approach to address California's STD crisis by expanding access to STD care in an equitable way."

Background.

Sexually Transmitted Diseases. STDs are diseases or infections caused by bacteria, viruses, or parasites that are generally acquired through sexual contact. There are approximately dozens of STDs, including chlamydia, gonorrhea and syphilis. STDs may cause mild and severe symptoms, and can lead to severe health consequences if left untreated. STDs can increase the risk of human immunodeficiency virus (HIV) infection, cause chronic illness, infertility, or lead to pregnancy or newborn complications. In some circumstances, STDs do not show symptoms, and it is possible to be infected without knowing it – highlighting the importance of performing routine STD testing. It is also possible to contract an STD nonsexually, including from-mother-to-infant during pregnancy, childbirth, blood transfusions, or shared needles.

In April 2019, the Centers for Disease Control and Prevention (CDC) published data indicating that the annual cases of STDs in the United States continued to climb in 2019, reaching an all-time high for the sixth consecutive year. Among the findings, the CDC reported a nearly 30% increase in STDs between 2015 and 2019, and 2.5 million cases of chlamydia, gonorrhea and syphilis. The CDC notes that the sharpest increase was in cases of syphilis among newborns, which nearly quadrupled between 2015 and 2019.

In line with this national trend, California has also experienced a severe increase in STD infections. 2018 data from the California Department of Public Health shows a 45 percent increase in certain STDs over the last 5 years – including the largest increase in stillbirths related to congenital syphilis since 1995.

As the bill author notes, "the STD crisis affects communities across the state, but California youth, people of color, and gay, bisexual, and transgender people are disproportionately impacted. Statewide data indicate over half of all STDs in the state are experienced among California youth ages 15 – 24 years old. African Americans are 500% more likely to contract gonorrhea and chlamydia than their white counterparts. These disparities are expected to worsen during the COVID-19 pandemic. CDC studies suggest a range of factors may contribute to rising STD rates, including inequitable access to health care and culturally competent medical services, race, poverty, stigma, discrimination, and drug use."

In terms of U.S. health care costs, the CDC estimated that in 2018, chlamydia, gonorrhea, and syphilis combined accounted for $1.1 billion in direct medical costs, and that care for young people (ages 15-24) accounted for about 60% of these costs. New HIV infections cost $13.7 billion in direct lifetime medical costs, new HPV infections cost $755 million in direct lifetime medical costs, and all other STIs cost $1.4 billion in direct lifetime medical costs.

Expedited Partner Therapy. EPT is broadly defined as the clinical practice of treating the sex partner of a patient diagnosed with an STD by providing prescription medication to the patient to take to their partner or partners, without the health care provider first examining the partner. Although it is generally preferable that partners seek full clinical evaluation and treatment in a health care setting, EPT can be an effective method to treat a patient's partner if they are unable or unwilling to obtain medical care. But CDC evidence also suggests that EPT can decrease reinfection rates when compared with standard partner referrals for examination and treatment.

California law currently permits the practice of EPT: a physician and surgeon who diagnoses a sexually transmitted chlamydia, gonorrhea, or other sexually transmitted infection as determined by CDPH in an individual patient may prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners. In addition, nurse practitioners, certified nurse-midwives, and physician assistants may dispense, furnish, or otherwise provide prescription antibiotic drugs to the sexual partner or partners of a patient with a diagnosed STD without examination of the patient's sexual partner or partners.

According to the bill's sponsors, several challenges have been identified in delivering EPT to patients. For example, pharmacists do not have the ability to provide prescription antibiotic drugs to the sexual partner or partners of a patient without their names clearly identified on the prescription label. To address this barrier, this bill authorizes a pharmacist to dispense a prescription drug according to existing law and label the drug without the name of an individual if the prescription includes the words "expedited partner therapy" or the letters "EPT." To align this practice across the health care delivery system, SB 306 states that if a health care provider is unable to obtain the name of a patient's sexual partner for a drug intended for EPT use, the prescription must include the words "expedited partner therapy" or the letters "EPT." In addition, the bill requires a pharmacist to give written notification describing the right of an individual receiving EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions.

This bill also provides legal protections and immunity for health care providers providing EPT. SB 306 specifically prohibits civil, criminal, administrative action, sanction, or penalty against a pharmacist providing EPT, and protects health care providers from liability in a medical malpractice action or professional disciplinary action for the provider's use of EPT. SB 306 clarifies that this immunity is not absolute, and does not apply in cases of intentional misconduct, gross negligence, or wanton or reckless activity.

HIV Counselors. Existing law permits an HIV counselor who meets specified requirements to conduct rapid HIV and HCV testing. According to the author, HIV counselors, which are trained professionals working with California's most vulnerable populations, can provide rapid testing for HIV and hepatitis, but are not authorized to perform rapid tests for other common STDs. This bill would authorize an HIV counselor to perform specified STD tests, if the HIV counselor meets all existing statutory requirements and completes a training course that has been approved by the Office of AIDS.

Congenital Syphilis Screening. Congenital syphilis (CS) is a disease that occurs when a mother with syphilis passes the infection on to her baby during pregnancy. The CDC notes that CS can cause miscarriage, stillbirth, prematurity, low birth weight, or death shortly after birth. In 2018, CDPH reported a 900% increase in CS in California from 2012. As a result, California STD screening recommendations are aligning with national guidelines, which recommend all pregnant patients to receive syphilis screening at the first prenatal visit, with additional screening in the third trimester and at delivery of those with identified risk, including in communities and populations with high syphilis prevalence.

SB 306 codifies those recommendations, and requires every licensed health care professional engaged in providing prenatal care or attending a birthing patient at the time of delivery to

provide syphilis screening and testing as outlined in the most recent CDPH guidelines. The bill also clarifies that that this provision does not limit a local health jurisdiction to provide additional recommendations or guidelines for syphilis screening and testing, as long as the minimum testing and screening requirements established by the bill are complied with.

STD Home Test Kits. This bill requires every health plan contract and specific health insurance policies issued, amended, renewed or delivered on or after January 1, 2022 to provide coverage for home test kits for STD, including the laboratory costs of processing the kit, that are deemed medically necessary or appropriate to and ordered directly by a clinician or furnished through a standing order for patient use based on clinical guidelines and individual health needs. The California Health Benefits Review Program notes in its analysis that currently, an estimated 7% of enrollees in regulated health plans and policies have coverage for STD home test kits.

Prior Related Legislation.

AB 2280 (Leno, Chapter 771, Statutes of 2006) – Extended existing law that permits a physician or nurse practitioner, who diagnoses a sexually transmitted chlamydia infection, to prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners, to cover gonorrhea or other sexually transmitted disease infection, as determined by the CDPH.

ARGUMENTS IN SUPPORT:

Supporters note that this measure seeks to address the alarming rise of sexually transmitted infection rates in California – which has been exacerbated by the COVID-19 pandemic – by expanding access to STI prevention, testing and treatment statewide. Supporters argue that California must invest in strengthening our public health infrastructure and expanding access to STD services to communities most impacted by the STD crisis.

ARGUMENTS IN OPPOSITION:

The California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans collectively write in opposition: "[SB 306] will increase costs, reduce choice and competition, and further incent some employers and individuals to avoid state regulation by seeking alternative coverage options […] Large employers, unions, small businesses and hard-working families value their ability to shop for the right health plan – at the right price – that best fits their needs. Benefit mandates impose a one-size-fits-all approach to medical care and benefit design driven by the legislature, rather than consumer choice. [SB 306] will lead to higher premiums, harming affordability and access for small businesses and individual market consumers."

The California Chamber of Commerce writes in opposition: [SB 306] would require health care service plans to provide coverage for home test kits for sexually transmitted diseases as well as their associated laboratory processing costs. This mandate will cause health care premiums to rise for employers and employees in order to cover the cost of the coverage. California businesses have suffered staggering financial setbacks as a result of the COVID-19 pandemic and this bill will only add to that struggle by piling another expense onto employers who are trying to rebuild."

REGISTERED SUPPORT:

Access Reproductive Justice
Access Support Network
AIDS Healthcare Foundation
Alliance of Californians for Community Empowerment Action
American Academy of Pediatrics, California
APLA Health
Bienestar Human Services
Biocom California
Black Women for Wellness Action Project
Buen Vecino
Business & Professional Women of Nevada County
California Academy of Family Physicians
California Academy of Physician Assistants
California Association for Nurse Practitioners
California Black Health Network
California Hepatitis Alliance
California Latinas for Reproductive Justice
California LGBTQ Health and Human Services Network
California Life Sciences
California Nurse-midwives Association
California Pharmacists Association
California Physicians Alliance
California Society of Health-System Pharmacists
California State Board of Pharmacy
California Women's Law Center
CaliforniaHealth+ Advocates
Citizens for Choice
Community Clinic Association of Los Angeles County
County Health Executives Association of California
Courage California
Desert AIDS Project
Desert Aids Project D/b/a DAP Health
End Hep C SF
End the Epidemics: Californians Mobilizing to End HIV, Viral Hepatitis, STIs, and Overdose
Essential Access Health
Fresno Barrios Unidos
Harm Reduction Coalition
Harm Reduction Services
HIVE
Los Angeles LGBT Center
NARAL Pro-choice California
National Health Law Program
Plan C
Planned Parenthood Affiliates of California
Religious Coalition for Reproductive Choice California

San Francisco AIDS Foundation
Team Lily
The Los Angeles Trust for Children's Health
The Source LGBT+ Center
The Women's Foundation of California
Via Care Community Health Center
Western Center on Law & Poverty.
Women's Foundation California

REGISTERED OPPOSITION:

America's Health Insurance Plans
Association of California Life & Health Insurance Companies
California Association of Health Plans
California Chamber of Commerce

Analysis Prepared by: Patrick Le / B. & P. / (916) 319-3301

Date of Hearing: July 6, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 263 (Rubio) – As Amended June 28, 2021

SENATE VOTE: 38-0

SUBJECT: Real estate applicants and licensees: education requirements: fair housing and implicit bias training

SUMMARY: Requires the Department of Real Estate (DRE) to include an interactive participatory component within its three-hour course in fair housing, as part of its requirement for licensees to complete 45 hours of continuing education (CE). Requires a licensee, as part of the licensee's necessary 45 hours of CE, to successfully complete a two-hour course in implicit bias training.

EXISTING LAW:

1) Establishes the Department of Real Estate (DRE). (Business and Professions Code (BCP) § 10004 et seq.)

2) Requires the DRE Commissioner adopt regulations on a definition of basic requirements for continuing education of 45 clock hours of attendance at approved educational courses, seminars, workshops, or conferences, or their equivalent, achieved during a four-year period preceding license renewal, a basis and method for qualifying educational programs. (BPC § 10170.5 (a))

3) Requires that a real estate license not be renewed unless the applicant successfully completes 45 hours of CE, including all of the following (BPC § 10170.5 (a)):

    a) Three-hour course in ethics, professional conduct, and legal aspects of real estate (BPC § 10170.5 (a)(1));

    b) Three-hour course in agency relationships and duties in a real estate brokerage practice, including instruction in the disclosures to be made and the confidences to be kept in the various agency relationships between licensees and parties to real estate transactions (BPC § 10170.5 (a)(2));

    c) Three-hour course in trust fund accounting and handling (BPC § 10170.5 (a)(3));

    d) Three-hour course in fair housing (BPC § 10170.5 (a)(4));

    e) Three-hour course in risk management, including but not limited to principles, practices, and procedures calculated to avoid errors and omissions in the practice of real estate licensed activities (BPC § 10170.5 (a)(5));

f) Requires licensees to complete a three-hour course in management of real estate offices and supervision of real estate licensed activities, as defined (BPC § 10170.5 (a)(6));

g) Requires that 18 of the CE hours related to consumer protection shall include, but not be limited to, being related to forms of real estate financing relevant to serving consumers in the marketplace, land use regulation and control, pertinent consumer disclosures, agency relationships, capital formation for real estate development, fair practices in real estate, appraisal and valuation techniques, landlord-tenant relationships, energy conservation, environmental regulation and consideration, taxation as it relates to consumer decisions in real estate transactions, probate and similar disposition of real property, governmental programs such as revenue bond activities, redevelopment, and related programs, business opportunities, mineral, oil, and gas conveyancing, and California law that relates to managing community associations that own, operate, and maintain property within common interest developments, including, but not limited to, management, maintenance, and financial matters addressed in the Davis-Stirling Common Interest Development Act. (BPC § 10170.5 (a)(7))

h) Other courses and programs that will enable a licensee to achieve a high level of competence in serving the objectives of consumers who may engage the services of licensees to secure the transfer, financing, or similar objectives with respect to real property, including organizational and management techniques, including relevant information to assist a salesperson or broker in understanding how to be effectively supervised by a responsible broker or branch manager, that will significantly contribute to this goal. (BPC § 10170.5 (a)(8))

4) Requires that a real estate license shall not be renewed unless the DRE Commissioner finds the applicant has completed 45 hours of CEs over a four-year period, including an eight-hour survey course on the subjects listed above. (BPC § 10170.5 (a)(8)(b))

5) Establishes "successful completion" of a course as passing a final examination. (BPC § 10170.5 (a)(8)(d))

THIS BILL:

1) Requires a three-hour course in fair housing that shall include an interactive participatory component that allows a licensee to experience role-play situations as both a consumer and a professional licensee.

2) Requires that applicants complete a two-hour course in implicit bias training that includes both a component regarding the impact of implicit bias, explicit bias, and systemic bias on consumers historical and social impacts of those biases and; actionable steps licensees can take to recognize and address their own implicit biases.

3) Requires an applicant for a real estate broker or salesperson license to additionally complete a course in fair housing.

4) Changes the eight-hour survey course described above to a nine-hour survey course

FISCAL EFFECT: Unknown. This bill is keyed fiscal by Legislative Counsel.

COMMENTS:

Purpose. The *California Association of Realtors* is the Sponsor of the bill. According to the Author, "[This bill] will help correct generations of bias against people of color in housing practices by requiring real estate professionals to take implicit bias training as a pre-licensing requirement and a continuing education requirement. Owning a home is one of the most common pathways for families to establish financial stability for themselves and future generations. Unfortunately, the homeownership gap for people of color is real in California. Reports show that the Black homeownership rate and the Latino homeownership rate are far lower than California's overall homeownership rate. By including implicit bias training as a licensing requirement, [this bill] will help real estate professionals be better equipped to recognize and disrupt their implicit biases, allowing them to ensure the dream of homeownership can be achieved regardless of color."

Background. *Continuing Education for Real Estate Licensees*. Real estate brokers and salespersons must currently complete 45 hours of CE by attending educational courses, seminars, workshops, or conferences, or their equivalent, within a four-year period preceding license renewal application. Within those 45 hours, licensees must complete an eight-hour survey course on topics including: ethics, professional conduct, and legal aspects of real estate; agency relationships and duties in a real estate brokerage practice; trust fund accounting and handling; fair housing; risk management; and management of real estate offices and supervision of real estate licensed activities, among other topics.

DRE does not create or provide any courses through the department. DRE merely approves CE courses on a permissive basis.

Implicit Bias and Professions. According to the Stanford Encyclopedia of Philosophy, "implicit bias" can be described as "a term of art referring to relatively unconscious and relatively automatic features of prejudiced judgment and social behavior." In her 2019 book Biased: Uncovering the Hidden Prejudice That Shapes What We See, Think, and Do, Dr. Jennifer L. Eberhardt explains that "implicit bias is not a new way of calling someone a racist. In fact, you don't have to be a racist at all to be influenced by it. Implicit bias is a kind of distorting lens that's a product of both the architecture of our brain and the disparities in our society." Dr. Eberhardt goes on to describe how "bias is not limited to one domain of life. It is not limited to one profession, one race, or one country. It is also not limited to one stereotypic association."

In December 2015, the American Journal of Public Health published a systematic review titled Implicit Racial/Ethnic Bias Among Health Care Professionals and Its Influence on Health Care Outcomes. The review concluded that "most health care providers appear to have implicit bias in terms of positive attitudes toward whites and negative attitudes toward people of color." Additional studies have been published suggesting that implicit bias in regards to gender, sexual orientation and identity, and other characteristic has resulted in inconsistent diagnoses and courses of treatment being provided to patients based on their demographic. These trends take

into account not only the characteristics of the person being treated, but those of the licensed professional in correlation to that patient.

Implicit Bias in Real Estate: Long Island Undercover Investigation, the National Association of Realtors Workshop, and New York State Legislature Response. In December of 2019, Newsday published the results of a three-year, undercover investigation in Long Island by Newsday that found evidence of unequal treatment of Long Island residents—19% of the time against Asian Americans, 39% of the time against Hispanic Americans, and 41% of the time against Black Americans. Among other findings, the report states that real estate agents frequently directed white customers to areas with the highest white representation, and minority customers to more integrated areas. In response to this, in 2020 the National Association of Realtors (NAR) and the Perception Institute in New York developed a 50-minute, online training workshop to help members avoid implicit bias. In February 2021, the New York State Senate introduced 11 bills aimed at addressing bias and providing implicit bias training for real estate agents.

Implicit Bias in Real Estate: California. The Author provides a number of statistics to illustrate the need for implicit bias training in the real estate profession in California. According to a 2020 report by the Greenlining Institute, in California Black homeownership rate in California was only 35% and the Latino homeownership rate in California was only 42%. California's overall homeownership rate was calculated at 54.8% in 2017. In a 2018 study, the Brookings Institute found that similar homes in neighborhoods with similar amenities are worth 17.1% less in the Los Angeles area and 27.1% less in the San Francisco Bay area if these homes are located in Black-majority neighborhoods than if they are located in other neighborhoods.

Current Related Legislation. AB 948 (Holden) requires the Bureau of Real Estate Appraisers (BREA) to provide notice to multiple parties that a buyer is entitled to an unbiased appraisal of the property; requires the BREA to provide a check box on a complaint form asking if that person believes that the opinion of the value of the real estate is below market value; requires the BREA to collect demographic information and other relevant information to review the appraiser's practices; and, requires appraisers to complete continuing education (CE) on cultural competency. This bill is currently scheduled to be heard in Senate Judiciary Committee.

Prior Related Legislation. SB 464 (Mitchell, Chapter 533, Statutes of 2019) requires hospitals and alternative birth centers or primary care clinics that provide perinatal care to implement an implicit bias program for all health care providers involved in perinatal care of patients.

AB 242 (Kamlager-Dove, Chapter 418, Statutes of 2019) requires implicit bias training for all judges, judicial officers, and attorneys.

AB 243 (Kamlager-Dove) would have required peace officers to undergo training that includes and examines evidence-based patterns, practices, and protocols that make up racial and identity profiling, including implicit bias. (Status: This bill was held under submission in the Senate Committee on Appropriations)

AB 2626 (Jones-Sawyer) of 2016 would have required the Commission on Peace Officer Standards and Training to develop and disseminate training on procedural justice and implicit bias for all peace officers, and to incorporate procedural justice and implicit bias training into its

basic training by no later than June 1, 2018. (Status: This bill was held under submission in the Assembly Committee on Appropriations)

ARGUMENTS IN SUPPORT:

According to *Zillow*, "Zillow strongly believes in the importance of working with knowledgeable and effective real estate licensees to ensure that consumers are protected throughout the home buying and selling process.

Under current law, real estate licensees are required to complete a three-hour fair housing course that is part of 45 mandatory hours of continuing education for real estate license renewals. We understand and appreciate the importance of having real estate industry professionals who are well-versed in fair housing requirements. We also believe that requiring a course in implicit bias training that educates licensees on the impact of bias on consumers, as well as actionable steps they can take to recognize and address their own implicit biases, would help bring important new perspectives and expertise to the industry in California.

Housing across California remains a complex issue, and providing individuals with training in fair housing and implicit bias would help ensure that these important perspectives are more widely represented and reflected throughout the industry. Most importantly, bolstering these perspectives would help ensure that California's real estate industry more accurately reflects the needs and perspectives of all Californians."

REGISTERED SUPPORT:
California Association of Realtors (Sponsor)
Zillow Group

REGISTERED OPPOSITION:
None on file

Analysis Prepared by: Danielle Sires / B. & P. / (916) 319-3301Analysis Prepared by: Danielle Sires / B. & P. / (916) 319-3301

Date of Hearing: July 6, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 524 (Skinner) – As Amended June 28, 2021

NOTE: This bill is double referred and passed the Assembly Committee on Health on June 23, 2021, by of a vote of 11-1-3.

SENATE VOTE: 39-0

SUBJECT: Health care coverage: patient steering

SUMMARY: Prohibits a health plan, a health insurer, a self-insured employer plan, or respective agent, including a pharmacy benefits manager (PBM), from engaging in patient steering, including communicating to an enrollee or insured that they are required to use a particular pharmacy or offering health care coverage contracts or policies that include provisions that limit access to only pharmacy providers that are owned or operated by the health plan, health insurer, self-insured employer plan, or agent.

EXISTING LAW:

1) Licenses and regulates the practice of pharmacy, including pharmacists, pharmacies, and wholesalers of medical drugs and devices under the Pharmacy Law. (Business and Professions Code (BPC) § 4000-4427.8)

2) Establishes the California Board of Pharmacy to administer and enforce the Pharmacy Law. (BPC § 4001)

3) Establishes requirements and processes for the audits of pharmacy benefits and PBMs. (BPC §§ 4430-4441)

4) Defines "carrier" as a health care service plan, as defined in the Health and Safety Code, or a health insurer that issues policies of health insurance, as defined in Section 106 of the Insurance Code. (BPC § 4430(a); Health and Safety Code (HSC) § 1345; Insurance Code (INS) § 106)

5) Defines "health benefit plan" as any plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. "Health benefit plan" includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in the HSC, and a policy of health insurance, as defined in the INS, issued by a health insurer. (BPC § 4430(d); HSC § 1345; INS § 106)

6) Defines "pharmacy benefit manager" as a person, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or

grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs. (BPC § 4430(g))

7) Provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and the regulation of health insurers by the Department of Insurance. (HSC § 1340-1399.864; INS § 740-742.1)

8) Requires a health care service plan contract or health insurance policy that provides coverage for outpatient prescription drugs to cover medically necessary prescription drugs. (HSC § 1342.71(c))

THIS BILL:

1) Prohibits a health plan, a health insurer, a self-insured employer plan, or respective agent, including a PBM, from engaging in patient steering.

2) Defines "patient steering" as either of the following:

   a) Communicating to an enrollee or insured, verbally, electronically, or in writing, that they are required to have a prescription dispensed at, or pharmacy services provided by, a particular pharmacy or pharmacies if there are other pharmacies in the network that have the ability to dispense the medication or provide the services.

   b) Offering or including in contract or policy designs for purchasers of group health care coverage provisions that limit enrollees' or insureds' access to only those pharmacy providers that are owned or operated by the self-insured employer plan or self-insured employer plan's agent, or owned or operated by a corporate affiliate of the self-insured employer plan or self-insured employer plan's agent.

3) Excludes from the definition of "patient steering" the act of directing an enrollee or insured to a specific pharmacy for a specific prescription due to the need for special handling or clinical requirements that cannot be performed by other pharmacies in the provider network of the health care service plan, a health insurer, self-insured employer plan or self-insured employer plan's agent.

4) Provides that the requirements under this bill do not prevent a health plan, a health insurer, a self-insured employer plan, or respective agent, from offering enrollees or insureds financial incentives to use a particular pharmacy, including, but not limited to, reductions in copays or other financial incentives given to the enrollee or insured when the prescription is dispensed.

5) Prohibits a health plan, a health insurer, a self-insured employer plan, or respective agent, from prohibiting an in-network pharmacy from offering to match the financial incentives offered to an enrollee or insured.

6) Excludes from the provisions of the bill a self-insured employer plan administered by a health care service plan or its health insurer affiliate that is part of a fully integrated delivery system in which enrollees, including enrollees in a self-insured employer plan administered by the health care service plan or its health insurer affiliate, primarily use pharmacies that are

entirely owned and operated by the health care service plan and the enrollees, including enrollees in a self-insured employer plan administered by the health care service plan or its health insurer affiliate, may use any pharmacy in the self-insured employer plan's network that has the ability to dispense the medication or provide the services.

7) Makes various finding and declarations, including that evidence shows that limiting access to pharmacy providers is designed to eliminate competition and can result in higher costs for the patient and for the health care system as a whole and can result in patients losing connection with trusted providers and being unable to get the advice and consultation they need.

FISCAL EFFECT: According to the Senate Committee on Appropriations analysis of the June 14, 2021, version of this bill:

The Department of Managed Health Care (DMHC) anticipates the total cost of this bill to be approximately $95,000 and 0.5 personnel year (PY) in fiscal year (FY) 2021-22, $301,000 and 1.6 PYs in FY 2022-23, $288,000 and 1.6 PYs in 2023-24, and $72,000 and 0.4 PY in FY 2024-25 and ongoing annually thereafter (Managed Care Fund). A breakdown of DMHC's anticipated costs is as follows:

- Office of Legal Services short-term workload costs to conduct legal research and issue legal memorandums to clarify requirements: $226,000 and 1.2 PYs in FY 2022-23 and $216,000 and 1.2 PYs in FY 2023-24.
- Office of Plan Licensing workload costs to address review health plan documents, including Evidence of Coverages, provider contracts, and other disclosure forms: $44,000 and 0.2 PY in FY 2021-22, $22,000 and 0.1 PY in FY 2022-23, $21,000 and 0.1 PY in 2023-24 and ongoing annually thereafter.
- Office of Enforcement workload costs to address referrals: $51,000 and 0.3 PY in FY 2021-22, $53,000 and 0.3 PY in FY 2022-23, $51,000 and 0.3 PY in FY 2023-24 and ongoing annually thereafter.

The California Department of Insurance anticipates costs of $29,000 in FY 2021-22, $65,000 in FY 2022-23, and $53,000 ongoing (Insurance Fund) to address a potential increase in enforcement workload.

COMMENTS:

Purpose. This bill is sponsored by the *California Pharmacists Association.* According to the author, "patients are safer and better served when they can fill their prescriptions with pharmacists they know, who are familiar with their unique medical history, and who speak their language and have cultural competency. However, through a practice known as patient steering, pharmacy PBMs inform patients that they must have their prescriptions filled at a select pharmacy or pharmacies—usually a retail or mail order pharmacy owned by the PBM or health plan—even though there are other pharmacies in the network that the patient wishes to use and which can safely fill the prescription. Patients risk not having their prescription filled or having to pay out-of-pocket if they do not use the PBM's selected pharmacy. Requiring patients to use a select retail or mail order pharmacy can harm patients, including those who do not live near the retail pharmacy and those who cannot get their prescriptions delivered due to logistical reasons or privacy concerns if their package is intercepted. This bill prohibits patients from being

required to use a particular pharmacy when there is no clinical reason they must do so and ensures that patients can access whichever pharmacy in their network they prefer."

Background. A PBM is any person or entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer. Coverage management includes the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

PBMs negotiate the prices of prescription drugs, create and manage formularies, and several other functions key to the management of pharmacy benefits. PBM's interact with many parties in the pharmaceutical industry, including drug manufacturers, health plans and insurers, and pharmacies. This bill would prohibit those parties from unilaterally steering patients away from certain pharmacies or towards any particular pharmacy with limited exceptions.

Specialty Drugs and Clinical Requirements. There are some drugs and pharmaceuticals that require special storage and handling conditions or active patient management. As a result, some pharmacies must maintain special equipment, pharmacists with special qualifications, or other conditions that allow for the safe dispensing of specialty drugs. This bill contains a provision that allows the steering of a patient to specified pharmacies if other in-network pharmacies are unable to meet the special handling or clinical requirements of any drug.

Prior Related Legislation. AB 1803 (Committee on Health), Chapter 114, Statutes of 2019 required a pharmacy to inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, except as specified, and, if the customer pays the retail price, requires the pharmacy to submit the claim to the customer's health plan or health insurer beginning January 1, 2020.

AB 315 (Wood), Chapter 905, Statutes of 2018 required PBMs to register with the DMHC, to exercise good faith and fair dealing, and to disclose, upon a purchaser's request, information with respect to prescription product benefits, as specified.

SB 17 (Hernandez), Chapter 603, Statutes of 2017 required health plans and insurers that offer commercial products and file rate information with the DMHC or CDI to annually report specific information related to the costs of covered prescription drugs.

AB 2752 (Nazarian) of 2016, which was held in the Assembly Committee on Appropriations, would have required a health plan or a health insurer to annually notify an enrollee or insured that the enrollee's or insured's drug treatment or provider is no longer covered by the plan or policy.

AB 2400 (Nazarian) of 2016, which was held in the Assembly Committee on Appropriations, would have required health plans and health insurers to comply with a shortened internal grievance review process for formulary drugs.

AB 374 (Nazarian), Chapter 621, Statutes of 2015 authorized a request for an exception to a health plan's or health insurer's step therapy process for prescription drugs to be submitted in the same manner as a request for prior authorization for prescription drugs. Requires the health plan or insurer to treat, and respond to, the request in the same manner as a request for prior authorization for prescription drugs.

AB 339 (Gordon), Chapter 619, Statutes of 2015 required health plans and health insurers that provide coverage for outpatient prescription drugs to have formularies that do not discourage the enrollment of individuals with health conditions, and requires combination antiretrovirals drug treatment coverage of a single-tablet that is as effective as a multitablet regimen for treatment of Human immunodeficiency virus infection and acquired immune deficiency syndrome, as specified.

ARGUMENTS IN SUPPORT:

The sponsor of this bill, the *California Pharmacists Association (CPhA)*, "Patient steering occurs when a PBM moves a patient's prescription to a different pharmacy without their consent and that new pharmacy happens to be owned by the PBM – either a physical location or a mail-order pharmacy. Patients are then given a 'choice' of filling their covered prescriptions at the new pharmacy or pay full price out of pocket at the existing in-network pharmacy. The practice of patient steering is becoming increasingly problematic for patients who are losing their right to receive pharmacy services at locations convenient to them and/or where they have an established relationship with the pharmacist. While this practice happens primarily in the independent setting, it is increasingly happening in smaller chain settings who are not owned by PBMs…. While CPhA believes there is a role for pharmacy benefit managers, the problem lies with the inherent conflict of interest when a PBM is steering patients to their own pharmacies. It is at that point we must question whether decisions are made for the benefit of the patient or simply to increase profit margins."

APLA Health writes in support:

> Forcing patients to use a mail-order pharmacy or alternative pharmacy location can destroy the critical relationship between patients and their pharmacists who know them personally, including their medical history and any issues that may impact medication adherence. For many patients, their pharmacists are an indispensable resource to monitor drug-drug interactions and provide ongoing education and adherence support. Trusted pharmacists are also often the best source of accurate information about medication efficacy and side effects, which remain among the most persistent challenges to increasing uptake of HIV prevention medications.
>
> Mail-order pharmacies can also result in significant privacy and safety issues for some clients, including youth and others living in congregate settings, people experiencing domestic violence, people living in rural areas and others who may need to protect their confidential medical information. If these individuals do not have the option to discreetly pick up their medication at their local pharmacy, medications arriving via mail-order may be intercepted by someone who is not aware of their medical condition – threatening their housing, employment or even

physical security. These concerns are particularly salient for LGBTQ individuals, who may not be out to friends and family and could face stigma, discrimination, rejection and violence should their sexual orientation and/or gender identity be revealed.

ARGUMENTS IN OPPOSITION:

The *Pharmaceutical Care Management Association* writes in opposition:

> [This bill] seeks to expand the ability of non-specialty pharmacies to dispense specialty drugs which will increase costs for health plans and patients but, more importantly, put patients at risk.
>
> Under the guise of prohibiting so-called 'patient steering,' [this bill] would expand the ability of any network pharmacy to dispense a specialty drug even though that pharmacy even though it may not be under contract as a specialty network pharmacy. Qualifying as a network specialty pharmacy entails significantly more than agreeing to financial terms. Network specialty pharmacies meet independent, nationally recognized accreditation standards established by organizations such as the Joint Commission and the Utilization Review Accreditation Commission (URAC), which ensure quality services and patient safety.
>
> The latest amendments to the bill are confusing and deeply troublesome. First, the language confuses patient cost share with pharmacy reimbursement. First, a pharmacy (whether in network or not) has no influence over a patient's cost-sharing amounts/incentives as spelled out in their health plan. That decision is made by the health plan sponsor. Second, it is unclear as to whether the intent is to (a) allow patients to go to any pharmacy, thus eliminating the ability to create cost-saving pharmacy networks, or (b) prohibit pharmacy tiers, which lower costs for plans and patients. The amendment would eliminate any incentive for network pharmacies to offer discounted reimbursements to be in a preferred tier, resulting in higher costs for everyone.
>
> Furthermore, [this bill] would permit a network pharmacy not accredited or contracted as a specialty network pharmacy to dispense specialty drugs, putting patients at risk. The lack of acceptance of our proposed clarifying language related to 'specialty pharmacy,' coupled with the author's amendment, reveals the intended expansion of scope for retail pharmacies. Not only is this bill a concerning expansion of scope from a pharmacy practice perspective, but it also fails to protect Californians. This bill would expand a pharmacy's scope without ensuring patient and drug safety as a component of dispensing specialty drugs. Simply being a network pharmacy would be sufficient to act as a network specialty pharmacy under this bill

The *California Association of Health Plans (CAHP),* the *Association of California Life and Health Insurance Companies (ACLHIC),* and *America's Health Insurance Plans (AHIP)* write in opposition, "Health plans, insurers, and their contracted pharmacy benefit managers (PBMs)

design pharmacy networks with the consumer in mind. They contract with chain, independent, and mail order pharmacies to provide consumers with the choice of services that best fit their needs. They design preferred networks that allow patients to have access to high performing, lower cost options. All of this is done with the consumer's safety in mind – the pharmacy programs created by health plans, insurers, and PBMs are able to look across all of the patients' pharmacy activity to flag potential interactions, provide counseling for patients with chronic conditions, and suggest lower-cost alternatives. By focusing on pharmacies that provide cost-effective and high-quality care, health plans and insurers are ensuring consumers receive the best value for their health care dollars. [This bill] threatens these safety and cost saving measures. We are concerned that this bill would erode the use of 'preferred' networks that provide patients with additional cost saving measures."

AMENDMENTS:

1) *Incentive Matching*. There are questions raised about the impact of prohibiting in-network pharmacies from matching financial incentives on the overall benefit design process and downstream impacts on consumer premiums. Because those questions are largely outside the jurisdiction of this Committee, the bill should be amended to delete the language inserted after the bill passed the Assembly Committee on Health on June 28, 2021.

   On pages 3-4 of the bill, strike lines 36-39 and 1-2, on page 5, strike lines 3-7, and on page 6, strike lines 3-6:

   ~~(2) Notwithstanding paragraph (1), a self-insured employer plan or the agent of a self-insured employer plan shall not prohibit an in-network pharmacy from offering to match the financial incentives offered to an insured of the self-insured employer by the self-insured employer plan or its agent, as set forth in this subdivision.~~

2) *Offering Incentives.* To clarify that financial incentives being offered to enrollees or insureds can be affirmatively communicated by the offeror, the bill should be amended as follows:

   On page 3, lines 30-35, on pages 4-5, lines 37-39 and 1-2, and on pages 5-6, lines 37-39 and 1-2 insert "and communicating to" after "offering":

   (d) ~~(1)~~ This chapter does not prevent a self-insured employer plan or the agent of a self-insured employer plan from offering *and communicating to* enrollees or insureds financial incentives to use a particular pharmacy, including, but not limited to, reductions in copays or other financial incentives given to the enrollee or insured when the prescription is dispensed.

REGISTERED SUPPORT:

AfA Specialty Pharmacy Association
Aids Healthcare Foundation
APLA Health
California Chronic Care Coalition
California Dental Association
California Medical Association

California Nurses Association
Consumer Attorneys of California
Indian Pharmacists Association of California
National Multiple Sclerosis Society
United Nurses Associations of California

REGISTERED OPPOSITION:

America's Health Insurance Plans
American GI Forum Education Foundation of Santa Maria, California
Association of California Life & Health Insurance Companies
Black Chamber of Orange County
Breckpoint, Inc.
California African American Chamber of Commerce
California Association of Health Plans
California Business Roundtable
California Chamber of Commerce
California Hispanic Chambers of Commerce
California State Association of Electrical Workers
California State Pipe Trades Council
League of United Latin American Citizens
National Association for the Advancement of Colored People, Santa Maria-Lompoc Branch
National Latina Business Women Association of Los Angeles
Orange County Hispanic Chamber of Commerce
Pharmaceutical Care Management Association
San Diego County Hispanic Chamber of Commerce
Sheet Metal Workers' Local Union No. 104
Southwest California Legislative Council
Western States Council Sheet Metal, Air, Rail and Transportation

Analysis Prepared by: Vincent Chee / B. & P. / (916) 319-3301

Date of Hearing: July 6, 2021

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 509 (Wilk) – As Amended June 21, 2021

SENATE VOTE: 38-0

SUBJECT: Optometry: COVID-19 pandemic: temporary licenses

SUMMARY: Requires the California State Board of Optometry (Board) to issue a temporary license to practice optometry to applicants who are unable to meet certain examination requirements due to the state of emergency declared in response to the COVID-19 pandemic.

EXISTING LAW:

1) Establishes the Board for the licensure and regulation of optometrists, registered dispensing opticians, contact lens dispensers, spectacle lens dispensers, and nonresident contact lens dispensers. (Business and Professions Code (BPC) §§ 3000 *et seq.*)

2) Makes it unlawful for a person to engage in or advertise the practice of optometry without having first obtained an optometrist license from the Board. (BPC § 3040)

3) Provides that the practice of optometry includes the prevention, diagnosis, treatment, and management of disorders and dysfunctions of the visual system, as well as the provision of habilitative or rehabilitative optometric services, and specifically authorizes an optometrist who is certified to use therapeutic pharmaceutical agents to diagnose and treat the human eye for various enumerated conditions. (BPC § 3041)

4) Requires the Board to establish, by regulation, educational and examination requirements for licensure to ensure the competence of optometrists to practice, and provides that satisfactory completion of those educational and examination requirements shall be a condition for the issuance of an initial optometrist license. (BPC § 3041.2)

5) Makes passage of required examinations a prerequisite for licensure practice optometry in California, among other requirements. (BPC § 3046)

6) Requires that all examinations shall be practical in character, designed to ascertain applicants' fitness to practice the profession of optometry and conducted in the English language. (BPC § 3053)

7) Provides that the passing grades for the optometrist licensure examination shall be based on psychometrically sound principles of establishing minimum qualifications and levels of competency; further provides that if an applicant fails to pass any section of the examination, they may be examined in any succeeding examination held during the next five years only in those sections in which he or she failed to obtain a passing grade. (BPC § 3054)

THIS BILL:

1) Requires the Board to issue a temporary license to practice optometry to any applicant who would be eligible except that they are unable to immediately take the required Section III - Clinical Skills Examination developed by the National Board of Examiners in Optometry (NBEO), required for licensure under this chapter, due to the state of emergency, proclaimed by the Governor on March 4, 2020, in response to the COVID-19 pandemic.

2) Requires that any applicant for temporary licensure under the bill must meet all the following conditions:

   a) The person has never been previously licensed to practice optometry in the United States.

   b) The person pays the Board a fee of $100, or a fee in an amount as determined by the Board, not to exceed the reasonable cost of administering the program and submits an application to be a temporary licensee.

   c) The person has received approval from their accredited school of optometry that the person meets the educational requirements to practice optometry.

   d) The person satisfies all other conditions to licensure established by this chapter.

3) Provides that a temporary licensee is subject to the same rights and restrictions as a permanent licensee, except as specified.

4) Requires a temporary licensee to practice under the direct supervision of a supervising optometrist who has been licensed for a minimum of five years and has been certified for the treatment of glaucoma and submits who an application to be a supervising optometrist; additionally authorizes a licensed physician practicing ophthalmology to supervise a temporary licensee.

5) Defines “direct supervision” as meaning that a supervising optometrist oversees the activities of, and accepts responsibility for, the services rendered by a temporary licensee and requires that the supervising optometrist be physically present and immediately available in the facility or office in which the optometric services are being provided when the temporary licensee is with a patient.

6) Prohibits a temporary licensee from opening their own optometric office or place of practice.

7) Provides that a temporary license shall expire either upon the date that the temporary licensee completes all of the requirements for licensure or six months after the date the state of emergency in response to the COVID-19 pandemic has ended, whichever occurs first.

8) Codifies the application form for persons seeking temporary licensure.

9) Exempts the Board from any requirement to adopt regulations under the Administrative Procedure At.

10) Provides that the bill is an urgency statute necessary to protect public health and preserve the future health care workforce by ensuring that qualified optometry graduates are permitted to practice during the COVID-19 pandemic as soon as possible.

FISCAL EFFECT: According to the Senate Committee on Appropriations, negligible state costs per Senate Rule 28.8.

COMMENTS:

Purpose. This bill is sponsored by the **California Optometric Association**. According to the author:

> "The NBEO consists of three parts: Part I: Applied Basic Science; Part II: Patient Assessment and Management; Part III: Clinical Skills. Parts I and II are computerized exams taken at a Pearson VUE testing site in California. Part III is an in-person examination to test clinical skills and is taken at the NBEO testing center in North Carolina. The pandemic has made taking the test unnecessarily hazardous. Since Part III is an in-person examination, there are no west coast locations to take this test, and the NBEO is unwilling to open up any such locations, license applicants must fly across the country during the global pandemic to take the test, putting themselves and their community at increased risk of exposure. This bill addresses this issue by creating a temporary, provisional license, with additional requirements, that allows an optometry school graduate who has not taken Part III of the NBEO to temporarily practice optometry under the supervision of another optometrist. This temporary license is an essential measure that will ensure optometry students are not burdened with substantial student debt, without a way to start their optometry career and begin paying it off."

Background.

Applications for licensure in optometry require payment of a fee and proof that the applicant graduated from an accredited school of optometry, passed certain required examinations for licensure, and has not been convicted of a crime or disciplined for acts substantially related to the profession. School transcripts, examination score reports, letters of good standing from other states or licensing entities (when applicable), and LiveScan fingerprint results are sent directly to the Board from the agency of origin. The Board queries the National Practitioner Data Bank to identify whether the applicant has been disciplined by a regulatory board in another state.

Statute requires the Board to establish educational and examination requirements for licensure "to ensure the competence of optometrists to practice." The Optometry Practice Act requires that "all examinations shall be practical in character, designed to ascertain applicants' fitness to practice the profession of optometry and conducted in the English language." Statute further requires that "the passing grades for the licensure examination shall be based on psychometrically sound principles of establishing minimum qualifications and levels of competency." To become licensed as an optometrist in California, applicants must pass the California Laws and Regulations Exam (CLRE) and the national examination developed by the National Board of Examiners in Optometry (NBEO).

The CLRE is a jurisprudence examination that tests an applicant's knowledge and understanding of laws and regulations specifically applicable to the practice of optometry in California. As required by law, the Board works with the DCA's Office of Professional Evaluation Services (OPES) to develop the CLRE and ensure that it is psychometrically sound and appropriate for the profession. The CLRE is a computer-based exam administered through an examination vendor, PSI, Inc., nearly every day of the year. Applicants who fail the exam must wait 180 days to retake it.

The Board has required the NBEO Parts I, II, and III examinations for licensure since 2001. Parts I and II of the NBEO Exam must be taken while still in optometry school and are computer-based. Part III of the examination is administered in person. Currently, all 50 states, the District of Columbia, and Puerto Rico all use the NBEO Exam for licensure. In 2020, the Board conducted a regular assessment of the NBEO Exam in partnership with the OPES and found that the examination meets the prevailing standards for validation and use of licensure examination in California. In FY 2019/20, the pass rate for the CLRE was approximately 93 percent, with an average of 89 percent over the prior fours. The California pass rate for the NBEO in FY 2019/20 was 91 percent and has averaged slightly over 90 percent during the prior four years.

Part III of the NBEO is administered exclusively at a testing site located in North Carolina. Prior to 2010, the Part III exam was given at each school of optometry. However, due to lack of consistency in staff training and administration of the test, NBEO consolidated all testing into one location in North Carolina. Since then, the NBEO has since considered opening of an additional location. The NBEO initially considered where most schools and candidates are located, with approximately two-thirds of applicants educated on the East Coast. The NBEO then analyzed lodging and transportation costs, city safety, real estate costs, and the cost and quality of living for its staff. The result of this analysis was a proposal to open testing locations in either Denver or Las Vegas. However, the NBEO has since announced that it is not pursing opening another location at this time, as it believes that a significant increase in per-student testing fees would be necessary to fund the expansion.

Without a testing site closer to California, applicants educated on the West Coast have had to travel to North Carolina to complete their examination requirements. This issue became particularly challenging during the COVID-19 pandemic when air travel was strongly discouraged and restricted by health officials. However, the Board is limited in terms of its ability to address the problem. The NBEO is a private organization that can choose where to offer its examinations. Currently, all 50 states, the District of Columbia, and Puerto Rico all use the NBEO Exam for licensure, so an elimination of the requirement would significantly impact license portability options for California optometrists.

As part of the state's response to the COVID-19 pandemic, on March 30, 2020, Governor Newsom announced his an initiative to "expand California's health care workforce and recruit health care professionals to address the COVID-19 surge" and signed Executive Order N-39-20. This executive order established a waiver request process under the DCA and included other provisions authorizing the waiver of licensing, certification, and credentialing requirements for health care providers.

Shortly thereafter, representatives of the California schools of optometry and the optometric profession requested a waiver to allow applicants to obtain licensure without having to travel to North Carolina during the pandemic to take the Part III examination, which for a time was unavailable altogether. This waiver was not granted. Subsequently, representatives of the profession worked with the Board to advocate for a temporary licensure program that would enable the Board to grant licensure without having to immediately take the Part III examination while the emergency is in place. The result is this legislation.

Under the provisions of this bill, an applicant who meets all the requirements for licensure except for completion of the Part III examination will be able to receive a temporary license. They would be restricted to practicing under supervision of a licensed optometrist and would not be allowed to open their own practice. The temporary license would expire upon completion of the examination or six months after the end of the declared state of emergency, whichever occurs earlier.

This bill does not resolve what will likely be a persistent issue wherein students must travel to North Carolina to meet California's licensing standards. Additionally, the bill does not apply to any future states of emergency or other scenarios where travel is restricted or hazardous. However, it does immediately resolve the most urgent issue and ensure that the state is not requiring students to travel while a public health emergency is still ongoing.

Current Related Legislation. AB 1534 (Assembly Committee on Business and Professions) would extend the sunset date for the Board and make various changes to the Optometry Practice Act. *This bill is pending in the Senate Committee on Business, Professions, and Economic Development.*

ARGUMENTS IN SUPPORT:

This bill is sponsored by the **California Optometric Association** (COA). According to the COA, "when the pandemic hit, the only testing agency recognized for optometry was forced to close and students were told they may not be able to be licensed on time. When the testing site opened back up, students were forced to travel across the country and put themselves and their families at great risk, just to take a test. This is unacceptable. The State Board of Optometry tried to intervene. However, there was no way for the board to force the testing agency to offer a second location for its test. After two public hearings on the issue, several approaches to solving the problem were ruled out. The board had no flexibility in its regulations to waive the test or to allow the colleges to determine competency. It was agreed that legislation would be necessary to allow a graduate to be able to practice in some capacity.

ARGUMENTS IN OPPOSITION:

None on file.

REGISTERED SUPPORT:

California Optometric Association *(Sponsor)*
Vision Service Plan

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301