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## SENATE COMMITTEE ON HEALTH

Senator Dr. Susan Talamantes Eggman, Chair

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**BILL NO:** SB 524  
**AUTHOR:** Caballero  
**VERSION:** April 10, 2023  
**HEARING DATE:** April 26, 2023  
**CONSULTANT:** Jen Flory

**SUBJECT:** Pharmacists: furnishing prescription medications

**SUMMARY:** Adds, to the Medi-Cal schedule of benefits, ordering, performing, and reporting any test classified as waived pursuant to the Clinical Laboratory Improvement Amendments that is used to guide diagnosis or clinical decisionmaking. Adds furnishing prescriptions pursuant to a test result that is used to guide diagnosis or clinical decisionmaking to the schedule as permitted by the other provisions of this bill that expand a pharmacist's scope of authority.

**Existing federal law:**

- 1) Establishes the Clinical Laboratory Improvement Amendments (CLIA), which regulates clinical laboratories that perform tests on human specimens and sets standards for facility administration, personnel qualifications and quality control. These standards apply to all settings, including commercial, hospital or physician office laboratories. [42 USC §263a; 42 CFR §493]
- 2) Defines CLIA-waived tests as simple laboratory examinations and procedures that are approved by the Food and Drug Administration (FDA) for home use, employ methodologies that are simple and accurate as to render the likelihood of erroneous results negligible or pose no reasonable risk of harm to the patient if the test is performed incorrectly. [42 CFR §493]

**Existing state law:**

- 1) Establishes the Medi-Cal program, administered by the Department of Health Care Services (DHCS), under which low-income individuals are eligible for medical coverage. [WIC §14000, et seq.]
- 2) Establishes a schedule of benefits covered under the Medi-Cal program, including the purchase of prescription drugs, subject to the Medi-Cal List of Contract Drugs and utilization controls. [WIC §14132]
- 3) Requires pharmacist services to be a covered benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare and Medicaid Services (CMS). Requires the following to be covered pharmacist services that may be provided to a Medi-Cal beneficiary, subject to DHCS protocols and utilization controls:
  - a) Furnishing travel medications;
  - b) Furnishing naloxone hydrochloride;
  - c) Furnishing self-administered hormonal contraception;
  - d) Initiating and administering immunizations;
  - e) Providing tobacco cessation counseling and furnishing nicotine replacement therapy;
  - f) Initiating and furnishing preexposure prophylaxis (PrEP), subject to limitations;
  - g) Initiating and furnishing postexposure prophylaxis (PEP); and,
  - h) Providing medication therapy management. [WIC §141432.968]

- 4) Requires DHCS to establish a fee schedule for the list of pharmacist services and requires the reimbursement rate for those services to be at 85% of the fee schedule of physician services under Medi-Cal. [WIC §141432.968]
- 5) Prohibits the performance of a CLIA-waived test unless the test is performed under the overall operation and administration of the laboratory director and 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. Permits pharmacists at community pharmacies to perform FDA-approved CLIA-waived tests that are for sale to the public in the form of an over-the-counter test kit, provided that the pharmacy has a federal certificate of waiver, 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 CLIA-waived. [BPC §1206.5, 1206.5]

**This bill:**

- 1) Adds ordering, performing, and reporting any test approved or authorized by the FDA used to guide diagnosis or clinical decisionmaking, and that is CLIA-waived, to the pharmacist services benefit in Medi-Cal.
- 2) Adds furnishing prescriptions pursuant to a test result that is used to guide diagnosis or clinical decisionmaking to the pharmacist benefit in Medi-Cal.

Business and Professions Code provisions

- 3) Clarifies that instead of performing a FDA-approved CLIA waived test for specified diseases and conditions, a pharmacist may order, perform, and report any test for those specific diseases and conditions.
- 4) Permits a pharmacist to furnish prescriptions for SARS-CoV-2, influenza, streptococcal pharyngitis, sexually transmitted infection, and conjunctivitis after receiving appropriate test results until January 1, 2034. Requires a pharmacist to utilize the most recent relevant and appropriate evidence based clinical guidelines published by the federal Centers for Disease Control and Prevention (CDC), or the Infectious Diseases Society of America, or other clinically recognized recommendations, in providing the patient care for SARS-CoV-2, influenza, streptococcal pharyngitis, sexually transmitted infection, and conjunctivitis.
- 5) Requires prescription drugs, devices, or treatments furnished by a pharmacist to follow the Board of Pharmacy and the Medical Board of California standardized procedures and protocols, which will include requirements for appropriate pharmacist training to furnish the treatments, as specified. Requires a pharmacist to document the testing services provided, as well as any prescription drugs, devices, or other treatment furnished to the patient pursuant to the test result, in the patient's record in the record system maintained by the pharmacy. Requires the pharmacist to maintain records of prescription medications furnished to each patient.
- 6) Requires all pharmacies or health care facilities in which pharmacists are furnishing treatments must provide an area designed to maintain privacy and confidentiality of the patient that is not susceptible to distraction of the pharmacist.

**FISCAL EFFECT:** This bill has not been analyzed by a fiscal committee.

**COMMENTS:**

1) *Author's statement.* According to the author, healthcare has become inaccessible for many Californians, especially in rural California. This lack of access has often forced Californians to face expensive emergency room visits, lengthy drives, and long wait times in order to find treatment for illnesses. Nearly nine in ten Californians live within five miles of a community pharmacy, so the role of a pharmacist in orchestrating a patient's care is a critical resource. Recognizing the essential role of pharmacies, the Department of Consumer Affairs (DCA) gave pharmacists the authority to prescribe a COVID-19 treatment, Paxlovid, directly to patients. When this authority expires, patients' access to testing and treatment for COVID-19 at pharmacies will end. In addition to COVID-19, pharmacists have the authority to perform testing for many other diseases. This allows pharmacists to provide direct treatment for patients following positive test results for certain, easily treatable conditions. These conditions include COVID-19, influenza, sexually transmitted infections, strep throat, and conjunctivitis. Expanding access to treatment directly by a pharmacist may often be the fastest way for an individual to get treatment. This bill will increase access to healthcare and protect the health of thousands of Californians.

2) *Federal and State Requirements for Clinical Laboratory Testing.* A facility that performs laboratory tests on human specimens for diagnosis or assessment must be certified under CLIA. CLIA certification requirements vary depending on the complexity of the laboratory tests performed. The three complexities are waived, moderate, and high complexity. In general, the more complicated the test, the more stringent the requirements under CLIA. As defined by CLIA, waived tests are simple tests with a low risk for an incorrect result. Waived tests include tests listed in the CLIA regulations, tests cleared by the FDA for home use, and tests approved for waiver by the FDA using the CLIA criteria. In order for the FDA to approve a test device as waived, the manufacturer must show that the test is accurate and consistent when performed by untrained individuals. This includes performing studies conducted using participants without laboratory training, no prior experience of the test, and no verbal instruction. The study participants must be able to generate accurate results using only the product label and included instructions.

Because waived tests are essentially consumer-level products, facilities that use only waived tests are eligible for a certificate of waiver. Those with a certificate of waiver are not subject to the CLIA requirements as long as the tests are performed according to the manufacturer's instructions. However, CLIA still requires that all laboratories meet individual state personnel license requirements. Under California law, all laboratory tests classified under CLIA must be performed by personnel specified in statute under the overall operation and administration of a laboratory director, with limited exceptions, including for pharmacists in some circumstances. This bill expand the circumstances under which pharmacists could perform specified CLIA-waived tests and authorize pharmacists to provide direct treatment following positive test results for COVID-19, influenza, strep throat, sexually transmitted infections, and conjunctivitis.

3) *Pharmacy services in Medi-Cal.* AB 1114 (Eggman, Chapter 602, Statutes of 2016) added to the Medi-Cal schedule of benefits specified pharmacist services, including furnishing travel medications, naloxone hydrochloride, self-administered hormonal contraception, immunizations and tobacco cessation counseling and nicotine replacement therapy, subject to

CMS approval and DHCS protocols and utilization controls. AB 1114 added these services to Medi-Cal after prior legislation expanded the scope of practice for pharmacists to conform Medi-Cal with existing state policy. It also required DHCS to establish a fee schedule for the list of pharmacist services that would be 85% of the fee schedule for physician services under the Medi-Cal program. Since then, additional benefits, including PrEP, PEP, and medication therapy management have been added.

According to the Medi-Cal provider manual chapter on Pharmacist Services, pharmacies must be Medi-Cal enrolled pharmacies in order to bill for these services, and furnishing pharmacists must be enrolled as an ordering, referring, and prescribing provider for claims to be reimbursed through the Medi-Cal fee-for-service program. For the vast majority of beneficiaries enrolled in Medi-Cal managed care plans, billing is handled directly through the plan. The recent change to Medi-Cal Rx, which carved the provision of prescription drugs out of Medi-Cal managed care did not apply to pharmacy services that are billed as medical services. These services use medical claim codes (CPT or Current Procedural Terminology), thus they are not carved out. This bill would conform the Medi-Cal pharmacist services benefit to include the testing and treatment in the expanded pharmacist scope of practice described above.

- 4) *Double referral.* This bill was heard in the Senate Business, Professions and Economic Development Committee on April 17, 2023, and passed with a 10-2 vote.
- 5) *Related legislation.* SB 339 (Wiener) requires health plans and insurers to cover HIV PrEP and PEP furnished by a pharmacist, including costs for the pharmacist's services and related testing ordered by the pharmacist. Permits a pharmacist to furnish up to a 90-day course of PrEP, or beyond 90 days if specified conditions are met. *SB 339 is set to be heard in this committee on April 26, 2023.*
- 6) *Prior legislation.* SB 409 (Caballero, Chapter 604, Statutes of 2021) authorizes pharmacists and pharmacies to perform, under specified conditions, any aspect of any FDA-approved or authorized point-of-care test for the presence of SARS-CoV-2 or influenza that is classified as CLIA-waived.

AB 133 (Committee on Budget, Chapter 143, Statutes of 2021) added medication therapy management to the Medi-Cal pharmacy services benefit to improve health outcomes of beneficiaries at risk of treatment failure due to noncompliance or other factors.

AB 1328 (Irwin of 2021) would have authorized a pharmacist to perform all clinical laboratory tests all CLIA-waived tests that can lawfully be used within the pharmacist's practice and updated settings in which a pharmacists can perform waived tests. *AB 1328 was held on the Senate Appropriations suspense file.*

SB 159 (Wiener, Chapter 532, Statutes of 2019) added a 60-day supply of PrEP and PEP to the Medi-Cal pharmacy services benefit, among other things.

SB 446 (Stone of 2019) and SB 1264 (Stone of 2018) would have required Medi-Cal to provide coverage for hypertension medication management services provided by a pharmacist. *SB 466 was held on the Senate Appropriations suspense file and SB 1264 was held on the Assembly Appropriations Committee suspense file.*

AB 1114 (Eggman, Chapter 602, Statutes of 2016) added, to the schedule of Medi-Cal benefits, specified pharmacist services, subject to CMS approval and DHCS protocols and utilization controls.

AB 1535 (Bloom, Chapter 326, Statutes of 2014) authorizes a pharmacist to furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both Pharmacy Board and the Medical Board of California, in consultation with specified entities.

SB 493 (Hernández, Chapter 469, Statutes of 2013) allowed pharmacists to furnish self-administered hormonal contraceptives, nicotine replacement products, and prescription medications not requiring a diagnosis that are recommended for international travelers; order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies; order and administer routine vaccinations; and provide consultation on drug therapy, disease management, and prevention.

- 7) *Support.* This bill is sponsored by the California Community Pharmacy Coalition, a project of the California Retailers Association, who write that for many Californians, especially those living in rural communities, access to health care is limited. A 2018 study found that on average, driving to a hospital in a rural community takes 17 minutes – a distance that is often too far for those in need of care. Community pharmacies, however, help close this gap, meeting the need for more equitable access to care. In addition to providing critical medications to millions of Californians, pharmacists provide consultation, training and education to patients about drug therapy, disease management, and disease prevention; administer all FDA-approved immunizations for individuals age three and older; independently furnish FDA-approved opioid antagonists to patients; furnish self-administered birth control, nicotine replacement products, and standard travel medications to patients; and order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. Although pharmacists are authorized to perform testing for several health care conditions, they are not authorized to prescribe treatment for many of these ailments. This bill is a common-sense solution to this problem by expanding the treatments pharmacists are authorized to perform to include COVID-19, Influenza, Strep, Conjunctivitis and STIs. Expanding pharmacists' authorization will increase healthcare equity and allow patients to receive testing and treatment for specified conditions directly from the pharmacy, allowing those with limited access to health care to receive treatment quickly.
- 8) *Opposition.* The California Medical Association writes that tests authorized in a pharmacy currently are not comprehensive health screenings, which means they cannot paint a complete picture of the patient's health status. Allowing pharmacists to furnish prescriptions could lead to dangerous health outcomes for communities and will set a harmful precedent regarding direct patient care in retail pharmacies. This bill evaluates a patient's health based on individual test results; assessing health in this way would diminish the total patient care approach preferred by physicians and patients. The American College of Obstetricians and Gynecology, District IX opposes for similar reasons and adds that with the varying list of CLIA-waived tests available today, they are concerned that pharmacists simply do not possess the knowledge needed on the disease or condition they are testing and if they are authorized to treat that condition it will lead to dangerous health outcomes.

- 9) *Oppose unless amended.* The United Food and Commercial Workers, Western States Council seek amendments to require pharmacies to hire an additional pharmacist to provide only the services prescribed by this bill to ensure that pharmacists who are currently overworked and understaffed are not even more burdened and those offering these services can provide better patient care. They also request that the area for patient consults in which a pharmacist is furnishing treatment be enclosed to ensure privacy and confidentiality.

**SUPPORT AND OPPOSITION:**

- Support:** California Community Pharmacy Coalition (sponsor)  
Board of Supervisors County of Madera  
California Hepatitis C Task Force  
California Life Sciences  
California Pharmacists Association  
City of Huron  
City of Kerman  
City of King  
City of Madera  
City of Mendota  
City of Merced  
Democratic Women of Monterey County  
Hazel Hawkins Memorial Hospital  
International Foundation for Autoimmune and Inflammatory Arthritis  
Nisei Farmers League  
San Benito County
- Oppose:** American College of Obstetricians and Gynecologists District IX  
California Chapter of the American College of Cardiology  
California Medical Association  
United Food and Commercial Workers, Western States Council (unless amended)

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