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# SENATE COMMITTEE ON APPROPRIATIONS

Senator Anthony Portantino, Chair  
2023 - 2024 Regular Session

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## SB 524 (Caballero) - Pharmacists: furnishing prescription medications

**Version:** May 1, 2023

**Policy Vote:** B., P. & E.D. 10 - 2, HEALTH  
9 - 0

**Urgency:** No

**Mandate:** Yes

**Hearing Date:** May 15, 2023

**Consultant:** Janelle Miyashiro

**Bill Summary:** SB 524 authorizes a pharmacist to furnish medications to treat various diseases and conditions based on the results of a federal Food and Drug Administration (FDA) test the pharmacist ordered, performed, or reported and adds these additional pharmacy services to the Medi-Cal schedule of benefits, as specified.

### Fiscal Impact:

- The Board of Pharmacy (BOP) reports costs of \$178,000 over a two-year period for a limited-term staff to develop standardized procedures and perform associated regulation and education work (Pharmacy Board Contingent Fund).
- Unknown, ongoing significant costs pressures to the Medi-Cal program (General Fund and federal funds)
- Unknown, likely significant fiscal impact to the Department of Health Care Services (DHCS) to establish a fee schedule for the expanded list of pharmacist services benefits under Medi-Cal (General Fund).
- The Medical Board of California and California Department of Public Health do not anticipate a fiscal impact.

**Background:** *Clinical Laboratory Improvement Amendments Tests.* A facility that performs laboratory tests on human specimens for diagnosis or assessment must be certified under the Clinical Laboratory Improvement Amendments (CLIA). There are three CLIA categorizations: waived tests, moderate complexity tests, and high complexity tests. In general, the more complicated the test, the more stringent the requirements to perform that test, including increased training and licensing of laboratory personnel. The FDA determines the complexity of CLIA laboratory tests. 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 waiver by the FDA using the CLIA criteria.

*Current Pharmacist Practice Authority.* Under current law, pharmacists are permitted to care for patients and assist other professionals in addition to their own duties. They can:

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

- Practice 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 CLIA-waived and 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.
- Perform routine drug-therapy related patient assessment procedures and order drug therapy-related laboratory tests in specified circumstances and settings, including: 1) 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; and 2) 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, agency, clinic, service plan, or physician.

In addition to those in the general pharmacy licensing space, advanced practice pharmacists are authorized to do patient assessments; order and interpret drug-therapy related tests; refer patients to health care providers; evaluate/manage diseases; initiate, adjust, or discontinue drug therapy, as specified.

Depending on their setting, pharmacists' scope of practice can diminish or expand. For example, pharmacists in any setting may administer the following tests and medications: toxicology, drug-therapy, and disease management and protection; over the counter (OTC) tests for blood glucose and hemoglobin levels; hormonal contraceptives; prescription medications that do not require a prescription for travel purposes; nicotine replacement products; HIV preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP); routine and the COVID-19 vaccination; skin puncture if the test is CLIA-waived and a person could perform the test at home themselves; certain dialysis drugs; and opioid antigen injections.

However, other tests, medications, and procedures require pharmacists to practice: in a health care facility; in a licensed home health agency; in a licensed correctional clinic; in a licensed clinic in which there is physician oversight; with 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 with a physician, in accordance with the policies, procedures, or protocols of that facility, agency, clinic, service plan, or physician. Settings generally offer varying degrees of supervision by medical professionals depending on the setting. In these settings, pharmacists may: complete drug-therapy patient assessments (such as taking temperature, pulse, and respiration); order drug-therapy related laboratory tests; administer drugs and biologics by injection; initiate and adjust drug regime by patient provider.

Some care models in pharmacy settings like CVS Minute Clinics look like an urgent care clinic, and provide minor illness and injury care, screenings and monitoring, vaccinations and injections, and physicals, are meant to increase patient access by allowing them to see relevant care providers for basic health needs. These include a pharmacist as a provider partner but rely on other providers like nurse practitioners and physician assistants to provide services that a pharmacist is not currently authorized to offer or perform in this setting.

*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 the Centers for Medicare and Medicaid Services (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.

### **Proposed Law:**

- Authorizes, until January 1, 2034, a pharmacist to furnish prescription medications pursuant to the results of a test used to guide the diagnosis or clinical decision making for the following illnesses, conditions, or diseases: SARS-CoV-2, influenza, streptococcal pharyngitis, or conjunctivitis.
  - Requires a pharmacist to utilize the most relevant and appropriate evidence-based clinical guidelines or other clinically recognized recommendations in providing patient care services for these illnesses.
  - Requires any prescription drug, device, or other treatment for these illnesses to be furnished in accordance with standardized procedures or protocols designed and approved by the BOP and the MBC, including requirements for appropriate pharmacist training to furnish the drugs, devices, or other treatments.

- Requires the pharmacist maintain documentation about any testing services and treatments provided related to these illnesses.
- Authorizes a pharmacist to order, perform, and report any test approved or authorized by the FDA that is classified as waived under CLIA.
- Provides that the above are additional covered pharmacist services that may be provided to a Medi-Cal beneficiary.

**Related Legislation:** SB 339 (Wiener, 2023) authorizes a pharmacist to furnish up to a 90-day course of HIV PrEP, or beyond 90-days if specified conditions are met and requires health plans and insurers to cover PrEP and PEP furnished by a pharmacist, including costs for the pharmacist's services and related testing. SB 339 is pending on the Suspense File in this committee.

**Staff Comments:** The boards and bureaus within the Department of Consumer Affairs are special fund agencies whose activities are funded by regulatory and license fees and generally receive no support from the General Fund. New legislative mandates, even those modest in scope, may in totality create new cost pressures and impact the entity's operating costs, future budget requests, or license fees.

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