



- 4) Authorizes a pharmacist to perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:
  - a) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration. (BPC § 4052.1(a)(1))
  - b) Ordering drug therapy-related laboratory tests. (BPC § 4052.1(a)(2))
  - c) Administering drugs and biologicals by injection pursuant to a prescriber's order. (BPC § 4052.1(a)(3))
  - d) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility. (BPC § 4052.1(a)(4))
  - e) Receiving appropriate training as required by the policies and procedures of the licensed health care facility. (BPC § 4052.1(b))
- 5) Authorizes a pharmacist to perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional clinic, a licensed clinic in which there is physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician:
  - a) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration. (BPC § 4052.2(a)(1))
  - b) Ordering drug therapy-related laboratory tests. (BPC § 4052.2(a)(2))
  - c) Administering drugs and biologicals by injection pursuant to a prescriber's order. (BPC § 4052.2(a)(1))
- 6) 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)
- 7) 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))
- 8) 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))

- 9) 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))
- 10) 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))
- 11) Establishes the definition, duties, and qualifications of a “laboratory director” for purposes of clinical laboratories and testing. (BPC § 1209)
- 12) Defines “laboratory director” as any person who is any of the following:
  - a) A duly licensed physician and surgeon. (BPC § 1209(a)(1))
  - b) Only for purposes of a clinical laboratory test or examination classified as waived:
    - i) A licensed clinical laboratory scientist. (BPC § 1209(a)(2)(A))
    - ii) A licensed limited clinical laboratory scientist. (BPC § 1209(a)(2)(B))\
    - iii) A licensed naturopathic doctor. (BPC § 1209(a)(2)(C))
    - iv) 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))
  - c) Otherwise licensed to direct a clinical laboratory under the chapter on clinical laboratory technology. (BPC § 1209(a)(3))
  - d) 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))
- 13) 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)

- 14) 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)
- 15) Establishes that anyone may perform a waived test in a licensed laboratory. (BPC § 1241)
- 16) Authorizes a pharmacist to independently initiate and administer COVID-19 vaccines approved or authorized by the FDA, as specified. (BCP § 4052.8 (a))

*Existing Federal Law:*

- 1) Establishes CLIA under federal law, 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. (Code of Federal Regulations (CFR) Title 42 § 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. (CFR Title 42 § 493)

**This bill:**

- 1) Authorizes, until January 1, 2034, a pharmacist to furnish medications to treat SARS-CoV-2, influenza, streptococcal pharyngitis, sexually transmitted infection, and conjunctivitis.
- 2) 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.
- 3) Permits a pharmacist to furnish prescriptions for SARS-CoV-2, influenza, streptococcal pharyngitis, sexually transmitted infection, and conjunctivitis after receiving appropriate test results. 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.

- 4) Requires prescription drugs, devices, or treatments furnished by a pharmacist as specified to follow the BOP and the Medical Board of California standardized procedures and protocols, which will include requirements for appropriate pharmacist training to furnish the treatments, as specified.
- 5) Requires a pharmacist to document, to the extent possible, 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.
- 6) Requires the pharmacist to maintain records of prescription medications furnished to each patient.
- 7) States 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.
- 8) Adds ordering, performing CLIA-waived tests, and furnishing prescriptions pursuant to the result from a test used to guide diagnosis or clinical decisionmaking as covered services that pharmacists may provide to a Medi-Cal beneficiary.

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

**COMMENTS:**

1. **Purpose.** The California Community Pharmacy Coalition is the Sponsor of the bill. 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 10 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. SB 524 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 provide the fastest way for an individual to get treatment. SB 524 will increase access to healthcare and protect the health of thousands of Californians.”

## 2. Background.

*Federal and State Regulation 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.

While CLIA establishes minimum federal standards, it allows states to enact more stringent state law requirements. At the federal level and in California, anyone may perform a waived test in a licensed laboratory. This bill would permit pharmacists and pharmacies to perform COVID-19 and influenza tests classified as waived under CLIA outside of the licensed laboratory setting, as long as a laboratory director oversaw the process. The bill also endeavors to add a pharmacist-in-charge to the definition of laboratory director.

*Drug Dispensing.* Current law prohibits a prescriber from dispensing drugs or dangerous devices to patients in the prescriber’s office or place of practice without specified conditions being met. These conditions include the following:

- The dangerous drugs or dangerous devices are dispensed to the prescriber’s own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.
- The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
- The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.
- The prescriber fulfills all of the labeling requirements imposed upon pharmacists, all of the specified recordkeeping requirements and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.
- The prescriber does not use a dispensing device unless the prescriber personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded, as specified.
- The prescriber, before dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

- The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.
- A certified nurse-midwife who functions pursuant to a standardized procedure or protocol as specified, a nurse practitioner who functions pursuant to a standardized procedure as specified, or protocol, a physician assistant who functions as specified, or a naturopathic doctor who functions as specified, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

“Prescriber” here refers to a person who holds a physician’s and surgeon’s certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, a certificate to practice podiatry, or a certificate to practice as a nurse practitioner practicing, as specified, and who is duly registered by the Medical Board of California, the Osteopathic Medical Board of California, the California State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, the Podiatric Medical Board of California, or the Board of Registered Nursing.

*Current Pharmacist Practice Authority.* According to California law, pharmacy as a practice is “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.”

In addition to their own duties, pharmacists are permitted to care for patients and assist other professionals. 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.

*Authority in Certain Settings.* 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.

*Recent Efforts to Expand Pharmacist Scope of Practice.* In the past few years, there have been efforts to expand a pharmacist's scope of practice and to provide healthcare services to a more full extent of their training. In 2019, the Legislature authorized a pharmacist to initiate and furnish HIV preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP). In 2014, the Legislature authorized a pharmacist to furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the BOP and Medical Board of California. In 2013, the legislature 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. This year, if passed and signed into law, SB 339 (Wiener) of 2023 would authorize a pharmacist to furnish up to a 90-day course of preexposure prophylaxis (PrEP), or beyond 90-days if specified conditions are met, and requires the Board of Pharmacy (Board or BOP) to adopt emergency regulations to implement these provisions by July 1, 2024, among other things.

*Additional Authority In Response To the COVID-19 Pandemic.* In 2020, the state of California undertook efforts to combat the COVID-19 pandemic by expanding pharmacist professional authority. In May 2020, the Governor issued an Executive Order (EO) to allow pharmacists to order COVID-19 tests in individual patients, without coordination with the patient's primary care provider or diagnosing prescriber. The EO also allows pharmacists to collect test specimens necessary for tests. The EO requires that: tests must be authorized by the FDA; the pharmacist must be "competent and trained to collect the specimen needed for the particular test"; and the specimen must be collected consistent with the provisions of an Emergency Use Authorization issued by the FDA. A public health, commercial, or clinical laboratory must still analyze the tests. However, under the EO, pharmacists can serve as qualified laboratory testing personnel—but only in an appropriately licensed or registered laboratory, and only under the direction of a laboratory director. Later in the year, the Governor also issued new authority for pharmacy technicians to administer COVID-19 vaccines and tests.

In 2020, the California Legislature passed AB 1710 (Wood, Chapter 123, Statutes of 2020), which expanded a pharmacist's scope of authority to independently initiate and administer COVID-19 vaccines approved by the federal Food and Drug Administration (FDA) in addition to the ACIP and the CDC.

In 2021, SB 409 (Caballero, Chapter 604, Statutes of 2021) authorized 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, the virus that causes COVID-19, or influenza that is classified as waived under Clinical Laboratory Improvement Amendments (CLIA). The bill also made conforming changes in provisions related to clinical laboratories to authorize that testing and include pharmacist-in-charge, as specified, in the definition of laboratory director. Finally, the bill required pharmacy and a pharmacist-in-charge to maintain documents related to testing and compliance in a specified manner. This bill was

sponsored by the California State Board of Pharmacy, which is not currently listed on support or opposition for this bill.

*Test to Treat Sites.* As noted in the CDPH's "Test-to-Treat" playbook, "test-to-treat as a concept generally applies to any efforts to ensure the key elements of (1) testing, (2) prescriber, and (3) medication occur expeditiously. This is particularly critical for COVID-19, as therapeutics must be given within 5-7 days of symptoms onset in order to be effective. With the advent of at-home antigen tests and telehealth, expedited access may include streamlined steps that take place outside of a physical provider office or clinic site."

CDPH currently approves OptumServe sites to offer antigen testing, telehealth prescribing for COVID-positive patients, and on-site Paxlovid and molnupiravir dispensing in one setting, as opposed to obtaining a prescription fill at an offsite traditional pharmacy.

BPC § 4062(b) authorizes, during a declared federal, state, or local emergency, the BOP to waive application of any provisions of the Pharmacy Law or BOP regulations if, in BOP's opinion, the waiver will aid in the protection of public health or the provision of patient care. Per BPC § 4062(d), the BOP is permitted to extend any of its waivers issued under BPC § 4062(b), by 90 days after the end of a declared state of emergency.

Since a key aspect of the CDPH's Test-to-Treat program involves dispensing therapeutics, the BOP waived Article 12 of Pharmacy Law which requires compliance with various requirements for storage and dispensing of drugs. Under its continued authority to issue waivers during a state of emergency, on April 19, 2022, the BOP issued a limited waiver applicable only to the CDPH, which waived specified statutory restrictions on entities operating a testing site approved by the CDPH to dispense COVID-19 oral therapeutics from state supplies, under the following specified conditions:

- The Approved Site complies with all conditions of the FDA approval or authorization of the COVID-19 Oral Therapeutic issued under an EUA, guidance of the federal Health and Human Services Agency and the FDA, and applicable federal dispensing laws.
- The Approved Site complies with all of the required conditions of any agreement or attestation required to be signed by organizations participating in the federal Program.
- The Approved Site also complies with all guidance and requirements established by CDPH.

The BOP's waiver also required Test-to-Treat sites to comply with a series of additional requirements relating to drug container labeling, storage, and recordkeeping. The BOP's waiver was set to expire at the end of 2022; the waiver was subsequently extended on December 5, 2022. In the Governor's October 2022 press release declaring the end of the State's COVID-19 State of Emergency effective, February 28, 2023, the Governor noted, "To maintain California's COVID-

19 laboratory testing and therapeutics treatment capacity, the Newsom Administration will be seeking two statutory changes immediately upon the Legislature's return: 1) The continued ability of nurses to dispense COVID-19 therapeutics; and 2) The continued ability of laboratory workers to solely process COVID-19 tests."

In response to this, AB 269 (Berman) authorized a person to perform an analysis of samples to test for SARS-CoV-2, the virus that causes COVID-19, in a clinical laboratory or a city, county, or city and county public health laboratory if they meet certain requirements. The law also authorized an entity contracted with and approved by the California Department of Public Health (CDPH) to operate a designated COVID-19 testing and dispensing site to acquire, dispense, and store COVID-19 oral therapeutics, as defined, at or from a designated site, until January 1, 2024.

3. **Related Legislation.** SB 339 (Wiener) of 2023 would authorize a pharmacist to furnish up to a 90-day course of preexposure prophylaxis (PrEP), or beyond 90-days if specified conditions are met, and requires the Board of Pharmacy (Board or BOP) to adopt emergency regulations to implement these provisions by July 1, 2024. It would also require a health care service plan and health insurer to cover PrEP and postexposure prophylaxis (PEP) furnished by a pharmacist, including costs for the pharmacist's services and related testing ordered by the pharmacist.

AB 269 (Berman, Chapter 1, Statutes of 2023) authorizes a person to perform an analysis of samples to test for SARS-CoV-2, the virus that causes COVID-19, in a clinical laboratory or a city, county, or city and county public health laboratory if they meet certain requirements. This bill also authorizes an entity contracted with and approved by the California Department of Public Health (CDPH) to operate a designated COVID-19 testing and dispensing site to acquire, dispense, and store COVID-19 oral therapeutics, as defined, at or from a designated site, until January 1, 2024.

SB 409 (Caballero, Chapter 604, Statutes of 2021) authorized 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, the virus that causes COVID-19, or influenza that is classified as waived under Clinical Laboratory Improvement Amendments (CLIA). The bill also made conforming changes in provisions related to clinical laboratories to authorize that testing and include pharmacist-in-charge, as specified, in the definition of laboratory director.

AB 1328 (Irwin) of 2021 would have authorized: a pharmacist to perform all clinical laboratory tests that are classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) that can lawfully be used within the pharmacist's practice and updates settings in which a pharmacist can perform waived tests; a pharmacist to order and interpret tests for the purpose of promoting patient health, rather than just for monitoring and managing the efficacy of drug therapies as current law specifies; the pharmacist-in-charge (PIC) of a pharmacy to be the laboratory director of a laboratory certified to perform all CLIA-waived tests. (*Status: This measure was held in the Senate Committee on Appropriations.*)

AB 1710 (Wood, Chapter 123, Statutes of 2020) authorized a pharmacist to independently initiate and administer COVID-19 vaccines approved or authorized by the FDA, as specified.

SB 159 (Weiner, Chapter, Statutes of 2019) authorized a pharmacist to initiate and furnish HIV preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP), as specified.

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

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.

- 4. Arguments in Support.** The California Community Pharmacy Coalition writes in sponsorship and support: “SB 524 builds upon this foundation by allowing pharmacists to independently furnish treatment for five common conditions following a positive test result. Although pharmacists are authorized to perform testing for several health care conditions pursuant to SB 409, they are not authorized to prescribe treatment for many of these ailments. SB 524 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. The increased access to care provided by this bill will protect the health of thousands of Californians. This is necessary now more than ever, as pharmacies have become one of the most accessible health care providers for Californians.”

The California Hepatitis C Task Force and The City of Kerman write in support: “Currently, pharmacists are authorized to perform testing for several common health care conditions, but they are not authorized to administer treatment for many of these ailments. SB 524 is a commonsense solution to this problem by expanding the treatments pharmacists are authorized to provide. 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. The increased access to care provided by this bill will protect the health of thousands of Californians. Because it will increase healthcare access for Californians and expand efficient testing and treatment for several common conditions, we are in strong support of SB 524.”

California Life Sciences writes in support: “By building on the DCA waiver and previous legislation authorizing pharmacists to perform certain tests, SB 524 allows

pharmacists to prescribe treatment for common conditions for which they can currently perform tests – including COVID-19, influenza, sexually transmitted infections, strep throat, and conjunctivitis, expanding access to critical health care services for Californians.”

The California Pharmacists Association writes in support: “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.

While this has increased access points for patients to be tested, it did not address the issue of treatment. It is often difficult to see primary health providers due to the well-known shortage. This bill will address that issue, by giving patients the ability to receive their medication by the pharmacist who conducted the test if they so choose.”

Hazel Hawkins Memorial Hospital, Nisei Farmers League, San Juan Bautista Rotary Club, County of San Benito, and City of Huron writes in support: “SB 524 allows pharmacists to prescribe treatment for certain common conditions for which pharmacists can currently perform tests. These conditions include COVID-19, influenza, sexually transmitted infections, strep throat, and conjunctivitis. With nearly nine in 10 Californians living within five miles of a community pharmacy, the role of the pharmacist in orchestrating a patient’s care is an underused resource. For many patients, community pharmacies are their primary access point for health care. Pharmacists are rigorously trained to provide treatments to patients. Getting tested and treated directly by a pharmacy may often be the fastest way for an individual to get treatment, and stop the spread of illness. This bill provides increased access and protects the health of thousands of Californians, especially in rural parts of the state.”

International Foundation for Autoimmune & Auto inflammatory Arthritis (AiArthritis) writes in support: “Many patients with autoimmune or autoinflammatory arthritis disease are on immunosuppressive medication. A trip to urgent care or the emergency room for a routine illness can be dangerous. Hours waiting in a packed waiting room can end with serious consequences. A quick trip to the local community pharmacy is the perfect solution. In addition to this, many residents of California live more than 15 miles from the nearest health care facility. For many, this distance is prohibitive. For these patients, that local pharmacy is their primary access point for health care, and we should allow those healthcare professionals to help stop the spread of illness in those communities.”

5. **Arguments in Opposition.** American Congress of Obstetricians & Gynecologists District IX writes in opposition: “Healthcare cannot be provided in a vacuum. SB 524 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 tests performed in a pharmacy are not comprehensive health screenings and fail to provide a complete picture of the patient’s health status.

Additionally, healthcare professionals, including pharmacists, should have sufficient knowledge on the disease or condition they are testing. With the varying list of waived tests available today, we are concerned that pharmacists simply do not possess that knowledge. This concern is further elevated by SB 524's authorization of pharmacists to now treat that condition. Simply put, SB 524 will lead to dangerous health outcomes for our communities and further create a tiered system of healthcare."

The California Medical Association writes in opposition: "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. This bill allowing pharmacists to furnish prescriptions could lead to dangerous health outcomes for our communities. We respectfully urge an oppose position to ensure that a harmful precedent is not set 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."

United Food and Commercial Workers, Western States Council writes in opposition: "This bill would dramatically expand the number of services pharmacists would be lawfully permitted to provide without first resolving the problem -- exhaustively documented and verified by the Board of Pharmacy -- of chain drug stores dramatically understaffing their pharmacies to boost profits. For example, each of the many additional services permitted by the bill could easily consume 30 minutes of a pharmacist's time yet the bill makes no provision for how these already-overworked licensed professionals will find the hours in the workday to perform them...In 2021, after hearing from the public and licensees on the need to address working conditions of pharmacist and pharmacy staff, the California Board of Pharmacy conducted a workforce survey to better understand the issues and needs of community pharmacists. The survey results were stark, showing the difference in working conditions between an independent pharmacy, which is owned and operated by a licensed pharmacist, and a chain community pharmacy setting, which is owned and operated by a large corporation. In the survey it was reported by pharmacists that: 91% of chain pharmacists stated that staffing in their primary worksite is NOT appropriate to ensure adequate patient care. Compared to 63% of independent pharmacists who said that staffing IS adequate; 35% of pharmacists in the chain setting indicated that they have on average 3-5 medication errors in a month and another 45% said they have 1-2 medication errors a month. That is 80% of chain pharmacists sharing that at least one medication error is happening a month. Medication errors which can cause severe patient harm and potentially death; 83% of pharmacists said they do NOT have time to provide appropriate patient consultations. Patient consultations, which are the last check to make sure the patient is getting the right medication in the right quantity and dosage. Compared to 68% in the independent pharmacy setting who said they DO have time to give appropriate patient consultations; 95% of pharmacists indicated they are required to offer ancillary services at their pharmacy, such as immunizations, hormonal contraception, and naloxone. 78% of chain pharmacists said they do NOT currently have time to provide adequate screening prior to the administration of an immunization. 40% of these pharmacists administer 21-50 immunizations in one-shift and 35% of these pharmacists have over 300 scripts to process in one-shift.

Pharmacists are saying they do not have time to perform the proper review for immunizations currently in their scope of practice, will they have time to perform even more stringent reviews before administering treatment for a wide variety of illnesses?”

6. **Policy Considerations and Question: Should pharmacists provide these added services to all patient populations?** While pharmacists are already authorized to provide testing for a number of conditions and diseases, this bill then allows pharmacists to treat COVID, influenza, strep, sexually transmitted infections, and conjunctivitis, conditions that may in many cases be minor and easily treated, but in some instances could be serious or exist alongside a number of other diseases or conditions. This bill also does not differentiate treatment options for patients with existing conditions or other diseases, nor does it make any differentiation on the option to treat based on a patient’s age. While CVS Minute Clinics, for example, serve patients over 18 months of age, the Author should continue discussing the whether there should be differentiations for pediatric patients or those with existing conditions. When the Legislature originally expanded pharmacists’ authority in 2013 via SB 493 (Hernandez, Chapter 469, Statutes of 2013), these considerations were raised and discussed. Treatment such as antibiotics may lead to positive outcomes for California patients who would receive services by a pharmacist under this bill, but particularly given the impact of certain viruses, which may not respond to certain medication treatment, on the systems of patients who could also test positive for bacterial conditions like some named in this bill, it is important that “treatment” be considered as one of a number of tools aimed at enhancing overall patient care. In balancing the need to ensure access to care throughout the state but also considering the implications and impacts this bill would have on Californians with existing conditions and certain patient populations, the Author should continue to work with the Board of Pharmacy and other key stakeholders to determine the safest path forward for pharmacy clients and patients.

#### **SUPPORT AND OPPOSITION:**

##### Support:

California Community Pharmacist 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, CA  
City of King  
City of Madera  
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  
San Juan Bautista Rotary

Opposition:

American Congress of Obstetricians & Gynecologists  
California Chapter of American College of Cardiology  
California Medical Association  
United Food and Commercial Workers, Western States Council

**-- END --**