

PHARMACIST-DELIVERED PREP/PEP IN CALIFORNIA

CHANGES UNDER SENATE BILL 339 IN 2024

POLICY BACKGROUND

California's Senate Bill 159 (SB 159, 2019) enabled pharmacists to independently provide post-exposure prophylaxis (PEP) and up to 60 days of pre-exposure prophylaxis (PrEP) for HIV prevention. SB 159 implementation began in late 2020, but as of <u>late 2022</u>, few pharmacists reported that these services were available in their pharmacies. To help realize the goal of widespread access to PrEP/PEP, SB 339 was signed into law in 2024.

SUMMARY OF AMENDMENTS

Significant changes in the law due to passage of SB 339 include:

(1) expansion of time limits imposed on pharmacist-initiated PrEP from 60 days to 90 days and beyond;

(2) expansion of drugs to include those recommended by the CDC;

(3) removal of PEP-specific requirements; and

(4) exclusion of Medi-Cal managed care plans contracting with the California Department of Health Care Services if such services are not included in the contract.

What remains the same after the passage of SB 339 is:

(1) pharmacists are authorized to furnish PrEP and PEP;

(2) pharmacists must receive California State Board of Pharmacy-approved training before initiating PrEP/PEP services; and

(3) consultation cannot be waived by patients seeking PrEP/PEP.

CALIFORNIA PHARMACIST STUDY FINDINGS

Changes in the law are supported by findings from the <u>California Pharmacist Study</u> and summarized in the Table. By late 2022, only 11% and 13% of the over 900 pharmacists and pharmacy students surveyed reported that pharmacists at their pharmacy initiate PrEP and PEP as authorized by SB 159, respectively. About 27% of respondents had training on providing PrEP/PEP in a pharmacy setting. One third (34%) of respondents rated finding a referral primary care provider (PCP) to continue PrEP as difficult, a potential barrier to implementing SB 159, and 42% agreed that providing 60 days of PrEP was insufficient to ensure successful linkage to longer term care. More than half (53%) rated allocating staff time for PrEP services as difficult, given that only the medication is covered by insurance.

Implementation domain	Prior law under Senate Bill 159 (2019)	Changes with Senate Bill 339 (2024)
Basic requirements	 Authorizes pharmacists to furnish PrEP/PEP Pharmacist consultation with patient cannot be waived for PrEP Drug meets clinical eligibility recommendations according to <u>CDC 2017 guidelines</u> and subsequent guidelines Pharmacist must notify patients' PCP or give patients list of providers that can provide ongoing care for PrEP 	 Expansion to include prescription drugs recommended by CDC to reduce a person's chance of contracting HIV
Training and education	• Pharmacist must complete a training program approved by the California State Board of Pharmacy, in consultation with the Medical Board of California	 No change
Time limits for PrEP continuation	 Pharmacists may furnish at least 30 days and up to 60 days of PrEP if conditions are met: Negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the FDA Patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist Patient does not report taking any contraindicated medications Counseling is provided Pharmacist maintains records of PrEP provided A maximum of 60 days is permitted once every 2 years 	 Negative HIV test results must be obtained consistent with CDC guidelines. All other conditions remain unchanged, and if met, pharmacists may furnish up to 90 days of PrEP. Maximum may be increased beyond 90 days if conditions are met: Pharmacist ensures that patient receives testing and follow-up care consistent with CDC guidelines, which may include timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity Pharmacist notifies patient's PCP or gives patient list of providers that can provide ongoing care for PrEP Counseling is provided Pharmacist maintains records of PrEP provided

Implementation domain	Prior law under Senate Bill 159 (2019)	Changes with Senate Bill 339 (2024)
PEP initiation requirements	 Pharmacists may furnish PEP if conditions are met: Pharmacist screens patient and determines the exposure occurred within the previous 72 hours and patient otherwise meets the clinical criteria for PEP consistent with CDC guidelines Pharmacist provides CLIA-waived HIV testing or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If patient refuses to undergo HIV testing but is otherwise eligible for PEP under this section, pharmacist may furnish PEP Counseling is provided including information about PrEP 	Conditions to furnish PEP are removed
Payment for services	 Prohibits health insurers or pharmacy benefit managers to prohibit pharmacists from dispensing PrEP/PEP Prohibits insurance companies to require prior authorization or step therapy for PrEP/PEP 	 New exception for Medi-Cal managed care plans contracting with the California Department of Health Care Services if services are excluded from coverage under the contract

PrEP: pre-exposure prophylaxis, PEP: post-exposure prophylaxis, CDC: Centers for Disease Control and Prevention, PCP: primary care provider, FDA: Food and Drug Administration



NEXT STEPS FOR IMPLEMENTATION

Under SB 339, pharmacists can furnish PrEP on an ongoing basis, as long as they provide evidence of clinical monitoring including testing (e.g., HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy) and follow-up care consistent with CDC guidelines. While the law authorizes Medi-Cal payment for pharmacists' services under SB 159 and now SB 339, there is little indication that reimbursement to pharmacists for their services has become widespread, and this has been documented as a key barrier. It is unclear whether the new exception granted to Medi-Cal managed care plans will have an effect on payment to pharmacists. Additionally, there remains a lack of parity between what pharmacists receive under Medic-Cal (85% of the fee schedule for physician services under the Medi-Cal program) as opposed to what physicians receive. While the passage of Assembly Bill 317 (Weber, 2024) successfully sought parity in payment for health services delivered by pharmacists, it is unclear as to the law's application to health plans including but not limited to Medi-Cal. Additional support for payment for pharmacists' services may be provided under other state and local funding initiatives (e.g., PrEP Assistance Program). However, more administrative changes and ongoing support may be required before pharmacists in all settings are paid fully for their PrEP/PEP services rendered.

Additional data are needed about the demand for pharmacy-based PrEP/PEP services among people who could benefit and whether and how these services may address disparities in PrEP up-take in California. In addition, identifying high priority sites will help to efficiently scale-up training and implementation of pharmacy-based PrEP/PEP and shape future inquiries on pharmacists' role in furnishing PEP and strengthening the PrEP continuum.

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