



Pharmacist-Initiated PrEP and PEP

Introduction

According to the Centers for Disease Control and Prevention (CDC), an estimated 1.2 million people in the United States are currently living with HIV.¹ While some communities have experienced continuing declines in new HIV diagnoses, HIV continues to disproportionately impact certain segments of our population, particularly in the Southern region, including gay, bisexual, and other men who have sex with men (GBM), Black Americans, Latinx communities, transgender people, young people, people who use drugs, and rural residents.^{2,3}

BACKGROUND: Pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) are two biomedical prevention strategies for HIV-negative persons. PrEP is a course of medications used to prevent the transmission of HIV in people who have not yet been diagnosed with HIV while PEP is an emergency course of treatment for individuals after a single high-risk exposure to the virus.⁴ PEP must be taken within 72 hours after the exposure and continued for four weeks, while PrEP can be taken daily on an ongoing basis for as long the patient needs the medication. Studies have shown that PrEP can reduce the risk of contracting HIV from injections by 74% and from sexual activity by up to 99%.⁵ It is also a key part of the federal government's plan to reduce new HIV transmissions by 90% by 2030.⁶

Gaps in PrEP and PEP Access

Fewer than 25 percent of those who would benefit from PrEP are using these medications.⁷ PrEP uptake is particularly low in populations most vulnerable to contracting HIV. While Black Americans, Latinx-identified individuals, rural residents in the South, serodiscordant couples, and Black and Latinx gay, bisexual and other men who have sex with men (GBM) have a higher indication and need for PrEP, usage

is lowest amongst these groups.⁸ These communities face multiple barriers to accessing PrEP and PEP, including systemic racism, lack of provider education and awareness, high costs of drugs, limited access to health insurance, and lower access to health care providers and sexual health services.⁹

New Access Points and Providers

Diversifying the health care settings and types of providers offering PrEP and PEP can potentially address some of these existing barriers. Many of the people most at risk to become diagnosed with HIV are also more likely to find roadblocks to accessing health care or experience stigma with providers. However, this same population is more likely to engage with their community pharmacist than with other providers.¹⁰ As such, there have been significant efforts to allow pharmacists to initiate and administer PrEP and PEP without a prescription from a primary health care provider.

This brief examines the opportunities and challenges with pharmacy-initiated PrEP and PEP treatment; offers considerations for states, pharmacists, and other entities looking to explore pharmacy-initiated PrEP and PEP treatment; and describes the current legal and statutory landscape around pharmacy-initiated PrEP and PEP.

Pharmacist-Initiated PrEP and PEP Treatment: Opportunities and Challenges

Community Trust and Accessibility

The accessibility afforded to potential patients by community pharmacies presents a great opportunity for them to provide initial PrEP and PEP treatment without a clinician's prescription. Most patients must schedule an appointment with a nurse practitioner or primary care physician for the initial clinical visit and then continue to meet with a provider every three months for additional testing. This is a significant barrier to PrEP and PEP uptake due to reduced access to primary care and sexual health facilities in underserved communities most impacted by HIV. Black and Latinx communities are particularly burdened by lack of access to primary care in their respective communities.¹¹ Added to that challenge is the historical marginalization facing these populations within health care systems, including lower admission rates and higher mortality in emergency departments.^{12,13}

Alternatively, with more than 60,000 community pharmacies throughout the United States, individuals with an indication for PrEP and PEP often have greater access to pharmacies than to primary care offices.¹⁴ Nearly nine in 10 Americans live within five miles of a pharmacy.¹⁵ Many pharmacies have extended hours (many have moved to 24-hour care), patients can walk in without a set appointment, and pharmacists provide more opportunities for community engagement. Community pharmacies have played a more extensive role in helping individuals manage their care over the years, and studies suggest a positive correlation between increased pharmacist engagement in primary care and lower medical errors, better health outcomes, and enhanced patient satisfaction.¹⁶

The accessibility of community pharmacies and pharmacists, coupled with patient trust for pharmacists, make community pharmacies and pharmacists ideal providers of PrEP and PEP for individuals in communities where these medications are most needed, and barriers to access are most significant. Instead of having to schedule an appointment with a primary care provider or practitioner, individuals can go to their local pharmacy and engage about PrEP and PEP with someone they regularly speak with about their health. An individual can drive to their local pharmacy without scheduling an appointment at almost any time, even on the weekend, and can get treatment in a timely fashion from someone they know and trust. The availability of pharmacist-led care is particularly salient for those who need PEP, as pharmacies may be better situated to provide emergency medications within the required 72-hour window. Many of the barriers to access are therefore eliminated through using pharmacies, rather than primary care providers, as the starting point for providing PrEP and PEP treatments.

Pharmacists' Existing Knowledge on Medication Counseling

Community pharmacists regularly engage with patients in discussions regarding the proper use of medications. These pharmacists provide vital information regarding the proper use of medications and the importance of medication adherence.¹⁷ Studies show higher levels of medication adherence when pharmacists are involved in a patient's care.¹⁸

Since pharmacists already regularly assist patients with medication adherence and other patient care services, they can provide the same advice and assistance to increase uptake and maintenance of PrEP and PEP. Pharmacists can use their relationship with patients to ensure vulnerable populations not only are provided with PrEP and PEP but take these medications properly. Pharmacy-initiated PrEP and PEP is expected to achieve at least the same positive outcomes as other pharmacy-led medication adherence initiatives.

Collaborative Practice Agreements between Pharmacies and Primary Care Providers

Pharmacists are already delivering and managing PrEP care successfully through collaborative practice agreements (CPAs). CPAs create formal relationships between pharmacists and primary care providers that allow the pharmacist to provide expanded services to patients outside the pharmacist's typical scope of practice. Under a CPA, a primary care provider refers patients to pharmacists and delegates patient care functions that pharmacists can provide autonomously under specified situations and conditions. Specifically, collaborative drug therapy management (CDTM) enabled by CPAs allows pharmacists to assume greater responsibility for performing patient assessments; order drug therapy-related laboratory tests; administer drugs; and initiate, adjust, or discontinue medication regimens.¹⁹ Studies have shown that patient health improves significantly when pharmacists partner with physicians and other primary care health providers to provide and manage patient care pursuant to a CPA.²⁰

There have been numerous CPAs between pharmacists and primary care providers aimed at expanding the role pharmacists play in prescribing PrEP and PEP. For example, the San Francisco Department of Public Health and a community pharmacy developed a CPA pilot program that allowed pharmacists to prescribe and initiate PrEP and PEP to prevent HIV transmissions and increase uptake in vulnerable populations.²¹ The CPA involved a pharmacy in the heart of San Francisco's Mission District, an urban Latinx community particularly vulnerable to HIV transmission.²² The CPA consisted of a community pharmacy technician, four community pharmacists, and a physician to provide oversight.²³ During the 20 months that the CPA program existed, 53 patients completed a PrEP initiation visit and six patients received PEP. Of those that participated, 96% filled their prescriptions.²⁴

The Kelley-Ross Pharmacy in Seattle, Washington created a pharmacist-managed HIV PrEP clinic under the supervision of a physician medical director pursuant to a CPA.²⁵ Among 695 patients who initiated PrEP through this model between March 2015 and February 2018, only 19% were lost to follow up. Furthermore, the team was able to secure complete financial assistance and coverage for almost all (98%) patients.²⁶

Other community pharmacies and state and local health departments have used the success of these two programs as the basis to advocate for their own CPAs. Successful CPAs such as those in San Francisco and Seattle show that pharmacy-based PrEP and PEP initiation can increase uptake and provide the basis for expanding the ability of pharmacists to provide PrEP and PEP without an initial consultation by a primary care provider.

Lack of Pharmacy Education Regarding Sexual Health Risk Assessments

While pharmacists have a wide range of knowledge related to medication and adherence, education gaps persist when it comes to PrEP and PEP. A survey of community pharmacists in Florida found that nearly 70% of pharmacists were not familiar with PrEP guidelines, and 71% did not have enough knowledge to provide adherence counseling on PrEP.²⁷ In a separate 2019 study, 40% of student pharmacists were unable to demonstrate knowledge of PrEP initiation guidelines, including knowing that a negative HIV test is required for initiation.²⁸ In a cross-state survey of pharmacists in Nebraska and Iowa, researchers determined that only 42% of the respondents were familiar with the

use of PrEP, 25% were familiar with the CDC guidelines for PrEP usage, and only 12% had any experience counseling patients on antiretrovirals specific to PrEP and PEP use.²⁹

This education gap presents a challenge to implementing laws and statutes related to pharmacy-initiated PrEP and PEP. Training would have to include continuing education in PrEP and PEP. Additionally, in states where pharmacists are permitted to access electronic medical records and interpret tests, pharmacists need training and education to evaluate PrEP- and PEP-specific records and tests. Moreover, since the community pharmacist will have to expend considerable resources educating and counseling patients, it is critical that pharmacists are able to get reimbursed for their education and medical adherence efforts.

State Laws and Regulations on Pharmacist's Scope of Practice

While a growing number of states permit pharmacists to prescribe or deliver medications, the scope of this prescription authority is often limited to birth control, naloxone, tobacco cessation products, and travel medicine.³⁰ To date, only 16 jurisdictions allow pharmacists to initiate contraceptives by standing order without a provider and while 49 states allow pharmacists to dispense naloxone, only four states allow pharmacists to dispense naloxone under prescriptive authority laws rather than under a standing order or CPA.³¹ Even in states that allow CPAs under pharmacy regulations, pharmacists may need to meet additional licensing requirements before they are eligible to prescribe PrEP or PEP.³² Moreover, in 19 states, pharmacists are prohibited from ordering, reviewing, and interpreting lab tests.³³ This presents challenges and limitations to pharmacists being able to provide HIV related counseling and can impact how pharmacists approach initiation of PrEP and PEP.

Key Considerations for Pharmacist-Initiated PrEP and PEP State Legislation

Reimbursement, Prior Authorization, and Other Insurance Policies

Laws and legislation should clearly outline the PrEP and PEP-related services insurance providers should cover. Some states have clear guidance in proposed bills about the services that pharmacists would be able to bill private insurance and Medicaid for reimbursement purposes. However, it is less clear in other states how pharmacists would be reimbursed for services if their proposed bills were enacted. While Medicaid and most private insurance providers cover PrEP and PEP, it is not a requirement for them to cover PrEP and PEP when pharmacists initiate the treatments.

Training and Education

Additional training presents an opportunity to educate pharmacists on PrEP and PEP's pharmacology, potential drug interactions, and CDC guidelines. It would further help pharmacists better assist patients in obtaining PrEP as well as help them navigate Ryan White HIV/AIDS Program and other funding programs. Since many community pharmacists do not have access to electronic medical records or laboratory records, training on lab values may be helpful for those that would potentially have to conduct or order HIV tests as more states permit pharmacists to review medical records.

Quantity and Continuation of PrEP/PEP Treatment

Many states place timelines on how long pharmacists can prescribe PrEP and PEP before requiring a referral in their proposed and enacted legislation. Apart from Colorado, most of the states considering pharmacy-initiated PrEP and PEP bills limit PrEP to 60 days and allow one full course of PrEP before requiring the pharmacists to refer the patient to a primary care practitioner (New York only permits pharmacists to initiate seven days of PEP before requiring a referral). However, this is more stringent than the CDC's 90-day prescription recommendation. Because community pharmacies are more accessible to most populations than primary care, it may potentially be beneficial to expand the timeline pharmacists are able to continue to prescribe PrEP and PEP without requiring a referral. This expansion

may potentially also allow pharmacists to engage patients on other aspects of their care, medication adherence, and overall health.

Existing State Prescribing Protocols and Collaborative Practice Agreements

Proposed legislation around pharmacy-initiated PrEP and PEP may potentially interface with existing state prescribing protocols and CPAs. As previously mentioned, 19 states restrict pharmacists' ability to initiate treatment and prescribe without a practitioner's prescription. Pharmacists, health departments, and other entities use CPAs to grant pharmacists the ability to be more involved with treating and prescribing medications for patients.

State Laws (or Proposed Laws) Allowing Pharmacists to Administer PrEP and PEP

Updated 7/13/2021

More and more states are proposing and have enacted legislation allowing pharmacists to initiate PrEP and PEP without a prescription. States across the country have proposed legislation that would similarly allow pharmacists to initiate PrEP and PEP. Most of these proposals and enacted legislation have similar provisions. For one, most would limit pharmacy-initiated PrEP and PEP to a specified time-period and mandate pharmacists to refer patients for follow-up care. The proposed bills typically require pharmacists to complete additional training by their respective states' boards of pharmacy before self-prescribing PrEP and PEP. Also, most states have introduced limitations on prior authorization and step therapy requirements that insurers can impose for PrEP and PEP drugs and their delivery fees by mandating coverage of the pharmacist's evaluation and dispensing services.

This chart details the following states have either proposed or passed legislation relating to pharmacy-initiated PrEP and PEP (see Appendix 1 for a more in-depth analysis of the proposed or enacted legislation):

State	Bill Number	Status of Legislation (In Committee, Passed, Failed, Enacted)	PrEP or PEP without Rx through pharmacist	Quantity Limits for PrEP or PEP without Rx	Other Requirements for Pharmacists and Insurers Under Proposed Bill
CA	SB 159	Enacted October 2019	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply of PrEP in a two-year period or a full 28-day regimen of PEP	Expands Medi-Cal schedule of benefits to include PrEP and PEP, requires private insurance companies to cover PrEP and PEP. Pharmacists must complete training program approved by California State Board of Pharmacy
CO	HB 1061	Passed July 2020	PrEP and PEP	Pharmacists may prescribe and dispense PrEP and PEP pursuant to a non-patient specific standing order	Requires private insurers to cover PrEP and PEP prescribed by a pharmacist and pay consultative fee to pharmacists
FL	HB 607 and SB 928	Died In Professions Public Health Subcommittee in House Chamber and Senate Health Policy Committee in 2021	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply of PrEP in a two-year period or a full 28-day regimen of PEP	Requires insurers cover PrEP and PEP without prior authorization or step therapy
ME	LD 1115	Signed into law June 18, 2021	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply of PrEP in a two-year period or a full 28-day regimen of PEP	Requires insurers to cover PrEP and PEP prescribed by pharmacists without prior authorization or step therapy
MD	SB 878	Adjourned sine die in 2021	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply of PrEP in a two-year period or a full 28-day regimen of PEP	Insurers prohibited from imposing prior authorization or step therapy requirements
MA	SD 2258	Introduced February 2021	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply of PrEP in a two-year period	Health department required to develop statewide drug therapy protocols for dispensing PrEP and PEP

State	Bill Number	Status of Legislation (In Committee, Passed, Failed, Enacted)	PrEP or PEP without Rx through pharmacist	Quantity Limits for PrEP or PEP without Rx	Other Requirements for Pharmacists and Insurers Under Proposed Bill
MN	HF 855 and SF 340	Introduced in House in February 2021 and in Senate in March 2021	PrEP and PEP	Allows pharmacists to dispense PrEP or a full 28-day regimen of PEP	Prohibits insurers from requiring step therapy or prior authorization before pharmacists can dispense PrEP and PEP Pharmacists must complete training program by state board of pharmacy before dispensing PrEP and PEP
MI	HB 370 and SB 79	Adjourned sine die in 2021	PrEP	Allows pharmacists to dispense 30-day supply of PrEP without prescription	Requires state board of registration for the healing arts and the state board of pharmacy to jointly develop rules and regulations for training pharmacists
NV	SB 325	Signed into law on June 6, 2021	PrEP and PEP	Allows pharmacist to dispense PrEP or a full 28-day regimen of PEP	Prohibits insurers from requiring step therapy or prior authorization before pharmacists can dispense PrEP and PEP Pharmacists must complete training program by state board of pharmacy before dispensing PrEP and PEP
NJ	SB 1039	Referred To Senate Budget And Appropriations Committee as of March 2021	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply of PrEP in a two-year period or a full 28-day regimen of PEP	Requires insurers to cover PrEP and PEP prescribed by pharmacists without prior authorization or step therapy and Medicaid reimbursement for PrEP and PEP prescribed by pharmacists. Requires New Jersey State Board of Pharmacy to develop training for pharmacists
NY	SB 129	Enacted 2017	PEP	Allows pharmacists to dispense 7 days of PEP without prescription	
NY	AB A2198 and SB S728	Introduced February 2020, Reintroduced in 2021 and currently in Assembly and Senate	PrEP and PEP	Allows pharmacists to dispense up to 60-day supply of PrEP without prescription in two-year period; no changes to PEP dispense	Pharmacists must complete training program to dispense PrEP and PEP
NC	SB 575	Referred to House Committee on Rules as of May 2021	PrEP and PEP	Allows immunizing pharmacists and clinical pharmacist practitioners to prescribe PrEP and PEP	Requires medical board and board of pharmacy to implement programs to certify immunizing pharmacists and clinical pharmacist practitioners. Does not detail how long pharmacists may dispense PrEP or PEP before referring patient to practitioner
VA	HB 2079	Waiting for passage in Virginia senate (2021)	PrEP and PEP	Amends Virginia's code to allow pharmacists to prescribe PrEP and PEP without prescription	Bill does not specify how many courses of treatment a pharmacist can provide before they must refer the patient

Conclusion

Ending the HIV epidemic ultimately requires expanded HIV testing, treatment for those diagnosed with HIV, and an increased uptake in PrEP and PEP to prevent new diagnoses. Community pharmacies offer great potential to assist with uptake for various reasons. Namely, community pharmacies are easily accessible and already assist with a variety of issues related to general health and medication adherence. Community pharmacists are also highly trained individuals who can be trained to administer PrEP and PEP. CPAs among pharmacists, primary care facilities, and local health departments have already shown that pharmacies can successfully administer PrEP and PEP.

Existing prescribing protocols make pharmacy-initiated PrEP and PEP, and ultimately ending the HIV epidemic, far from a reality. To combat this, states have passed or proposed legislation to enable pharmacists to dispense an initial round PrEP and PEP without a practitioner's prescription. State chambers throughout the country are currently debating their own versions of similar bills. What yet remains to be seen is how these laws and amended regulations will work out. Health department HIV programs may also have a crucial role to play in developing and approving training protocols for pharmacists to initiate PrEP and PEP. And because of the COVID-19 pandemic, many states are diverting resources to combat the coronavirus, which may prolong when other states will take up the strategy. Still, pharmacy-initiated PrEP and PEP promise to be crucial strategies to increase uptake of the intervention and ultimately end the HIV epidemic.

Appendix I: State Laws (or Proposed Laws) Allowing Pharmacists to Administer PrEP and PEP

Updated 7/13/2021

More and more states are proposing and have enacted legislation allowing pharmacists to initiate PrEP and PEP without a prescription. States across the country have proposed legislation that would similarly allow pharmacists to initiate PrEP and PEP. Most of these proposals and enacted legislation have similar provisions. For one, most would limit pharmacy-initiated PrEP and PEP to a specified time period and mandate pharmacists to refer patients for follow-up care. The proposed bills typically require pharmacists to complete additional training by their respective states' boards of pharmacy before self-prescribing PrEP and PEP. Also, most states have introduced limitations on prior authorization and step therapy requirements that insurers can impose for PrEP and PEP drugs and their delivery fees by mandating coverage of the pharmacist's evaluation and dispensing services.

The following states have either proposed or passed legislation relating to pharmacy-initiated PrEP and PEP:

*New York – SB 129 (2017); AB A2198 and SB S728 (2021-2022, pending)*³⁴

New York was the first state to allow pharmacists to initiate PEP without a practitioner's prescription. Under SB 129, signed into law in 2017, pharmacists can dispense seven days of PEP medication without a prescription from a health care provider. On March 14, 2017, the New York State Board of Regents amended the pharmacist scope of practice regulations to allow licensed pharmacists acting under a non-patient specific standing order from a licensed physician or practitioner to dispense seven days of PEP.³⁵ To participate as a licensed practitioner under a non-patient specific standing order, the licensed physician or nurse practitioner must be available to provide follow-up appointments for patients who initiated PEP in the pharmacy, establish agreements with other healthcare providers to accept referrals of patients within one to three days, and respond to calls from pharmacists in cases where a patient has a negative reaction to a PEP regimen.

The New York state legislature introduced legislation in February 2020 that would further expand pharmacists' scope of practice by enabling them to prescribe PrEP without a prescription. Like SB 129, companion bills SB S728 and AB A2198 would permit pharmacists to prescribe PrEP pursuant to a standing order from a licensed physician or nurse practitioner. This legislation, if passed, would require pharmacists prescribing PrEP to complete a training program developed by the New York Department of Health. Pharmacists would be limited to prescribing no more than a 60-day supply of PrEP medications per patient in one single two-year period. Further, patients must provide test results to show that they have not been diagnosed with HIV before initiating PrEP or PEP. If the patient does not provide documentation of negative HIV test, legislation says that a pharmacist may recommend a test. These bills are currently sitting in the Senate and House Higher Education Committees responsible for amending laws impacting pharmacist scope of practice. Notably, the proposed legislation does not mention insurance coverage, prior authorization, or step therapy.

*California – SB 159 (2019)*³⁶

California is the first state to allow pharmacists to administer both PrEP and PEP without a prescription from a health care provider. SB 159, signed into law in October 2019, permits pharmacists to prescribe up to a 60-day supply of PrEP in a two-year period or a full 28-day regimen of PEP. The law also expands the Medi-Cal schedule of benefits to include PrEP and PEP as pharmacist services, so low-income individuals can receive PrEP and PEP prescribed by a pharmacist with little to no cost-sharing. Additionally, the legislation requires private insurance companies to cover PrEP and PEP prescribed by a pharmacist and restricts insurers from requiring patients to obtain prior authorization or step therapy to obtain PrEP or PEP. However, coverage protections for PrEP and PEP under both Medicaid and private insurance is limited to no more than a 60-day supply in a two-year period when initiated by a pharmacist.

In order to initiate PrEP or PEP, pharmacists must complete a training program approved by the California State Board of Pharmacy. The training must include information on the use of PrEP and PEP, HIV prevention, interpreting HIV tests, and linking individuals to primary care. Once the pharmacist completes the training, the pharmacist can opt in to prescribing PrEP and PEP. Further, before pharmacists can prescribe PrEP or PEP, the patient must provide test results indicating that he or she is HIV negative. If the patient cannot provide test results, the pharmacist may order and interpret tests.

*Colorado – HB 1061 (2020)*³⁷

Colorado passed legislation permitting pharmacy initiation of PrEP and PEP in July 2020. HB 1061 allows pharmacists to prescribe and dispense PrEP and PEP pursuant to a non-patient specific standing order from a physician, physician assistant, or advanced practice nurse. The law directs the state board of pharmacy, the state medical board, and the state board of nursing, in collaboration with the department of public health, to develop statewide drug therapy protocols for pharmacists to prescribe and dispense PrEP and PEP. Colorado's law does not impose quantity limits on pharmacy-initiated PrEP nor limit the frequency with which pharmacists can prescribe PrEP or PEP to a given patient.

Colorado's law prohibits health insurance providers from requiring step therapy or prior authorization for PrEP and PEP. Further, HB 1061 requires private insurance plans to cover PrEP and PEP prescribed by a pharmacist and pay a consultative fee to pharmacists for prescribing PrEP or PEP.

*New Jersey – SB 1039 (2020)*³⁸

New Jersey's legislation was introduced on January 30, 2020 and referred to the Senate Budget and Appropriations Committee on March 9, 2021. SB 1039 would allow pharmacists to prescribe up to 60 days of PrEP in a two-year period or one complete 28-day course of PEP, require insurance companies to cover PrEP and PEP prescribed by pharmacists without prior authorization or step therapy for the time period pharmacists are permitted to prescribe PrEP and PEP, and require Medicaid reimbursement for PrEP and PEP prescribed by pharmacists. This bill would only allow pharmacists to prescribe PrEP and PEP if the patient had not previously been furnished with any PrEP or PEP treatments within the last two years. The proposed bill requires patients to provide test results affirming their HIV negative status. In the absence of such results, pharmacists would be able to order tests to confirm the patient's status. The bill would further mandate the New Jersey State Board of Pharmacy to develop training, in consultation with the health department, around PrEP, PEP, and HIV prevention for pharmacists before they can opt into prescribing PrEP without a prescription from a provider.

*Florida – HB 607*³⁹ *and SB 928 (2021)*⁴⁰

Florida introduced legislation in both legislative chambers in January 2021. HB 607 and SB 928 would allow pharmacists to prescribe up to 60 days (prescribed as two 30-day supplies) of PrEP within a two-year period or one complete 28-day course of PEP. It would further establish training requirements pharmacists must complete in order to be allowed to initiate PrEP and PEP. Florida's proposed bills would also require insurance companies to cover PrEP and PEP without prior authorization or step therapy and specifies that insurers and pharmacy benefit managers cannot refuse to cover PrEP or PEP solely on the basis that it was prescribed by a pharmacist. Patients would have to confirm their HIV-negative status before pharmacists can initiate PrEP or PEP. Alternatively, pharmacists would be permitted to order tests if needed to confirm the patient's status. Unfortunately, both bills died in their respective chambers. This will be updated if the bills are subsequently reintroduced.

*Virginia – HB 2079 (2021)*⁴¹

Virginia's House of Representatives introduced HB 2079 in February 2021 to amend and reenact portions of Virginia's code related to pharmacists' ability to prescribe and treat certain conditions. The proposed bill would permit pharmacists to initiate PrEP and PEP without a practitioner's prescription. While the proposed bill does require pharmacists to refer patients to a primary care provider, the bill does not specify how many courses of

treatment a pharmacist can provide before they must refer the patient. The bill would further mandate the board of pharmacy to develop training for pharmacists before they can initiate PrEP and PEP. While the bill passed in Virginia's House chamber, the companion bill has not passed in the state's senate chamber.

*Massachusetts – SD 2258 (2021)*⁴²

Massachusetts introduced legislation in both legislative chambers on February 24, 2021. The bill would permit pharmacists to initiate PrEP and PEP without a prescription from a health care provider but does not provide much detail about pharmacy-initiated PEP. Under this proposal, pharmacists would be permitted to prescribe no more than 60 days of PrEP in a two-year period and the health department would be required to develop statewide drug therapy protocols for dispensing PrEP and PEP. Also, under the proposed bill, patients would either show test results to confirm their HIV negative status or pharmacists would be able to order tests to determine their status.

*North Carolina – SB 575 (2021)*⁴³

On April 6, 2021, several North Carolina state senators introduced SB 575, a wide range bill designed to allow certain pharmacists to prescribe, dispense, and administer certain treatment and medications. The proposed bill would, if passed and enacted, allow immunizing pharmacists and clinical pharmacist practitioners to prescribe PrEP and PEP. The proposed bill would also require the medical board and board of pharmacy to implement programs to certify immunizing pharmacists and clinical pharmacist practitioners before they are permitted to dispense PrEP and PEP. Notably missing from this proposed bill is whether pharmacists would only be permitted to dispense PrEP and PEP without a prescription for a defined time.

*Missouri – H.B. 370 and S.B. 79 (2021)*⁴⁴

In March 2021, a bipartisan team of Missouri state representatives and senators introduced H.B. 370 and S.B. 79. The companion bills permit pharmacists to dispense PrEP and PEP subject to a written protocol authorized by a licensed physician. Under the bills, pharmacists may furnish a 30-day supply of PrEP if the patient shows that they are HIV negative, the patient does not take any contraindicated medicines, and the pharmacist provides ongoing health counseling to the patient. Pharmacists will not be permitted to initiate more than one 30-day prescription of PrEP without a health care practitioner. The bills also instruct the state board of registration for the healing arts and the state board of pharmacy to jointly develop rules and regulations for training pharmacists and administering these bills. The bills adjourned sine die and will likely not be reintroduced in a future session.

*Maryland – SB 828 (2021)*⁴⁵

On February 9, 2021, Maryland senators introduced SB 828. This bill, if passed, would have authorized pharmacists to dispense up to a 60-day supply of PrEP and a complete course of PEP. In order to dispense PrEP or PEP, the patient must show proof of their HIV negative status. In the absence of such proof, the pharmacist would be able to order tests for the patient to confirm their HIV status. The bill would further mandate that the Maryland Medical Assistance Program to provide PrEP and PEP. Further, insurers would be prohibited from requiring prior authorization before a pharmacist dispenses PrEP and PEP. Unfortunately, the bill failed sine die after the last legislative session adjourned. It is not evident if the legislation will be reintroduced in future sessions.

*Nevada – SB 325 (2021)*⁴⁶

A bipartisan group of senators introduced SB 325 into Nevada's senate and house chambers in March 2021. This legislation allows pharmacists with sufficient liability coverage to dispense and administer PrEP and PEP. Pharmacists prescribing and dispensing PrEP and PEP must complete a two-hour course approved by the ACPE regarding treatment for PrEP and PEP for HIV-negative persons. The bill also requires insurers, Medicaid, and state employee plans to provide coverage and reimbursement for PrEP and PEP at a rate equal to other practitioners. The bill was signed by Governor Steve Sisolak on June 6, 2021 and will go into effect on October 1, 2021.

Minnesota – HF 855⁴⁷ and SF 340 (2021)⁴⁸

Minnesota introduced identical bills in both legislative chambers in February and March 2021. HF 855 and SF 340 would allow pharmacists to prescribe PrEP or one complete 28-day course of PEP. It would further establish training requirements pharmacists must complete to initiate PrEP and PEP. Minnesota's proposed bills would also require insurance companies to cover PrEP and PEP without prior authorization or step therapy. Patients would have to confirm their HIV-negative status before pharmacists can initiate PrEP or PEP. Alternatively, pharmacists would be permitted to order tests if needed to confirm the patient's status. Notably missing from Minnesota's legislation is limitations on how long pharmacists can initiate PrEP without a practitioner's prescription. However, the bill does require pharmacists to share dispensing information with the patient's primary care provider. Both bills remain in their respective chambers.

Maine – LD 1115 (2021)⁴⁹

Maine's legislation was introduced on March 22, 2021. LD 1115 will allow pharmacists to prescribe up to 60 days of PrEP in a two-year period or one complete 28-day course of PEP and require insurance companies to cover PrEP and PEP prescribed by pharmacists without prior authorization or step therapy for the time period pharmacists are permitted to prescribe PrEP and PEP. The proposed bill requires patients to provide test results affirming their HIV negative status. In the absence of such results, pharmacists would be able to order tests to confirm the patient's status. The bill would further mandate the Maine Board of Pharmacy to develop training around PrEP, PEP, and HIV prevention for pharmacists before they can opt into prescribing PrEP without a prescription from a provider. Governor Janet Mills signed LD 1115 into law on June 18, 2021.

ENDNOTES

- 1 Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2015–2019. HIV Surveillance Supplemental Report 2021 (May 2021), <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>.
- 2 *Id.*
- 3 *Supra* note 1.
- 4 Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP), Centers for Disease Control and Prevention (2020), available at <https://www.cdc.gov/hiv/clinicians/prevention/prep-and-pep.html>.
- 5 HRSA’s Ryan White HIV/AIDS Program: Expanding the Reach of Pre-Exposure Prophylaxis to End the HIV Epidemic (Sept. 2020), <https://hab.hrsa.gov/sites/default/files/hab/Publications/careactionnewsletter/careaction-PrEP-newsletter.pdf>
- 6 *Id.*
- 7 Maria L. Lopez, Implementing PrEP in the Pharmacy, *PHARMACY TODAY* (April 2020), [https://www.pharmacytoday.org/article/S1042-0991\(20\)30306-6/pdf](https://www.pharmacytoday.org/article/S1042-0991(20)30306-6/pdf)
- 8 *Id.*
- 9 *Id.*
- 10 *See infra* note 14.
- 11 *See* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3416972/> (a study of metropolitan zip codes that concluded that zip codes with predominantly African American residents were 67% more likely to have a primary care shortage than zip codes with predominately residents. The study also concluded that zip codes with predominantly Latinx residents were 27% more likely to have a primary care shortage).
- 12 *Id.*
- 13 <https://pubmed.ncbi.nlm.nih.gov/32671081/>
- 14 *Supra* note 8.
- 15 Ashley Chiara, The expanding role of pharmacists: A positive shift for health care, *COMMONWEALTH MEDICINE* (Mar. 26, 2019), <https://commed.umassmed.edu/blog/2019/03/26/expanding-role-pharmacists-positive-shift-health-care>.
- 16 Katherine J. Hartkopf, Kristina M. Heimerl, Kayla M. McGowan and Brian G. Arndt, *Expansion and Evaluation of Pharmacist Services in Primary Care*, 8 *PHARMACY* 2020 1, 3 (2020).
- 17 *Supra* note 8.
- 18 Maria Castelluci, Pharmacists take on medication adherence, *MODERN HEALTHCARE* (Dec. 14, 2019, 1:00 AM), <https://www.modernhealthcare.com/safety-quality/pharmacists-take-medication-adherence>.
- 19 Hammond RW, Schwartz AH, et al. Collaborative Drug Therapy Management by Pharmacists—2003, 23 *J. HUMAN PHARMACOLOGY AND DRUG THERAPY*, 1210 (2003).
- 20 Collaborative Practice Agreements and Pharmacists’ Patient Care Services, Center for Disease Control and Prevention, available at https://www.cdc.gov/dhbsp/pubs/docs/translational_tools_pharmacists.pdf
- 21 Maria Lopez, Jennifer Cocohoba, Stephanie E. Cohen, Nikole Trainor, Montica Levy and Betty Dong, Implementation of pre-exposure prophylaxis at a community pharmacy through a collaborative practice agreement with San Francisco Department of Public Health, 60 *J. AM. PHARMACISTS ASS’N* 138 (2020).
- 22 *Id.*
- 23 *Id.*
- 24 *Id.*
- 25 Elyse L. Tung, Annalisa Thomas, Allyson Eichner, and Peter Shalit, Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care, *SEXUAL HEALTH* (2018).
- 26 *Id.*
- 27 *Supra* note 8.
- 28 *Id.*
- 29 Jordan M. Broekhuis, Kimberly K. Scarsi, Harlan R. Sayles, Donald G. Klepser, Joshua P. Havens, Susan Swindells, and Sara H. Bares, Midwest pharmacists’ familiarity, experience, and willingness to provide pre-exposure prophylaxis (PrEP) for HIV, *PLOS ONE* (2018), available at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0207372>.
- 30 Nabila Ismail, Prescribing Authority for Pharmacists: Rules and Regulations by State GOODRX (Nov. 18, 2020, 2:38 PM), <https://www.goodrx.com/blog/prescriber-authority-for-pharmacists/>
- 31 Scope of Practice – Pharmacists, *AMERICAN ACADEMY OF FAMILY PHYSICIANS* (Jan. 2021), available at <https://www.aafp.org/dam/AAFP/documents/advocacy/workforce/scope/BKG-Scope-Pharmacists.pdf>.
- 32 *Supra* note 30.
- 33 Pharmacist Scope of Service, *AM. PHARMACISTS’ ASS’N* (2010), available at <https://www.pharmacist.com/sites/default/files/files/APhA%20-%20PAPCC%20Scope%20of%20Services.pdf>.
- 34 S.B.7704(a), (N.Y. 2010) (unenacted).

- 35 The Licensed Pharmacists Role in Initiating HIV Post-Exposure Prophylaxis: Overview and Frequently Asked Questions (Dec. 2017), available at https://www.health.ny.gov/diseases/aids/general/pep/docs/pharmacists_role.pdf.
- 36 HIV: preexposure and postexposure prophylaxis, S.B. 159, (Cal. 2019).
- 37 Human Immunodeficiency Virus Infection Prevention Medications, H.B. 20 – 1061, (Colo. 2020).
- 38 S.B. 1039, (N.J. 2020) (unenacted).
- 39 Antiretroviral Drugs, H.B. 607, (Fla. 2021) (unenacted).
- 40 Antiretroviral Drugs, S.B. 928, (Fla. 2021) (unenacted).
- 41 H.B. 2079 (Va. 2021).
- 42 An Act enabling pharmacists to prescribe, dispense and administer PrEP, S.D. 2258, (Mass. 2021) (unenacted).
- 43 Pharmacists Improve Public Health Needs, S.B. 575 (N.C. 2021) (unenacted).
- 44 HIV Prevention, H.B. 370 (Mo. 2021) (unenacted).
- 45 HIV Prevention Drugs – Dispensing by Pharmacists and Insurance 3 Requirements, S.B. 828 (Md. 2021) (adjourned sine die).
- 46 An act relating to health care; requiring the State Board of Pharmacy to prescribe a protocol authorizing a pharmacist to prescribe, dispense and administer drugs to prevent the acquisition of human immunodeficiency virus, S.B. 325 (Nev. 2021).
- 47 A bill for an act relating to health care; authorizing pharmacists to dispense HIV preexposure prophylaxis and HIV postexposure prophylaxis without a prescription, H.F. 855 (Minn. 2021) (unenacted).
- 48 A bill for an act relating to health care; authorizing pharmacists to dispense HIV preexposure prophylaxis and HIV postexposure prophylaxis without a prescription, S.F. 340 (Minn. 2021) (unenacted).
- 49 An Act to Improve Access to HIV Prevention Medicines, LD 1115 (Maine, 2021).