

# Pharmacist-Initiated PrEP and PEP

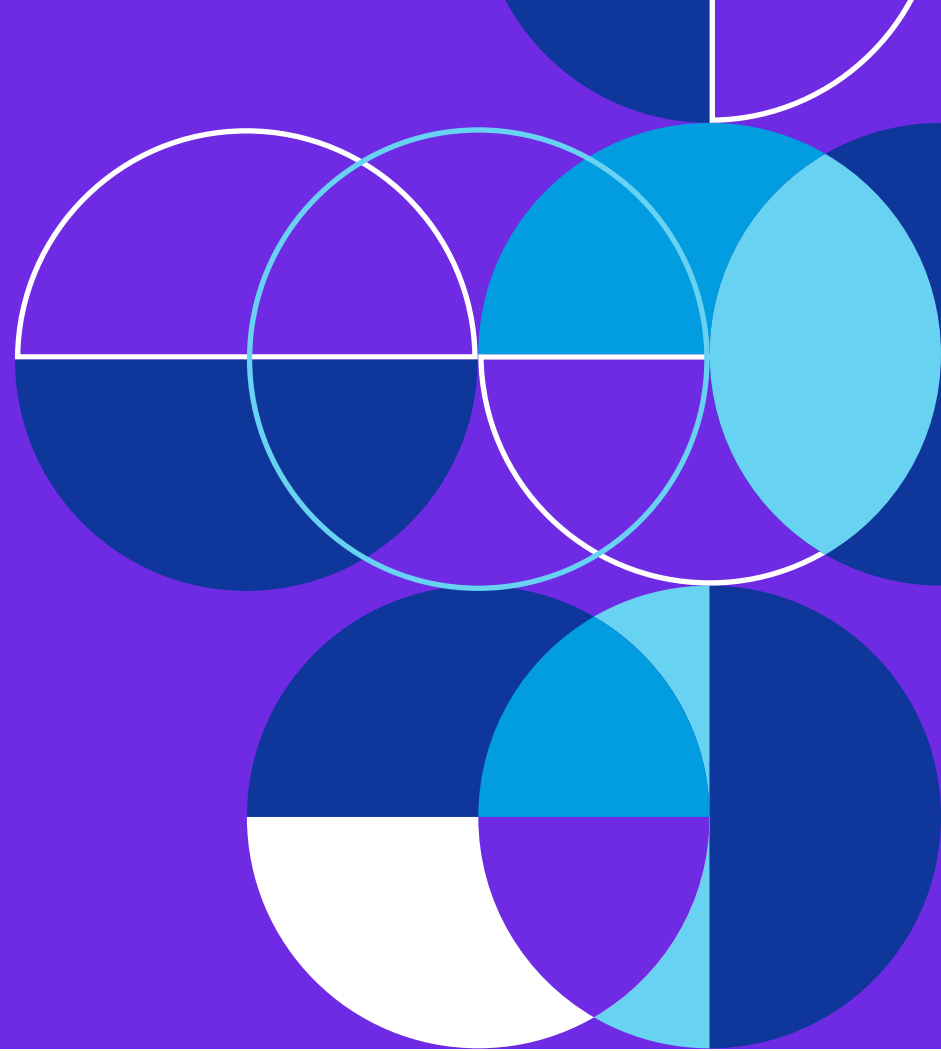




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## Introduction

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. 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.<sup>2,3</sup>

### 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.<sup>4</sup> 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%.<sup>5</sup> It is also a key part of the federal government's plan to reduce new HIV transmissions by 90% by 2030.<sup>6</sup>

### Gaps in PrEP and PEP Access

Fewer than 25 percent of those who would benefit from PrEP are using these medications.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup>

### 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.<sup>10</sup> 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.<sup>11</sup> 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.<sup>12,13</sup>

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.<sup>14</sup> Nearly nine in 10 Americans live within five miles of a pharmacy.<sup>15</sup> 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.<sup>16</sup>

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.<sup>17</sup> Studies show higher levels of medication adherence when pharmacists are involved in a patient's care.<sup>18</sup>

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.<sup>19</sup> 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.<sup>20</sup>

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.<sup>21</sup> The CPA involved a pharmacy in the heart of San Francisco's Mission District, an urban Latinx community particularly vulnerable to HIV transmission.<sup>22</sup> The CPA consisted of a community pharmacy technician,



four community pharmacists, and a physician to provide oversight.<sup>23</sup> 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.<sup>24</sup>

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.<sup>25</sup> 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.<sup>26</sup>

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.



*Image credit: Building Healthy Online Communities*

### **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.<sup>27</sup> 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.<sup>28</sup> 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.<sup>29</sup>

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.<sup>30</sup> 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.<sup>31</sup> 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.<sup>32</sup> Moreover, in 19 states, pharmacists are prohibited from ordering, reviewing, and interpreting lab tests.<sup>33</sup> 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 9/24/24

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
ARKANSAS	HB 1007	Passed on March 21, 2023	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply (must dispense at least a 30-day supply) of PrEP in a two-year period or a full 28-day regimen of PEP	Pharmacists must complete training program approved by Arkansas State Board of Pharmacy  Insurers prohibited from imposing prior authorization or step therapy requirements
CALIFORNIA	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
CALIFORNIA	SB 339	Passed January 29, 2024.	PrEP	Allows pharmacists to dispense 90-day supply of PrEP without prescription; Pharmacists may dispense beyond a 90-day supply of PrEP without a prescription if certain conditions are met	Requires all health insurers to cover pharmacist-furnished PrEP and costs for the pharmacist's services and related testing  Requires state board of pharmacy to adopt emergency regulations by 7/1/23 to implement these provisions

COLORADO	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
CONNECTICUT	HB 1102	Signed into law on June 7, 2023	PrEP and PEP	Allows pharmacists to dispense up to a 60-day supply of PrEP in a two-year period or a 30-day regimen of PEP	Pharmacists must complete training program approved by Connecticut State Board of Pharmacy
FLORIDA	HB 607 and SB 928	Failed to pass 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
FLORIDA	SB 416	Failed to pass in 2023	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
FLORIDA	HB 159	Enacted March 25, 2024	PEP	Pharmacists may initiate and dispense PEP pursuant to a collaborative practice agreement with a non-patient specific standing order.	Pharmacist must have at least \$250,000 of liability coverage and complete a Board-certified course on dispensing HIV prevention drugs.
ILLINOIS	HB 4430	Enacted January 1, 2023	PrEP and PEP	Pharmacists may prescribe and dispense PrEP and PEP pursuant to a non-patient specific standing order	Requires insurers cover PrEP and PEP services at a rate no less than 85% of the rate that the services are reimbursed when provided by a physician
KANSAS	H.B. 2747	Introduced 2/7/24 Died in committee 4/30/24	PEP	Allows pharmacists to dispense PEP via a statewide protocol established by the Kansas State Board of Pharmacy	N/A



LOUISIANA	H.B. 579	Passed 6/19/24	PrEP and PEP	Allows pharmacists to dispense up to a 30-day supply of PrEP or a full 28-day regimen of PEP	Pharmacists must complete training program approved by Louisiana Department of Health  Insurers required to reimburse pharmacists for PrEP and PEP-related services at a rate equal to a primary care provider.
MAINE	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
MARYLAND	SB 878	Failed to pass 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
MARYLAND	SB 355	Failed to pass in 2022	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
MASSACHUSETTS	SD 2258	Failed to pass in 2022	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
MASSACHUSETTS	SD 445	Introduced February 2023	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
MINNESOTA	HF 855 and SF 340	Failed to pass in 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 Minnesota State Board of Pharmacy before dispensing PrEP and PEP

MINNESOTA	HF 5247	Passed May 24, 2024	PrEP and PEP	Allows pharmacists to prescribe PrEP and PEP without prescription	Prohibits insurers from requiring step therapy or prior authorization before pharmacists can dispense PrEP and PEP  Pharmacists required to complete training course approved by the Accreditation Council for Pharmacy Education (ACPE) or the Minnesota State Board of Pharmacy
MISSOURI	HB 370 and SB 79	Failed to pass 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
MISSOURI	HB 476	Passed June 22, 2021	PEP	Allows pharmacists to dispense a full 28-day course of PEP twice in a two year period to a given patient	N/A
NEVADA	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
NEW JERSEY	SB 1039	Failed to pass 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 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
NEW MEXICO	SB 92	Passed 4/4/23	PrEP	Allows pharmacists to prescribe PrEP without prescription	Pharmacists must complete training program approved by New Mexico State Board of Pharmacy

NEW YORK	SB 129	Enacted 2017	PEP	Allows pharmacists to dispense 7 days of PEP without prescription	
NEW YORK	AB A2198 and SB S728	Introduced February 2020, Reintroduced in 2021	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
NEW YORK	SB 3297	Introduced January 2023	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
NORTH CAROLINA	SB 575	Failed to pass in 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
NORTH CAROLINA	SB 96	Signed into law on August 20, 2021	PEP	Allows immunizing pharmacist to prescribe PrEP and PEP pursuant to a standing order	Requires pharmacists to first qualify as an “immunizing pharmacist”
OREGON	HB 2958	Enacted September 25, 2021	PrEP and PEP	Allows pharmacists to dispense up to a 30-day supply of PrEP or a full 28-day regimen of PEP	Insurers prohibited from imposing prior authorization requirements  Requires insurers who cover pharmacist services to cover PrEP and PEP services at a rate equal to the rate that the services are reimbursed when provided by a physician

RHODE ISLAND	HB 6150	Introduced March 10, 2023	PrEP and PEP	Pharmacists may prescribe and dispense PrEP and PEP pursuant to a collaborative practice agreement or non-patient specific standing order	<p>Pharmacists must complete training program to dispense PrEP and PEP</p> <p>Requires health insurers to cover PrEP and PEP dispensed by pharmacists in the insurer's network</p> <p>Prohibits health insurers from require step therapy or prior authorization</p>
RHODE ISLAND	SB 573	Signed into law on June 22, 2023	PrEP and PEP	Pharmacists may prescribe and dispense PrEP and PEP pursuant to a collaborative practice agreement or non-patient specific standing order	<p>Pharmacists must complete training program to dispense PrEP and PEP</p> <p>Requires health insurers to cover PrEP and PEP dispensed by pharmacists in the insurer's network</p> <p>Requires health insurers to at least one version of both PrEP and PEP without any prior authorization or step therapy requirements</p>
TENNESSEE	SB 869	Signed into law on May 1, 2024	PEP	Allows pharmacists to prescribe PEP without prescription	N/A
UTAH	HB 178	Signed into law on March 16, 2021	PrEP and PEP	Allows 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
VIRGINIA	HB 2079	Enacted 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

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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

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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:

### **Connecticut – SB 1102 (2023)<sup>34</sup>**

In June of 2023, Connecticut passed legislation, SB 1102, granting pharmacists the authority to independently initiate both PrEP and PEP. SB 1102, which has since been codified under Conn. Gen. Stat. Ann. § 20-633f, allows pharmacists to prescribe up to a 60-day supply of PrEP within a two-year period and a full 30-day regimen of PEP. SB 1102 mandates that pharmacists complete a training program approved by the Connecticut State Board of Pharmacy that must address: 1) obtaining a patient's complete sexual history; 2) delivering positive HIV-related test results; and 3) utilizing PrEP for patients who have tested negative for HIV. However, the legislation does not address pharmacist reimbursement or other insurance provisions. SB 1102 was signed into law on June 7, 2023.

### **Louisiana – HB 579 (2024)<sup>35</sup>**

In 2024, Louisiana passed legislation, HB 579, allowing pharmacists to prescribe and dispense both PrEP and PEP under a statewide protocol. HB 579 authorizes pharmacists to prescribe up to a 30-day supply of PrEP and a full course of PEP without needing a standing order from a primary care provider. The law also mandates that pharmacists notify a patient's primary health care provider about any PEP-related services; if the patient lacks a primary provider, pharmacists must make a good faith effort to refer them to one. Pharmacists must complete a training course approved by the Louisiana Department of Health that covers 1) PrEP and PEP usage, 2) financial assistance programs for PrEP and PEP, and 3) strategies for accessing state and federal resources to provide the same level of care for patients regardless of insurance coverage status. Notably, the legislation requires health care insurers to reimburse pharmacists for PrEP and PEP-related services at a rate equal to that of a primary care provider. HB 579 was signed into law on June 19, 2024.

**New York – SB 129 (2017)<sup>36</sup>; SB 7704A<sup>37</sup>; SB 3297 (2023)<sup>38</sup>**

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.<sup>39</sup> 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 bill SB 7704A would permit pharmacists to prescribe PrEP pursuant to a standing order from a licensed physician or nurse practitioner. This legislation, if passed, would permit pharmacists to independently prescribe PrEP under certain conditions. Pharmacists independently prescribing PrEP would need to complete a training program developed by the New York Department of Health. Pharmacists would also 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. Pharmacists would also need to ensure that the patient is without any other noticeable signs or symptoms of HIV and that the patient does not report taking any contradicting medications. Finally, pharmacists would also be required to furnish patients with department-published information on PrEP and inform the patient of the need to see a physician for subsequent PrEP prescriptions. Notably, the proposed legislation does not mention insurance coverage, prior authorization, or step therapy.

While SB 7704A has been sitting in the Senate and House Higher Education Committee responsible for amending laws impacting pharmacist scope of practice since January 2022, New York legislature introduced new legislation in January 2023 that mirrors SB 7704A. This new legislation, SB 3297, is an exact copy of SB 7704A and serves as a reintroduction of the bill. SB has been sitting in the Senate Higher Education Committee since January of 2023.

**California – SB 159 (2019)<sup>40</sup>; SB 339 (2024)<sup>41</sup>**

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.

California passed additional legislation in January 2024 that further expands Californian pharmacists' ability to independently prescribe PrEP. The bill, SB 339, authorizes a pharmacist to furnish up to a 90-day supply of PrEP or PrEP beyond a 90-day supply, if certain conditions are met. In addition to the requirements outlined in SB 159, SB 339 states that a pharmacist seeking to furnish PrEP beyond a 90-day supply must ensure the following: 1) the patient receives testing and follow-up care consistent with CDC guidelines, 2) services provided by the pharmacist are recorded in the patient's record and maintained in the pharmacy's record system, and 3) the patient's primary care provider is notified of the pharmacist's compliance with all statutory requirements relating to prescribing PrEP. If the patient does not have a primary care provider, then the pharmacist must provide a list of local primary care providers.

SB 339 also extends insurance coverage by requiring health care service plans to cover pharmacist-furnished PrEP and costs for the pharmacist's services and related testing. Furthermore, the bill requires the California State Board of Pharmacy to adopt emergency regulations to implement these provisions by October 31, 2024.

### **Colorado – HB 1061 (2020)<sup>42</sup>**

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.

On November 28, 2023, the Colorado State Board of Pharmacy established a Statewide Protocol<sup>43</sup> that permits all pharmacists (with either a Doctor of Pharmacy degree or at least 5 years of experience as a licensed pharmacist) who have completed an ACPE-accredited course approved by the Colorado State Board of Pharmacy to prescribe PrEP and PEP. Once completing the required course, Colorado pharmacists may independently prescribe unlimited quantities of PrEP and PEP.

Colorado's Statewide Protocol requires pharmacists to establish a process to communicate with a patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider (or is unable to provide contact information for their primary care provider) the pharmacist must provide the patient with a written record of the drugs or devices furnished, any lab tests ordered, and any test results. The Statewide Protocol also specifies that a pharmacist seeking to initiate PrEP may either conduct a rapid CLIA-waived



test or draw blood from the patient and send the sample to a laboratory for testing. Additionally, when dispensing PrEP or PEP, the Statewide Protocol requires pharmacists to provide counseling on the following: 1) the proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate); 2) the importance of medication adherence with relation to efficacy of PrEP/PEP; 3) signs/symptoms of acute HIV infection and recommended actions; 4) consistent and correct use of condoms and prevention of STIs; 5) the necessity of follow up care with a primary care provider for routine care; and 6) the importance and requirement of testing for HIV, renal function, hepatitis B, and sexually transmitted infections. .

#### **New Jersey – SB 1039 (2020)<sup>44</sup>**

New Jersey introduced SB 1039 on January 30, 2020. SB 1039 would have allowed pharmacists to prescribe up to 60 days of PrEP in a two-year period or one complete 28-day course of PEP, required 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 required Medicaid reimbursement for PrEP and PEP prescribed by pharmacists. This bill would have only allowed 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 bill also would have required patients to provide test results affirming their HIV negative status. In the absence of such results, pharmacists would have been able to order tests to confirm the patient's status. The bill would have further mandated 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 could opt into prescribing PrEP without a prescription from a provider. The bill was referred to the Senate Budget and Appropriations Committee on March 9, 2021. Unfortunately, SB 1039 died in this committee.

#### **Florida – HB 607<sup>45</sup> and SB 928 (2021)<sup>46</sup>; SB 416 (2023)<sup>47</sup>; HB 159 (2024)<sup>48</sup>**

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.

Florida legislature introduced new legislation in January 2023 that mirrored SB 928. This new legislation, SB 416, was an exact copy of SB 928 and served as a reintroduction of the bill. Regrettably, SB 416 died in Florida Senate's Health Policy Committee on May 5, 2023.

Florida passed legislation, HB 159, in March 2024 that expands pharmacists' ability to initiate and dispense PEP. HB 159, which has since been codified into section 465.1861 of Florida's Code<sup>49</sup>, permits pharmacists to initiate and dispense PEP pursuant to a non-patient specific standing order through a collaborative practice agreement with a primary care provider. Before initiating PrEP, HB 159 requires a pharmacist to complete a course approved by the Florida Board of Pharmacy that covers the following: 1) performance of patient assessments; 2) point-of-care testing

procedures; 3) safe and effective treatment of HIV exposure with HIV infection prevention drugs, including, but not limited to, consideration of the side effects of the drug dispensed and the patient's diet and activity levels; 4) identification of medication contraindications; and 5) identification of patient comorbidities in individuals with HIV requiring further medical evaluation and treatment, including, but not limited to, cardiovascular disease, lung and liver cancer, chronic obstructive lung disease, and diabetes mellitus.

### **Virginia – HB 2079 (2021)<sup>50</sup>**

Virginia passed legislation in 2021 to amend and reenact portions of Virginia's code related to pharmacists' ability to prescribe and treat certain conditions. HB 2079, which has since been codified into sections 54.1-3300 and 54.1-3303.1 of the Code of Virginia, permits pharmacists to initiate PrEP and PEP without a practitioner's prescription. The law requires pharmacists to refer patients to a primary care provider. HB 2079 also directed the state board of pharmacy to develop a statewide drug therapy protocol for pharmacists to prescribe and dispense PrEP and PEP.

The Virginia Board of Pharmacy established a statewide protocol, which has been in effect since December 2021, for pharmacists seeking to independently furnish PrEP.<sup>51</sup> Pharmacists are required to complete a comprehensive training program related to the prescribing and dispensing of HIV prevention and medications. The protocol provides patient intake forms the pharmacist must have the patient fill out prior to prescribing PrEP. These forms outline the standardized PrEP assessment and treatment care pathway that Virginian pharmacists are to follow. The pharmacist initiating treatment and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing as part of their patient assessment. Patients who test reactive or indeterminate for HIV, gonorrhea, chlamydia, syphilis, or Hepatitis B must be referred to a primary care provider for evaluation, diagnosis, and treatment.

### **Massachusetts – SD 2258 (2021)<sup>52</sup>; SD 445 (2023)<sup>53</sup>**

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. On June 30, 2022, the bill passed the Senate and was sent to the House. The bill was referred to the House Committee on Ways and Means on July 7, 2022. Unfortunately, SD 2258 died in this committee.

The Massachusetts Senate introduced new legislation in January 2023 that mirrors SD 2258. This new legislation, SD 445, is an exact copy of SD 2258 and serves as a reintroduction of the bill. The bill, which has since been renumbered as SB 2480, has been sitting in the Massachusetts committee on House Ways and Means since October 2023.

**North Carolina – SB 575 (2021)<sup>54</sup>; SB 96 (2021)<sup>55</sup>**

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. On May 11, 2021, the bill passed the Senate and was sent to the House. The bill was referred to the Committee on Rules, Calendar, and Operations of the House on May 13, 2021, and has since died in committee.

On February 16, 2021, a similar bill was introduced into the state senate and was signed into law on August 20, 2021. The bill, SB 96, expanded the scope of practice of immunizing pharmacists to allow the prescribing, dispensing, and administration of certain specified medications. To qualify as an immunizing pharmacist, a pharmacist must: 1) hold CPR certification issued by the American Heart Association or the American Red Cross, or an equivalent certification; 2) complete a vaccine administration certificate program that is accredited by the CDC, ACPE, or a similar health authority or professional body approved by the Board of Pharmacy; 3) maintain documentation of three hours of continuing education every two years, designed to maintain competency in the disease states, drugs, and vaccine administration; 4) complete training approved by the Division of Public Health's Immunization Branch for participation in the North Carolina Immunization Registry; 5) notify the North Carolina Board of Pharmacy and the North Carolina Medical Board of immunizing pharmacist status; and 6) administer vaccines, long-acting injectable medications, or immunizations. SB 96 states that if these qualifications are met, then the immunizing pharmacist may prescribe PEP pursuant to a standing order.

On March 28, 2022, the North Carolina State Health Director signed and released a standing order<sup>56</sup> that permits all immunizing pharmacists to prescribe PEP.

**Missouri – H.B. 370 and S.B. 79 (2021)<sup>57</sup>; H.B. 476 (2021)<sup>58</sup>**

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 died in their respective chambers and will likely not be reintroduced in a future session.

In 2021, Missouri enacted legislation, HB 476, allowing pharmacists to prescribe and dispense PEP pursuant to a non-patient specific standing order. HB 476 did not address the implementation of pharmacist-initiated PEP beyond the fact that pharmacists must obtain a standing order from a licensed physician in order to do so. Rather, HB 476 called for the State Board of Pharmacy to establish regulations regarding the implementation of pharmacist-initiated PEP. HB 476 was signed into law on June 22, 2021, and codified under Mo. Ann. Stat. § 338.730.

While HB 476 called for the establishment of supplemental regulations outlining the implementation of pharmacist-initiated PEP, it was not until 2023 that such regulations were enacted. The regulation, Mo. Code Regs. Ann. tit. 20, § 2220-6.025, was enacted on February 23, 2023 and imposed additional requirements for pharmacist-initiated PEP. The regulation permits pharmacists to prescribe a full 28-day course of PEP pursuant to a non-patient specific standing order, but only twice within a two-year period for any given patient. Pharmacists are also required to notify a patient's primary health care provider about any PEP-related services or, if the patient lacks a primary provider, provide a list of local primary health care providers or clinics. The regulation states that pharmacists may also prescribe PEP pursuant to a standing order issued by the Director of the Missouri Department of Health and Senior Services. However, the Director of the Missouri Department of Health and Senior Services has yet to issue such a standing order.

#### **Maryland – SB 828 (2021)<sup>59</sup>; SB 355 (2022)**

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 was unsuccessful and did not pass the Senate.

On January 21, 2022, SB 355 was introduced to the Maryland Senate. This legislation closely mirrored SB 828 and was intended to serve as a modified reintroduction of SB 828. The difference between SB 828 and SB 355 is that SB 355 would have permitted pharmacists to dispense only up to a 30-day supply of PrEP (as opposed to SB 828's 60-day supply). Furthermore, SB would have limited pharmacists to prescribe no more than a combined 60-day supply of PrEP to the same patient within a two-year period. SB 355 would have still permitted pharmacists to dispense a complete course of PEP.

On March 10, 2022, SB 355 passed the Senate and was sent to the House. The bill was referred to the House Health and Government Operations Committee on March 15, 2022, and has since died in committee.

#### **Nevada – SB 325 (2021)<sup>60</sup>**

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 related services 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 855<sup>61</sup> and SF 340 (2021)<sup>62</sup>; HF 5247 (2024)<sup>63</sup>**

Minnesota introduced identical bills in both legislative chambers in February and March 2021. HF 855 and SF 340 would have allowed pharmacists to prescribe PrEP or one complete 28-day course of PEP. It would have further established training requirements pharmacists must complete to initiate PrEP and PEP. The bills also would have required insurance companies to cover PrEP and PEP without prior authorization or step therapy. Patients would have had to confirm their HIV-negative status before pharmacists could initiate PrEP or PEP. Alternatively, pharmacists would have been permitted to order tests if needed to confirm the patient's status. Unfortunately, both bills died in their respective chambers.

On May 24, 2024, Minnesota passed legislation, HF 5247, allowing pharmacists to prescribe and dispense PrEP and PEP under a statewide protocol, which will go into effect on January 1, 2025. HF 5247 will enable pharmacists to independently initiate unlimited quantities of both PrEP and PEP. Before pharmacists may utilize this authority, HF 5247 mandates that pharmacists complete a training course approved by the Accreditation Council for Pharmacy Education (ACPE) or the Minnesota State Board of Pharmacy. Additionally, the legislation addresses reimbursement by prohibiting insurers from requiring prior authorization or step therapy to cover PrEP and PEP – although health plans are not obligated to cover all therapeutically equivalent versions without prior authorization or step therapy if at least one version is covered without these restrictions. Furthermore, starting January 1, 2026, pharmacists will be defined as healthcare providers solely for the purpose of initiating PrEP and PEP – ensuring insurers reimburse them for PrEP and PEP-related clinical services.

**Maine – LD 1115 (2021)<sup>64</sup>**

Maine's legislation was introduced on March 22, 2021. LD 1115, which has since been codified<sup>65</sup> under Maine's statutes governing professions and occupations, allows pharmacists to prescribe up to 60 days of PrEP in a two-year period or one complete 28-day course of PEP. The bill also requires 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. Additionally, the bill requires patients to provide test results affirming their HIV negative status. In the absence of such results, pharmacists are able to order tests to confirm the patient's status. The bill requires 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.

**Illinois – HB 4430<sup>66</sup>**

Illinois passed legislation in 2022 that amends and expands portions of Illinois's code<sup>67</sup> related to pharmacists' ability to prescribe and treat certain conditions. The bill, HB 4430, allows pharmacists to prescribe and dispense PrEP and PEP pursuant to a non-patient specific standing order issued by a licensed physician or the medical director of a county or local health department. HB 4430 also permits pharmacists to provide initial assessment services, which include running laboratory tests. Under this bill, pharmacists seeking to initiate and dispense PrEP and PEP must first complete an educational training program accredited by the Accreditation Council for Pharmacy Education or Department of Financial

and Professional Regulation related to PrEP and PEP. HB 4430 also requires pharmacists to inform a patient's primary health care provider of any services related to the initiation and dispensing of PrEP or PEP. If a patient does not have a primary health care provider, then the pharmacist must give a list of primary health care providers or clinics in the area. The bill 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.

HB 4430 also requires insurers, including state Medicaid, to provide coverage and reimbursement for PrEP and PEP services at a rate no less than 85% of the rate that the services are reimbursed when provided by a physician. The bill was signed by the Governor on June 10, 2022, and went into effect on January 1, 2023.

### **Oregon – HB 2958<sup>68</sup>**

Oregon passed legislation in 2021 that authorizes pharmacists to prescribe and dispense up to a 30-day supply of PrEP and a complete course of PEP. In order to dispense PrEP or PEP, pharmacists are also authorized to order laboratory tests to confirm the patient's HIV status. The bill, HB 2958, mandates that health insurers covering services within a pharmacist's scope of practice must provide reimbursement at a rate equal to the rate that the services are reimbursed when provided by a physician. Furthermore, HB 2958 prohibits health insurers from requiring prior authorization before a pharmacist dispenses PrEP and PEP. The bill was signed by the Governor on June 23, 2021, and went into effect on September 25, 2021.

### **Utah – HB 178<sup>69</sup>**

Utah passed legislation in 2021 to amend and reenact portions of Utah's code related to pharmacists' ability to prescribe and treat certain conditions. HB 178, which has since been codified into section 58-17b-627 of the Utah Code, permits pharmacists to initiate PrEP and PEP without a practitioner's prescription. The bill does not impose quantity limitations on the number of times a pharmacist may prescribe PrEP or PEP to a single patient. HB 178 is silent as to pharmacist reimbursement for PrEP and PEP related services. HB 2079 also directed the Department of Commerce's Division of Occupational and Professional Licensing to develop regulatory guidance for pharmacists to prescribe and dispense PrEP and PEP.

The Division of Occupational and Professional Licensing established a regulation<sup>70</sup> and a statewide protocol<sup>71</sup> for pharmacists seeking to independently furnish PrEP. The regulation requires pharmacists to inform patients' primary care providers (if the patient has one) of the prescription. The protocol provides patient intake forms that the pharmacist must have the patient fill out prior to prescribing PrEP. These forms outline the standardized PrEP assessment and treatment care pathway that Utah pharmacists are to follow. The pharmacist initiating treatment and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing as part of their patient assessment. Patients who test reactive or indeterminate for HIV, gonorrhea, chlamydia, syphilis, or Hepatitis B must be referred to a primary care provider for evaluation, diagnosis, and treatment. A patient who answers "yes" to having condomless sex within the past two weeks must also be referred.

**Arkansas – HB 1007<sup>72</sup>**

Arkansas introduced legislation in its House in January 2023. The legislation, HB 1007, passed on March 21, 2023, and will be enacted as Act 314. HB 1007 allows pharmacists to prescribe up to a 60-day supply (with a requirement of prescribing at least a 30-day supply) of PrEP or one complete 28-day course of PEP. In order to initiate PrEP or PEP, pharmacists must complete a training program approved by the Arkansas State Board of Pharmacy. The training must include information on the use of PrEP and PEP and financial assistance for PrEP and PEP. Further, before pharmacists can prescribe PrEP or PEP, the patient must provide test results confirming their HIV status. If the patient cannot provide test results, the pharmacist may order and interpret tests. HB 1007 also prohibits insurers from requiring prior authorization or step therapy to cover PrEP and PEP.

**New Mexico – SB 92<sup>73</sup>**

New Mexico introduced legislation in its Senate on January 17, 2023. The legislation, SB 92, was soon after signed into law on April 4, 2023. SB 92 permits pharmacists to initiate and dispense PrEP without a practitioner's prescription. The bill does not impose quantity limitations on the number of times a pharmacist may prescribe PrEP or PEP to a single patient. SB 92 is silent as to pharmacist reimbursement for PrEP related services. SB 92 also directs the State Board of Pharmacy to develop a protocol and regulatory guidance for pharmacists to prescribe and dispense PrEP.

The State Board of Pharmacy has previously established a statewide protocol in 2021<sup>74</sup> that enables pharmacists to initiate and dispense PEP without a practitioner's prescription. To prescribe PEP pursuant to this protocol, a pharmacist is required to complete two hours of ACPE-approved continuing education regarding HIV PEP every two years.

To prescribe PrEP, pharmacists must follow a statewide protocol similar to the PEP protocol that the Board of Pharmacy will establish. However, the Board of Pharmacy has yet to establish a protocol regarding pharmacists seeking to prescribe PrEP. Pharmacists in New Mexico must wait until such a statewide protocol is released until they may prescribe PrEP.

**Rhode Island – HB 6150<sup>75</sup>; SB 0575<sup>76</sup>**

On March 10, 2023, Rhode Island introduced legislation in its House. The bill, HB 6150, sought to broaden pharmacists' scope of practice and ensure health insurance coverage of HIV prevention medication. HB 6150 would have permitted pharmacists to dispense PrEP and PEP pursuant to a collaborative practice agreement with or a non-patient specific standing order from a primary care provider. Alternatively, HB 6150 would have granted the Rhode Island Board of Pharmacy the authority to establish a statewide protocol for pharmacists to follow if they wish to prescribe PrEP and PEP without using a collaborative practice agreement or standing order.

HB 6150 would have allowed pharmacists to prescribe up to a 60-day supply (with a requirement of prescribing at least a 30-day supply) of PrEP or one complete 28-day course of PEP. In order to initiate PrEP or PEP, pharmacists would have been required to complete a training program approved by the Rhode Island State Board of Pharmacy. The training would have had to include information on the prescribing of PrEP and PEP – including the process of testing for HIV. Further, before pharmacists could prescribe PrEP or PEP, the patient would have to provide test results

from within the last seven days confirming their HIV status. If the patient could not provide test results, the pharmacist would have been able to order and interpret tests. The bill would have required pharmacists to refer a patient who tests positive to HIV to a primary care practitioner. After prescribing PrEP or PEP, the pharmacist would have been required to notify the patient's primary care provider. If the patient did not have a primary care provider, then HB 6150 would have required a pharmacist to provide a list of local primary care providers.

HB 6150 would have also prohibited insurers from requiring prior authorization or step therapy to cover PrEP and PEP. Furthermore, the bill would have required health insurers to cover PrEP and PEP dispensed by pharmacists in the insurer's network.

Unfortunately, HB 6150 died in the Rhode Island House in June of 2023.

However, Rhode Island was able to successfully pass legislation that mirrored HB 6150 just weeks later. The legislation, SB 575, was signed into law on June 22, 2023. SB 575 permits pharmacists to prescribe PrEP and PEP under a non-patient specific standing order. While the bill explicitly permits the Rhode Island Board of Pharmacy to establish a statewide standing order, the board has yet to do so, which requires pharmacists to obtain a standing order from a primary care practitioner. SB 575 imposes a quantity limit, allowing pharmacists to prescribe a 60-day supply of PrEP no more than twice in a two-year period and a complete 28-day course of PEP. Pharmacists must notify a patient's primary care provider if they prescribe PrEP or PEP – or provide a list of local providers if the patient does not have one. Before initiating PrEP or PEP, pharmacists must first complete a training program approved by the Rhode Island Board of Pharmacy covering the use of protocols for prescribing and dispensing HIV prevention drugs, laboratory testing requirements, and best practices for counseling patients. Health insurance plans issued or renewed after January 1, 2024, must cover PrEP and PEP without prior authorization or step therapy requirements and cannot impose copayments or deductibles for these medications.

### **Tennessee – SB 0869<sup>77</sup>**

In May 2024, Tennessee passed legislation, SB 869, granting pharmacists the authority to independently initiate PEP without requiring a standing order from a primary care provider. The law imposes no quantity limits on pharmacy-initiated PEP, nor does it restrict the frequency with which pharmacists can prescribe PEP to a given patient. Additionally, pharmacists are not required to undergo any special training to prescribe PEP. The legislation does not address reimbursement or other insurance provisions for pharmacists providing PEP services. SB 869 was signed into law on May 1, 2024, and has since been codified under Tenn. Code Ann. § 63-10-204.



<sup>1</sup> 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>.

<sup>2</sup> *Id.*

<sup>3</sup> *Supra* note 1.

<sup>4</sup> 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>.

<sup>5</sup> 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>

<sup>6</sup> *Id.*

<sup>7</sup> 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)

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> See *infra* note 14.

<sup>11</sup> 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).

<sup>12</sup> *Id.*

<sup>13</sup> <https://pubmed.ncbi.nlm.nih.gov/32671081/>

<sup>14</sup> *Supra* note 8.

<sup>15</sup> 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>.

<sup>16</sup> 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).

<sup>17</sup> *Supra* note 8.

<sup>18</sup> 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>.

<sup>19</sup> Hammond RW, Schwartz AH, et al. *Collaborative Drug Therapy Management by Pharmacists—2003*, 23 J. HUMAN PHARMACOLOGY AND DRUG THERAPY, 1210 (2003).

<sup>20</sup> 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](https://www.cdc.gov/dhbsp/pubs/docs/translational_tools_pharmacists.pdf)

<sup>21</sup> 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).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> 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).

<sup>26</sup> *Id.*

<sup>27</sup> *Supra* note 8.

<sup>28</sup> *Id.*

<sup>29</sup> 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>.

<sup>30</sup> 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/>

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<sup>67</sup> 225 Ill. Comp. Stat. Ann. 85/3, 85/43.5; 305 Ill. Comp. Stat. Ann. 5/5-5.12d.

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<sup>73</sup> S.B. 92 (N.M. 2023).

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