Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative Practice Agreements

Introduction

According to the most recent statistics from the Centers for Disease Control and Prevention, nearly 1.2 million people in the United States live with HIV, including over 150,000 people whose infections are undiagnosed.[i] Certain groups experience disproportionate rates of new HIV diagnoses, including Black and Latinx Americans, gay, bisexual, and other men who have sex with men (GBM), young people, and people residing in the South.[ii]

> **BACKGROUND:** There are two highly effective biomedical interventions that prevent transmission of HIV in people who are HIV-negative: pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). PrEP is a medication that a person at risk for HIV takes every day to prevent transmission through sex or injection drug use, while PEP is an emergency course of treatment that is taken within 72 hours after a potential exposure to HIV and is continued for four weeks.[iii] Injectable PrEP is a form of PrEP that is administered by injection every two months.[iv]

Barriers to PrEP

PrEP can reduce the risk of getting HIV from sex by 99%, and from injection drug use by 74%.[v] However, fewer than 25% of individuals who would benefit from PrEP use the medication.[vi] While more than half of new HIV infections in the United States occur in southern states, only 30% of PrEP users reside in the southern region.[vii] PrEP uptake is the lowest among groups with the greatest need for the medications, including rural Americans in the South, Black and Latinx individuals, Black and Latinx GBM, and serodiscordant* couples.[viii] These communities face major barriers to accessing PrEP, including a lack of knowledge about the medications, stigma around HIV, bias from healthcare providers, distrust of the medical establishment, inability to afford the medications, and systemic racism.[ix] Diversifying the healthcare settings and provider types that offer HIV care could address some of these barriers.

Accessibility of Pharmacists

Reduced access to primary care and sexual health clinics also creates a significant barrier to PrEP and PEP uptake, especially for Black and Latinx communities.[x] Pharmacies offer a more accessible option for

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* "Serodiscordant couple" refers to intimate relationships where one partner is HIV-positive, and another partner is HIV-negative. Advances in HIV Prevention for Serodiscordant Couples - PMC (nih.gov).

many people seeking care as 90% of Americans live within 5 miles of a pharmacy.[xi] Pharmacies often provide services for extended hours, some up to 24 hours a day, and patients can receive care without an appointment, making them a more accessible option than primary care for many individuals. Furthermore, pharmacists can provide referrals and linkage to mainstream health care. Pharmacists are also consistently rated as one of the most trusted healthcare professionals,[xii] making them ideal providers of PrEP and PEP in communities that need to access these services the most. As a result, significant efforts have been made to allow pharmacists to independently initiate and administer PrEP and PEP.

Pharmacist-Initiated PrEP & PEP

A pharmacist's authority to independently initiate PrEP or PEP can come from one of the three following sources: 1) a standing order, 2) a statewide protocol, or 3) directly from a statute.[xiii]

A standing order authorizing a pharmacist's ability to distribute PrEP or PEP can either be a statewide standing order or a standing order directly from a primary care provider (PCP).

A statewide standing order is when a state government official, often the State Health Director with a Doctor of Medicine (MD), issues written authorization for a specified drug (e.g., PrEP or PEP) that any pharmacist licensed to practice in the state may utilize. A statewide standing order is non-patient specific, meaning it grants pharmacists the authority to independently distribute specified drug/s to anyone within a certain population. For example, non-patient specific standing orders for PrEP allow a pharmacist to distribute PrEP to any persons at risk of contracting HIV. The authority for a statewide non-patient specific standing order would be granted by statute.[xiv]

A standing order from a PCP is a blanket prescription that is either 1) specific to a single patient or 2) specific to a population of patients. The former is a patient specific standing order, meaning a PCP grants authority for a specific pharmacist to independently distribute a specified drug (e.g., PrEP or PEP) to a single patient. The latter is a non-patient specific standing order, meaning a PCP grants authority for a specific pharmacist to independently distribute a specified drug to anyone within a certain population. For example, non-patient specific standing orders for PrEP are for any individuals at risk of contracting HIV. A statute permitting pharmacists to initiate PrEP or PEP may require a standing order from a primary care provider.

A statewide protocol is when the State Board of Pharmacy establishes guidelines that a pharmacist must follow in order to independently distribute a specified drug (e.g., PrEP or PEP). The authority for a State Board of Pharmacy to establish a statewide protocol would be granted by statute. This statutory authority may be granted under a statute generally authorizing the Board to establish binding regulations regarding the practice of pharmacy.[xv]

A statute refers to a written law enacted by a state's legislature.[xvi] A statute may directly grant pharmacists the authority to independently initiate PrEP or PEP, or indirectly grant pharmacists the authority to do so through a standing order (either a statewide standing order or a standing order from a PCP) or a statewide protocol.[xvii]

Pharmacists with the authority to independently initiate PrEP or PEP (whether it comes from a standing order, statewide protocol, or directly from a statute) may face several limitations. Common constraints include the need to undergo specific training before the pharmacist may distribute PrEP or PEP, limitations on how much non-prescribed PrEP or PEP the pharmacist may distribute to a single patient, and issues with reimbursement. Training requirements and quantity limits serve as accessibility barriers as they place time and cost burdens on pharmacists, restrict members of the community from possessing PrEP and PEP, and prevent pharmacists from being reimbursed for PrEP and PEP-related services. Granting pharmacists the authority to independently distribute unlimited quantities of PrEP and PEP and establishing legal requirements for proper pharmacist reimbursement facilitates PrEP and PEP's purpose – stopping new HIV infections.

Figure 1. Oral PrEP[*]

State	Do pharmacists have the legal authority to distribute oral PrEP without a prescription from a primary care provider (PCP)?	Authority	*Does the pharmacist need a standing order from a PCP?*	*Quantity limits for PrEP or PEP*	Other Requirements for Pharmacists and Insurers
Alabama	No	N/A	N/A	N/A	N/A
Alaska	No	N/A	N/A	N/A	N/A
Arizona	No	N/A	N/A	N/A	N/A
Arkansas	Yes	Statute: Arkansas Code § 17-92-101(17)(A)(i)(g) and (26); Arkansas Code § 17-92-115; Arkansas Code § 23-92-506(b)(6) and (7); Ark. Code	No	PrEP is limited to up to a 60-day supply. A complete 28-day course of PEP is permitted.	Pharmacists must first complete a training program. Pharmacists must also inform the patient's primary care provider of the prescription.

[*]**ORAL PREP:** This section addresses the legal authority for a pharmacist to distribute oral PrEP without a prescription from a primary care provider.

		Ann. § 23-99-1120			Insurers are prohibited from requiring prior authorization or step therapy.
California	Yes	Statute: Cal. Bus. & Prof. Code § 4052.02 and .03; Cal. Health & Safety Code § 1342.74; Cal. Ins. Code § 10123.1933; and Cal. Welf. & Inst. Code § 14132.968	No	PrEP is limited to up to a 60-day supply. A complete 28-day course of PEP is permitted.	Pharmacists must complete training program approved by California State Board of Pharmacy. Expanded Medi-Cal schedule of benefits to include PrEP and PEP, requires private insurance companies to cover PrEP and PEP.
Colorado	Yes	Standing Order: Colo. Rev. Stat. Ann. § 10-16-102(27.5), (38.5), (50.5), and (50.7); Colo. Rev. Stat. Ann. § 10-16-104 (18)(e); Colo. Rev. Stat. Ann. § 10-16-152; Colo. Rev. Stat. Ann. § 12-280-103(39)(c)(II)(C), (39)(d), and (39)(e);	Yes	No quantity limitations.	Health insurance providers are prohibited from requiring step therapy or prior authorization for PrEP and PEP. Private insurance plans are required to cover PrEP and PEP prescribed by a pharmacist and pay a consultative

		Colo. Rev. Stat. Ann. § 12-280-125.7; and Colo. Rev. Stat. Ann. § 25-1-130			fee to pharmacists for prescribing PrEP or PEP.
Connecticut	No	N/A	N/A	N/A	N/A
Delaware	No	N/A	N/A	N/A	N/A
D.C.	No	N/A	N/A	N/A	N/A
Florida	No	N/A	N/A	N/A	N/A
Georgia	No	N/A	N/A	N/A	N/A
Hawaii	No	N/A	N/A	N/A	N/A
Idaho	No	N/A	N/A	N/A	N/A
Illinois	Yes	Standing Order: 305 Ill. Comp. Stat. Ann. 5/5-5.12d; 225 Ill. Comp. Stat. Ann. 85/3, 85/43.5; 215 Ill. Comp. Stat. Ann. 5/356z.45; and 215 Ill. Comp. Stat. Ann. 5/356z.60	Yes	No quantity limitations	Pharmacists must complete training program approved by the ACPE or Department of Financial and Professional Regulation. Insurers required to 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.
Indiana	No	N/A	N/A	N/A	N/A
Iowa	No	N/A	N/A	N/A	N/A
Kansas	No	N/A	N/A	N/A	N/A
Kentucky	No	N/A	N/A	N/A	N/A
Louisiana	No	N/A	N/A	N/A	N/A
Maine	Yes	Statewide Protocol: Me. Rev. Stat. tit. 22, § 3174-M;	No	PrEP is limited to up to a 60-day supply. A complete 28-day course of	Insurers are required to cover PrEP and PEP prescribed by pharmacists without prior authorization

		Me. Rev. Stat. tit. 24-A, § 4317-D; Me. Rev. Stat. tit. 32, § 13702-A(28); Me. Rev. Stat. tit. 32, § 13786-E		PEP is permitted.	or step therapy.
Maryland	No	N/A	N/A	N/A	N/A
Massachusetts	No	N/A	N/A	N/A	N/A
Michigan	No	N/A	N/A	N/A	N/A
Minnesota	No	N/A	N/A	N/A	N/A
Mississippi	No	N/A	N/A	N/A	N/A
Missouri	No	N/A	N/A	N/A	N/A
Montana	No	N/A	N/A	N/A	N/A
Nebraska	No	N/A	N/A	N/A	N/A
Nevada	Yes	Statewide Protocol: Nev. Rev. Stat. Ann. § 639.0124; Nev. Rev. Stat. Ann. § 639.28085; Nev. Rev. Stat. Ann. § 689B.0312; and Nev. Admin. Code R039-21	No	No quantity limitations	Pharmacists must complete training program approved by the ACPE. Insurers required to cover PrEP and PEP services at a rate equal to the rate that the services are reimbursed when provided by a PCP.
New Hampshire	No	N/A	N/A	N/A	N/A
New Jersey	No	N/A	N/A	N/A	N/A
New Mexico	Yes (only PEP, ***not*** PrEP)	Statewide Protocol: N.M. Stat. Ann. § 61-11-2; N.M. Admin. Code 16.19.26.14; and Statewide Protocol	No.	No quantity limitations	Pharmacists must first complete a training program. Pharmacists must also inform the patient's

					primary care provider of the prescription.
New York	Yes (only PEP, ***not*** PrEP)	Standing Order: N.Y. Comp. Codes R. & Regs. tit. 8, § 63.13	Yes	Pharmacists may only dispense 7 days of PEP without prescription.	None
North Carolina	Yes (only PEP, ***not*** PrEP)	Statewide Standing Order: N.C. Gen. Stat. Ann. § 90-85.15B; N.C. Gen. Stat. Ann. § 90-85.3(i1); and Standing Order	No	A complete 28-day course of PEP is permitted.	A pharmacist must be certified as an immunizing pharmacist.
North Dakota	No	N/A	N/A	N/A	N/A
Ohio	No	N/A	N/A	N/A	N/A
Oklahoma	No	N/A	N/A	N/A	N/A
Oregon	Yes	Statute: Or. Rev. Stat. Ann. § 689.005; Or. Rev. Stat. Ann. § 689.704; Or. Rev. Stat. Ann. § 743A.051; Or. Rev. Stat. Ann. § 743B.425; and Or. Rev. Stat. Ann. § 743B.602	No	PrEP is limited to up to a 30-day supply. A complete 28-day course of PEP is permitted.	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. Insurers are prohibited from requiring prior authorization.
Pennsylvania	No	N/A	N/A	N/A	N/A
Puerto Rico	No	N/A	N/A	N/A	N/A
Rhode Island	No	N/A	N/A	N/A	N/A
South Carolina	No	N/A	N/A	N/A	N/A
South Dakota	No	N/A	N/A	N/A	N/A
Tennessee	No	N/A	N/A	N/A	N/A

Texas	No	N/A	N/A	N/A	N/A
Utah	Yes	Statute: Utah Code Ann. § 58-17b-627 and UT ADC R156-17b-627	No	No quantity limitations	None
Vermont	No	N/A	N/A	N/A	N/A
Virginia	Yes	Statewide Protocol: Va. Code Ann. § 54.1-3300; Va. Code Ann. § 54.1-3303.1 ; and Statewide Protocol			
Virgin Islands	No	N/A	N/A	N/A	N/A
Washington	No	N/A	N/A	N/A	N/A
West Virginia	No	N/A	N/A	N/A	N/A
Wisconsin	No	N/A	N/A	N/A	N/A
Wyoming	No	N/A	N/A	N/A	N/A

The table below, Figure 2., addresses the legal authority for a pharmacist to *administer* injectable PrEP, as not every state permits this. The authority to administer injectable PrEP is a separate issue from the authority to initiate oral PrEP. A prescription for injectable PrEP would be required in every scenario. Authority to prescribe is not addressed in Figure 2. Any additional mandates required of or restrictions imposed on the pharmacist are included.

Figure 2. Injectable PrEP*

State	Do pharmacists have the legal authority to administer injectable PrEP?	Authority	Limitations to Administration or Requirements for Pharmacists
Alabama	Yes	Ala. Code § 34-23-1	None
Alaska	Yes	Alaska Stat. Ann. § 08.80.480	None

*__INJECTABLE PREP__: This section addresses the legal authority for a pharmacist to *administer* injectable PrEP, as not every state permits this. A prescription would be required in every scenario. Authority to prescribe is not addressed in this section.

Arizona	Yes	Ariz. Rev. Stat. Ann. § 32-1901	None
Arkansas	Yes	Ark. Code Ann. § 17-92-101	The prescription must have explicit instructions from a primary care provider to administer.
California	Yes	Cal. Bus. & Prof. Code § 4016 and Cal. Bus. & Prof. Code § 4052	None
Colorado	Yes	Colo. Rev. Stat. Ann. § 12-280-103	None
Connecticut	No	N/A	N/A
Delaware	Yes	Del. Code Ann. tit. 24, § 2502	Pharmacist must notify patient's primary care provider (if patient designated one) within 72 hours of injection administration.
D.C.	No	N/A	N/A
Florida	No	N/A	N/A
Georgia	Yes	Ga. Code Ann. § 26-4-4 and Ga. Code Ann. § 26-4-5	None
Hawaii	Yes	Haw. Rev. Stat. Ann. § 461-1	None
Idaho	Yes	Idaho Code Ann. § 54-1705	None
Illinois	No	N/A	N/A
Indiana	Yes	Ind. Code Ann. § 25-26-13-2	None
Iowa	Yes	Iowa Code Ann. § 155A.3	None
Kansas	No	N/A	N/A
Kentucky	Yes	Ky. Rev. Stat. Ann. § 315.010	None

Louisiana	Yes	La. Stat. Ann. § 37:1164 and 46 La. Admin. Code Pt LIII, § 521	Pharmacist must undergo additional training in order to administer medications, which includes injectable drugs.
Maine	Yes	Me. Rev. Stat. tit. 32, § 13702-A	Pharmacist may only administer drugs, including injectable prescription drugs, in compliance with a treatment protocol established by a licensed practitioner. A copy of the original treatment protocol and any subsequent revisions to the treatment protocol must be kept on file.
Maryland	No	N/A	N/A
Massachusetts	No	N/A	N/A
Michigan	No	N/A	N/A
Minnesota	No	N/A	N/A
Mississippi	Yes	Miss. Code. Ann. § 73-21-73	None
Missouri	No	N/A	N/A
Montana	No	N/A	N/A
Nebraska	Yes	Neb. Rev. Stat. Ann. § 38-2806 and Neb. Rev. Stat. Ann. § 38-2837	None
Nevada	Yes	Nev. Rev. Stat. Ann. § 639.0124; Nev. Rev. Stat. Ann. § 639.28085; and Nev. Admin. Code R039-21 3	The following requirements must first be met: 1) complete an ACPE-approved course of training concerning the prescribing, dispensing and administering of such drugs; 2)

			maintain and make readily available proof of completion of said course; and 3) maintain professional liability insurance coverage of at least $1,000,000.
New Hampshire	Yes	N.H. Rev. Stat. Ann. § 318:1	None
New Jersey	No	N/A	N/A
New Mexico	Yes	N.M. Stat. Ann. § 61-11-2	None
New York	No	N/A	N/A
North Carolina	Yes	N.C. Gen. Stat. Ann. § 90-85.3A; N.C. Gen. Stat. Ann. § 90-85.3; and N.C. Gen. Stat. Ann. § 90-85.15B	An immunizing pharmacist may administer a long-acting injectable medication to an adult pursuant to a patient-specific prescription if the following requirements are met: 1) keep on file a record of the patient and drug administration and 2) notify within 72 hours the provider who wrote the prescription whether the drug was administered.
North Dakota	Yes	N.D. Admin. Code 61-04-11-02; N.D. Admin. Code 61-04-11-04; and N.D. Admin. Code 61-04-11-07	Pharmacist must be certified through an ACPE-approved course for drug administration. Pharmacist must receive a written protocol from a primary care provider that identified the following

			information: 1) identity of the practitioner issuing the order; 2) identity of the patient to receive the injection; 3) identity of the medication and dose to be administered; and 4) date of the original order and the dates or schedule, if any, of each subsequent administration. Pharmacist must also have a private space to administer injections.
Ohio	No	N/A	N/A
Oklahoma	Yes	Okla. Stat. Ann. tit. 59, § 353.1	None
Oregon	Yes	Or. Rev. Stat. Ann. § 689.005 and Or. Rev. Stat. Ann. § 689.655	None
Pennsylvania	Yes	63 Pa. Stat. Ann. § 390-9.2	The following requirements must be met: 1) complete an ACPE-approved course of training concerning the prescribing, dispensing and administering of such drugs; 2) maintain and make readily available proof of completion of said course; and 3) maintain professional liability insurance coverage

			of at least $1,000,000. Pharmacist must notify the individual's primary care provider, if known, within forty-eight hours of administration. A minimum of two hours of the thirty-hour requirement for continuing education for license renewal be dedicated to injectable medications.
Puerto Rico	No	N/A	N/A
Rhode Island	Yes	216 R.I. Code R. 40-15-1.2	None
South Carolina	Yes	S.C. Code Ann. § 40-43-30	None
South Dakota	Yes	S.D. Codified Laws § 36-11-2.2 and S.D. Admin. R. 20:51:31:15	Pharmacist required to undergo additional training to administer.
Tennessee	Yes	Tenn. Code Ann. § 63-10-204	None
Texas	No	N/A	N/A
Utah	Yes	Utah Code Ann. § 58-17b-102	None
Vermont	Yes	20-4 Vt. Code R. § 1400	None
Virginia	Yes	Va. Code Ann. § 54.1-3300	None
Virgin Islands	No	N/A	N/A
Washington	Yes	Wash. Rev. Code Ann. § 18.64.011	None
West Virginia	Yes	W. Va. Code R. 15-1-2	None
Wisconsin	Yes	Wis. Stat. Ann. § 450.01	None
Wyoming	Yes	Wyo. Admin. Code 059.0001.2 § 4	None

CLIA-Waived Testing

Laboratory tests conducted for the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Any facility performing such tests must obtain CLIA certification by registering with the federal Centers for Medicare and Medicaid Services (CMS).[xviii]

CLIA-waived tests include tests the Food and Drug Administration (FDA) has cleared for home use and tests that are approved for waiver under CLIA. Certain rapid HIV tests have been cleared by the FDA as CLIA-waived, and pharmacists must request a Certificate of Waiver in order to conduct these tests.[xix] Because an HIV test must be performed before PrEP is prescribed,[xx] the authority to conduct CLIA-waived tests is essential for a pharmacist's ability to independently initiate the medication.

Figure 3.

State	Do pharmacists have the legal authority to independently perform CLIA-waived tests?	Authority	Limitations to Performing Tests or Requirements for Pharmacists
Alabama	Yes	AL CLIA Tests	None
Alaska	Yes	Alaska Stat. Ann. § 08.80.337	None
Arizona	No	N/A	N/A
Arkansas	No	N/A	N/A
California	Yes	Ann.Cal.Bus. & Prof.Code § 1206.6; Ann.Cal.Bus & Prof Code § 4052.4; and Ann.Ca.Bus & Prof Code § 1209	In community pharmacy settings, pharmacists may only perform blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA.
Colorado	No	N/A	N/A
Connecticut	No	N/A	N/A
Delaware	Yes	Delaware Del. Code tit. 24, § 2502	None
D.C.	Yes	District of Columbia D.C. Code § 3-1201.02	None
Florida	No	N/A	N/A
Georgia	Yes	GA Code § 26-4-4	None
Hawaii	No	N/A	N/A
Idaho	Yes	Idaho Code § 54-1704	None

Illinois	Yes	Illinois 225 Ill. Comp. Stat. § 85/3	Statute specifically authorizes provision of CLIA-waived tests for PrEP and PEP initiation.
Indiana	No	N/A	N/A
Iowa	Yes	Iowa Code section 155A.46	Pharmacists may provide point of care testing and treatment for influenza, streptococcus A, and COVID-19 as well as point-of-care testing at the point of interaction between a pharmacist and a patient in response to a public health emergency.
Kansas	Yes	K.S.A. 65-16,131	Pharmacists may initiate test and treat under statewide protocol for flu, strep, and UTI.
Kentucky	No	N/A	N/A
Louisiana	No	N/A	N/A
Maine	No	N/A	N/A
Maryland	Yes	MD ADC 10.10.03.02	A pharmacist may obtain a letter of exception that allows them to independently perform the following CLIA-waived tests in a medical laboratory: whole blood glucose, Prothrombin Time/International Normalized Ratio, blood lipid for cholesterol, whole blood lead testing, and urine drug screens.
Massachusetts	No	N/A	N/A
Michigan	No	N/A	N/A
Minnesota	Yes	Minn. Stat. Ann. § 151.01(subd. 27)	The pharmacist may not modify drug therapy as a result of

			the clinical test without a CPA.
Mississippi	No	N/A	N/A
Missouri	No	N/A	N/A
Montana	No	N/A	N/A
Nebraska	No	N/A	N/A
Nevada	No	N/A	N/A
New Hampshire	No	N/A	N/A
New Jersey	No	N/A	N/A
New Mexico	No	N/A	N/A
New York	No	N/A	N/A
North Carolina	No	N/A	N/A
North Dakota	Yes	N.D. Admin. Code 61-04-10-06.	The following tests are included: total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides test by any accepted method; bilirubin, blood, glucose, ketone, leukocyte, nitrate, potential of hydrogen (pH), protein, specific gravity, and urobilinogen tests by nonautomated or automated urinalysis by dipstick; fecal occult blood by any accepted method; ovulation test by visual color comparison; qualitative urine pregnancy test by visual color comparison; erythrocyte sedimentation rate by any accepted nonautomated method; whole blood glucose by any accepted single analyte method; spun microhematocrit by any accepted method;

			hemoglobin by single analyte instrument or manual copper sulfate method; helicobacter pylori, influenza, mononucleosis, streptococcus group A, hepatitis C virus, and respiratory syncytial virus by immunoassay using a rapid test device that detects antibodies or antigens; prothrombin time international normalized ratio by mechanical endpoint; antibodies to HIV types 1 and 2; nicotine or cotinine test by urine; thyroid stimulating hormone test by blood; bone mass and bone mineral density test by any accepted method; and drug screening tests by urine.
Ohio	Yes	Ohio. Admin. Code 4729:1-3-01	The following conditions must be met: (1) The pharmacy or facility is certified by HHS as a clinical laboratory through the CLIA; (2) The pharmacy or facility has obtained a CLIA certificate of waiver from HHS; and (3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs ensures and documents that all pharmacists conducting CLIA-

			waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner.
Oklahoma	No	N/A	N/A
Oregon	Yes	O.R.S. § 689.661	None
Pennsylvania	Yes	63 P.S. § 390-9.5	Limited to COVID-19, influenza and streptococcal infections.
Puerto Rico	No	N/A	N/A
Rhode Island	Yes	5 R.I. Gen. Laws. Ann. § 5-19.1-2	Pharmacist is limited to the following: blood glucose, hemoglobin A1c, cholesterol tests, and/or other tests that are classified as waived under CLIA and are approved by the United States Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit.
South Carolina	No	N/A	N/A
South Dakota	No	N/A	N/A
Tennessee	No	N/A	N/A
Texas	No	N/A	N/A
Utah	No	N/A	N/A
Vermont	No	N/A	N/A
Virginia	No	N/A	N/A
Virgin Islands	No	N/A	N/A
Washington	No	N/A	N/A
West Virginia	No	N/A	N/A
Wisconsin	No	N/A	N/A
Wyoming	Yes	Wyo. Admin. Code 059.0001.20 § 4	None

Reimbursement for Pharmacist Clinical Services

Some states clearly indicate how pharmacists are to be reimbursed for PrEP and PEP-related services.[xxi] However, this is not always the case. For example, Utah passed legislation in 2021 authorizing pharmacists to initiate PrEP and PEP without a practitioner's prescription, but the law failed to outline if/how pharmacists should be reimbursed for that service. Because the law was silent as to reimbursement, pharmacists seeking to initiate PrEP and PEP have no guarantee that they will be reimbursed for their services when they initiate PrEP and PEP.[xxii]

Without the ability to be properly reimbursed for their services, pharmacists have no logistical incentive to prescribe PrEP – even if they are authorized to do so by statute. The issue of pharmacist reimbursement persists as a barrier to HIV care, and states must outline reimbursement for pharmacist clinical services to facilitate the distribution of PrEP and PEP.

Statutes should explicitly outline the PrEP and PEP-related services health insurance providers must cover. Additionally, statutes should either define pharmacists as providers or require equitable reimbursement rates between pharmacists and PCPs. While Medicaid and most private insurance providers cover PrEP and PEP, they are not required to cover PrEP and PEP when pharmacists initiate the treatments.

Figure 4.

State	Is there a law or regulation requiring Medicaid reimbursement for pharmacist-provided clinical services?	Authority	*Application to specific services*	*Required equity between pharmacists and other providers?*	*Does the law apply to Medicaid, state employee benefits, and/or private insurance?*
Alabama	Yes	Ala. Admin. Code 560-X-16-.06	Medicaid to reimburse for "professional services" provided by licensed pharmacists, including "vaccine administration, medication maintenance	No	Medicaid

			therapy adherence and other clinical services as designated by the Agency."		
Alaska	Yes	Alaska Stat. Ann. § 21.07.250	Broad Authority	No	No distinction across payers
Arizona	No	N/A	N/A	N/A	N/A
Arkansas	No	N/A	N/A	N/A	N/A
California	Yes	Medi-Cal Pharmacy Services	The law requires Medi-Cal to reimburse pharmacists for furnishing naloxone; self-administered hormonal contraception; initiating and administering immunization; furnishing nicotine replacement therapy; furnishing HIV pre-exposure and post-exposure prophylaxis; and furnishing travel medications	No	Medicaid
Colorado	Yes	Colorado Medicaid,	Applies to "medically necessary"	No	Medicaid

		Pharmacy Services	services provide by a pharmacist		
Connecticut	No	N/A	N/A	N/A	N/A
Delaware	No	N/A	N/A	N/A	N/A
D.C.	No	N/A	N/A	N/A	N/A
Florida	No	N/A	N/A	N/A	N/A
Georgia	No	N/A	N/A	N/A	N/A
Hawaii	Yes	Hawaii Medicaid Provider Manual	Applies to "other licensed provider services" provided by a licensed pharmacist.	No	Medicaid
Idaho	Yes	Idaho Medicaid Provider Manual	Applies to "medical services" provided by licensed pharmacist.	No	Medicaid
Illinois	No	N/A	N/A	N/A	N/A
Indiana	Yes	Indiana HB 1568	Only applies to birth control	No	Medicaid
Iowa	Yes	Iowa Medicaid Provider Manual	Only pharmaceutical care management services for complex patients.	No	Medicaid
Kansas	No	N/A	N/A	N/A	N/A
Kentucky	No	N/A	N/A	N/A	N/A
Louisiana	Yes	LA Medicaid	Administering immunizations (influenza, hepatitis, HPV, etc.) and family planning items/services.	No	Medicaid

Maine	No	N/A	N/A	N/A	N/A
Maryland	Yes	Medical Services Provider Manual	Unclear	No	Medicaid
Massachusetts	Yes	MA Pharmacy Covered Professional Services Microsoft Word - PHM Regs.docx (mass.gov)	The MassHealth Pharmacy Covered Professional Services List specifies certain services that may be provided by a pharmacy provider and payable through the Pharmacy Online Processing System (POPS). Services include the administration of numerous vaccines, including influenza, COVID-19, hepatitis A and B, HPV, and many others.	No	Medicaid
Michigan	Yes	Payment_Rates_for_MTM_Services.pdf (michigan.gov) MedicaidProviderMan	Pharmacists can be reimbursed for Medication Therapy Management (MTM) services	No	Medicaid

		ual.pdf (state.mi.us)			
Minnesota	Yes	Pharmacy Services (state.mn.us) Sec. 256B.0625 MN Statutes Medication Therapy Management Services (MTMS) (state.mn.us)	Pharmacists can be reimbursed for providing family planning services and supplies, administering vaccines, and providing MTM services.	No	Medicaid
Mississippi	Yes	Administrative Code (ms.gov)	Pharmacists can be reimbursed for disease state management services, including patient evaluation and education, drug therapy review, and other disease state management activities.	No	Medicaid
Missouri	Yes	Pharmacy Manual (momed.com)	Pharmacists can be reimbursed for participating in the MTM program, administering vaccines,	No	Medicaid

			and providing diabetes self-management training.		
Montana	No	N/A	N/A	N/A	N/A
Nebraska	No	N/A	N/A	N/A	N/A
Nevada	Yes	Pharmacists can bill Medicaid (nv.gov)	Pharmacists are reimbursed for more than 40 codes including the following services without a prescription: ordering certain HIV laboratory testing; the dispensing of self-administered hormonal contraceptives; the prescribing, dispensing and administration of drugs to prevent the acquisition of HIV.	No	Medicaid
New Hampshire	No	N/A	N/A	N/A	N/A
New Jersey	No	N/A	N/A	N/A	N/A
New Mexico	Yes	PHARMACEUTICAL SERVICE REIMBURSEMENT	Pharmacists are permitted to be certified to prescribe in areas such as hormonal	Yes, pharmacists must be reimbursed at the same rate as a PCP	Medicaid

			contraceptio n, tobacco cessation, immunizatio ns, Naloxone drug therapy, tuberculosis testing (serum prescribing, administratio n and follow up reading are included as a single submission), and HIV Post-Exposure Prophylaxis (PEP) therapy, in accordance with the written protocols approved by the NM Board of Pharmacy.	for the same service.	
New York	No	N/A	N/A	N/A	N/A
North Carolina	No	N/A	N/A	N/A	N/A
North Dakota	Yes	Pharmacy Medical Billing	Pharmacists are reimbursable for tobacco cessation counseling, immunizatio ns, and Medication Therapy Management (MTM) services.	No	Medicaid
Ohio	Yes	Pharmacy Provider Status	The following services are reimbursable	No	No

			: adherence checks, medication reconciliations, new medication counseling, disease state management, and transitions of care management		
Oklahoma	No	N/A	N/A	N/A	N/A
Oregon	Yes	Pharmacist Professional Billing	Pharmacists are reimbursed for prescribing hormonal contraception, prescribing smoking cessation products, initiating vaccination, administering immunizations, providing MTM, and preventive medicine counseling.	No	Medicaid
Pennsylvania	Yes	Naloxone Reimbursement	Pharmacists are reimbursed for dispensing generic Naloxone.	No	Medicaid
Puerto Rico	No	N/A	N/A	N/A	N/A
Rhode Island	No	N/A	N/A	N/A	N/A
South Carolina	No	N/A	N/A	N/A	N/A
South Dakota	No	N/A	N/A	N/A	N/A

Tennessee	Yes	MTM Therapy Management	MTM services are reimbursable. MTM services include medication reviews, pharmacotherapy consult, anticoagulation management, immunizations, health and wellness programs and many other clinical services.	No	Medicaid
Texas	No	Tex. Ins. Code Ann. § 1451.128 and Tex. Ins. Code Ann. § 1451.1261.	N/A	Pharmacist acting within scope of practice considered practitioner for a purposes of reimbursement. By being listed as a practitioner, an insurer may not discriminate against pharmacists for payment or reimbursement for services performed in the scope of that pharmacist's	N/A

				license if the same services or procedures are provided and covered by another listed health care practitioner.	
Utah	Yes	MTM Reimbursement	Medicaid-enrolled pharmacists in an outpatient setting are eligible for reimbursement for providing MTM services.	No	Medicaid
Vermont	Yes	Medicaid General Billing Pharmacy Provider Manual	Pharmacists can be reimbursed for ACIP approved vaccines and immunizations (cost of the vaccine and administration fee). Pharmacists can also conduct and be reimbursed for medically necessary EPSDT screenings/service with prior authorization	No	Medicaid

Virginia	Yes	Covered Services Billing Instructions	Pharmacists can be reimbursed for providing	No	Medicaid
Virgin Islands	No	N/A	N/A	N/A	N/A
Washington	Yes	WAC 182-530-7250: ; WAC 182-531-0100: ; WAC 182-531-0250: ; WAC 182-502-0002:	Numerous services are covered and include (but are not limited to) the following: vaccines, HIV/AIDS counseling/testing, tobacco/nicotine cessation counseling, and reproductive health services.	No	Medicaid
West Virginia	No	N/A	N/A	N/A	N/A
Wisconsin	Yes	Pharmacist Reimbursement	Pharmacists can be reimbursed for MTM services. The MTM benefit consists of Comprehensive Medication Review and Assessment services, which are private consultations between a pharmacist and a	No	Medicaid

			member to review the member's drug regimen. Medicaid also reimburses pharmacy providers for influenza immunizatio n services for both children and adult members and for allowable vaccines for children 6–18 years of age, even if the member is enrolled in a state-contracted MCO.		
Wyoming	No	N/A	N/A	N/A	N/A

Collaborative Practice Agreements

A collaborative practice agreement (CPA) establishes a formal relationship between a PCP and pharmacist whereby the PCP's supervision enables the pharmacist to broaden their scope of practice. Pharmacists must be authorized to engage in a CPA by statute or regulation. The purpose of a CPA is to explicitly define the patient care services a pharmacist may provide under certain situations and conditions.[xxiii] Each PCP/pharmacist relationship requires a unique CPA that can delegate to the pharmacist any patient care service(s) within the PCP's scope of practice.[xxiv] CPAs can be patient specific or non-patient specific, as dictated by statute or regulation.[xxv] A patient specific CPA is when a PCP grants a pharmacist the authority to provide healthcare services to a single specified patient, while a non-patient specific CPA applies to anyone within a certain population.

A CPA can serve as an alternative to pharmacists independently initiating PrEP and PEP. A CPA may be useful in 1) states that do not have legislation explicitly permitting pharmacists to independently initiate PrEP or PEP or 2) states that do have legislation explicitly permitting pharmacists to independently

initiate PrEP or PEP but are inaccessible due to additional requirements or reimbursement issues.* In the latter case, a pharmacist may find it easier to utilize a CPA than navigate additional training requirements or insurance reimbursement. Additionally, in states that do not authorize pharmacists to perform CLIA-waived tests, a CPA could grant a PCP the ability to delegate to a pharmacist the task of ordering HIV tests for the purpose of initiating PrEP.

Overall, CPAs present a viable alternative to the current lack of accessible legislation granting pharmacists the authority to independently initiate PrEP and PEP.

Figure 5.

State	Do pharmacists have the legal authority to enter into a CPA with a PCP?	Authority	Does the CPA have to be patient-specific?
Alabama	Yes	Ala. Code § 34-23-77; Ala. Admin. Code 680-X-2-.44	Yes
Alaska	Yes	Alaska Admin. Code tit. 12, § 52.240	No
Arizona	Yes	Ariz. Rev. Stat. Ann. § 32-1970	No
Arkansas	Yes	Ark. Code Ann. § 17-92-101(17)(A)(i)(e), (ix)(a)	Yes
California	Yes	Cal. Bus. & Prof. Code § 4052(a)(13)	No
Colorado	Yes	Colo. Rev. Stat. Ann. § 12-280-601, 602	No
Connecticut	Yes	Conn. Gen. Stat. Ann. § 20-631	No
Delaware	No	N/A	N/A

* Reimbursement issues may occur when a pharmacist independently initiates PrEP and PEP-related services because a pharmacist is not always considered a healthcare provider under insurance coverage policies. Under a CPA, the PCP would be designated as the healthcare provider and such insurance reimbursement issues would not arise.

D.C.	Yes	D.C. Mun. Regs. tit. 17, § 10001 and D.C. Code Ann. § 3-1202.08(h)(1)	No
Florida	Yes	Fla. Stat. Ann. § 465.1865; Fla. Admin. Code Ann. r. 64B16-31.001; Fla. Admin. Code Ann. r. 64B16-31.003; Fla. Admin. Code Ann. r. 64B16-31.005; Fla. Admin. Code Ann. r. 64B16-31.007; and Fla. Admin. Code Ann. r. 64B16-31.009	No
Georgia	Yes	Ga. Code Ann. § 43-34-24; Ga. Code Ann. § 26-4-50; and Ga. Comp. R. & Regs. 480-35-.02 through .07	Yes
Hawaii	Yes	Haw. Rev. Stat. Ann. § 461-1	No
Idaho	Yes	Idaho Admin. Code r. 24.36.01.351	No
Illinois	Yes	225 Ill. Comp. Stat. Ann. 85/43.5	No
Indiana	Yes	Ind. Code Ann. § 25-26-13-2; Ind. Code Ann. § 25-26-16-4.5; and Ind. Code Ann. § 155A.48	Yes
Iowa	Yes	Iowa Code Ann. § 155A.48	No
Kansas	Yes	Kan. Stat. Ann. § 65-1626a and Kan. Admin. Regs. 68-7-22	No
Kentucky	Yes	Ky. Rev. Stat. Ann. § 315.010(5) and 201 Ky. Admin. Regs. 2:220	No
Louisiana	Yes	La. Admin Code. tit. 46, Pt LIII, § 523	Yes

Maine	Yes	Me. Rev. Stat. tit. 32, § 13843 and Code Me. R. tit. 02-392 Ch. 39-A, § 3	No
Maryland	Yes	Md. Code Ann., Health-Gen. § 19-713.6 and Md. Code Regs. 10.34.29.03 through .07	It depends. A general CPA does not need to be patient-specific. However, a CPA specifically concerned with drug therapy management must be patient-specific.
Massachusetts	Yes	Mass. Gen. Laws Ann. ch. 112, § 24B ½; Mass. Gen. Laws Ann. ch. 112, § 24B ¾; and 247 Mass. Code Regs. 16.02 through .04	Yes
Michigan	No	N/A	N/A
Minnesota	Yes	Minn. Stat. Ann. § 151.01(subd. 27)	No
Mississippi	Yes	30 Code Miss. R. Pt. 2630, R. 2.3 and 30 Code Miss. R. Pt. 2630, R. 2.4	Yes
Missouri	Yes	Mo. Ann. Stat. § 338.010; Mo. Code Regs. Tit. 20 § 2150-5.024 ; Mo. Code Regs. Ann. tit. 20, § 2150-5.028 ; and Mo. Code Regs. Ann. tit. 20, § 2150-5.029	Yes
Montana	Yes	Mont. Admin. R. 24.174.524	No
Nebraska	Yes	Neb. Rev. Stat. Ann. § 38-2867.03	No
Nevada	Yes	Nev. Rev. Stat. Ann. § 639.2623 and Nev. Rev. Stat. Ann. § 639.2627	Yes
New Hampshire	Yes	N.H. Rev. Stat. Ann. § 318:16-a;	Yes

		N.H. Code Admin. R. Ph 1103.01; N.H. Code Admin. R. Ph 1104.01; and N.H. Code Admin. R. Ph 1105.01—.03	
New Jersey	Yes	N.J. Admin. Code § 13:39-13.3—.5	No
New Mexico	Yes	N.M. Stat. Ann. § 61-11B-3; N.M. Admin. Code 16.19.4.7; and N.M. Admin. Code 16.19.4.17	No
New York	Yes	N.Y. Educ. Law § 6801-a and N.Y. Comp. Codes R. & Regs. tit. 8, § 63.10	No
North Carolina	Yes	N.C. Gen. Stat. Ann. § 90-85.3A; N.C. Gen. Stat. Ann. § 90-18(c)(3a); N.C. Gen. Stat. Ann. § 90-18.4; and 21 N.C. Admin. Code 46.3101	Yes
North Dakota	Yes	N.D. Cent. Code Ann. § 43-15-31.4	No
Ohio	Yes	Ohio Rev. Code Ann. § 4729.01; Ohio Rev. Code Ann. § 4729.39; and Ohio Admin. Code 4729:1-6-01 – 03	No
Oklahoma	Yes	Okla. Stat. Ann. tit. 59, § 353.30 and Okla. Admin. Code 535:10-9-5	No
Oregon	Yes	Or. Rev. Stat. Ann. § 689.655; Or. Admin. R. 847-015-0040; Or. Admin. R. 855-006-0005(10); Or. Admin. R. 855-019-0250; and	Yes

		Or. Admin. R. 855-019-0260	
Pennsylvania	Yes	49 Code § 27.302 ; 63 Pa. Stat. Ann. §390-2(14) ; 63 Pa. Stat. Ann. § 390-9.1; and 63 Pa. Stat. Ann. § 390-9.3	No
Puerto Rico	No	N/A	N/A
Rhode Island	Yes	5 R.I. Gen. Laws Ann. § 5-19.2-2, 3 and R.I. Code R. 40-15-1.13	No
South Carolina	No	N/A	N/A
South Dakota	Yes	S.D. Codified Laws § 36-11-19.1(6)	No
Tennessee	Yes	Tenn. Code Ann. § 63-10-204(5) ; Tenn. Code Ann. § 63-10-217; Tenn. Comp. R. & Regs. 1140-15-.04; and Tenn. Comp. R. & Regs. 1140-03-.17	No
Texas	Yes	Tex. Occ. Code Ann. § 554.005 and 22 Tex. Admin. Code § 295.13	No
Utah	Yes	Utah Code Ann. § 58-17b-102; Utah Code Ann. § 58-17b-601; and Utah Admin. Code r. R156-17b-611	No
Vermont	Yes	Vt. Stat. Ann. tit. 26, § 2022(15)(B)(iii); Vt. Stat. Ann. tit. 26, § 2023; Vt. Admin. Code 20-4-26:1; and Vt. Admin. Code 20-4-1400:1.10(a)(8)	No
Virginia	Yes	Va. Code Ann. § 54.1-3300; Va. Code Ann. § 54.1-3300.1; and	Yes

		18 Va. Admin. Code 110-40-10 — 70	
Virgin Islands	No	N/A	N/A
Washington	Yes	Wash. Rev. Code Ann. § 18.64.011(28) and Wash. Admin. Code 246-945-350	No
West Virginia	Yes	W. Va. Code Ann. § 30-5-18; W. Va. Code Ann. § 30-5-19; W. Va. Code R. 11-8-3; W. Va. Code R. 11-8-4; and W. Va. Code R. 11-8-5	No
Wisconsin	Yes	Wis. Stat. Ann. § 450.033; Wis. Stat. Ann. § 49.46(2)(bh); and Wis. Admin. Code § 7.12	No
Wyoming	Yes	Wyo. Stat. Ann. § 33-24-101(b)(iii); Wyo. Admin. Code 059.0001.20 § 4 ; and Wyo. Admin. Code 059.0001.20 § 5	Yes

Conclusion

Increased uptake of PrEP and PEP to prevent new HIV diagnoses is essential to ending the HIV epidemic. Community pharmacies have great potential to increase uptake as they are accessible healthcare resources that can break down some of the barriers to PrEP and PEP. Granting pharmacists the authority to independently distribute unlimited quantities of PrEP and PEP and establishing legal requirements for proper pharmacist reimbursement are essential to stopping new HIV infections. Furthermore, pharmacists must be able to conduct CLIA-waived tests in order to effectively provide PrEP. Additionally, where injectable PrEP has been prescribed by a PCP, pharmacists need to have the authority to administer the medication. In the absence of accessible PrEP-specific legal authority, however, CPAs can serve as an alternative for pharmacists seeking to initiate PrEP and PEP. By establishing the necessary legal authority, pharmacist-initiated PrEP and PEP promise to be crucial strategies to increase uptake and ultimately end the HIV epidemic.

[i] Statistics Overview | Statistics Center | HIV/AIDS | CDC
[ii] Volume 34 | HIV Surveillance | Reports | Resource Library | HIV/AIDS | CDC
[iii] Now's the Time to Find Out About PrEP and PEP (cdc.gov)
[iv] What Is Injectable HIV PrEP? | CDC
[v] PrEP Effectiveness | PrEP | HIV Basics | HIV/AIDS | CDC
[vi] Maria L. Lopez, *Implementing PrEP in the Pharmacy*, Pharmacy Today (April 2020), https://www.pharmacytoday.org/article/S1042-0991(20)30306-6/pdf
[vii] Persistent PrEP Uptake Disparities Exist Among the States (ajmc.com).
[viii] Maria L. Lopez, *Implementing PrEP in the Pharmacy*, Pharmacy Today (April 2020), https://www.pharmacytoday.org/article/S1042-0991(20)30306-6/pdf
[ix] Barriers to the Wider Use of Pre-exposure Prophylaxis in the United States: A Narrative Review - PubMed (nih.gov)
[x] Residential Segregation and the Availability of Primary Care Physicians - PMC (nih.gov)
[xi] Provider Status for Pharmacists: It's About Time (pharmacytimes.com)
[xii] Trust, influence, and community: Why pharmacists and pharmacies are central for addressing vaccine hesitancy - Journal of the American Pharmacists Association (japha.org)
[xiii] *See* Figure 1
[xiv] Scope of Practice; APhA
[xv] Id.
[xvi] https://www.merriam-webster.com/dictionary/statute
[xvii] Scope of Practice; APhA
[xviii] CLIA |HIV Testing in Non-Clinical Settings | HIV Testing | HIV/AIDS | CDC
[xix] CLIA |HIV Testing in Non-Clinical Settings | HIV Testing | HIV/AIDS | CDC
[xx] Starting and Stopping PrEP | PrEP | HIV Basics | HIV/AIDS | CDC
[xxi] See H.B. 4430 (Ill. 2022).
[xxii] H.B. 178 (Utah 2021).
[xxiii] Collaborative Practice Agreements (CPA) and Pharmacists' Patient Care Services | APhA Foundation
[xxiv] CPA Toolkit_web.pdf (pswi.org)February-2022-Utah-Newsletter.pdf (nabp.pharmacy)
[xxv] See Figure 5.