

# Current Legislative Status of Pharmacy-driven PEP in the US

Katherine Esser<sup>1\*</sup>, Joan Duggan, MD<sup>2</sup>, Kaylee Scarnati<sup>1</sup>, Eric Sahloff, Pharm D<sup>3</sup>

<sup>1</sup>College of Medicine and Life Sciences, The University of Toledo, Toledo, OH 43614

<sup>2</sup>Division of Infectious Diseases, Department of Medicine, The University of Toledo, Toledo, OH 43614

<sup>3</sup>Division of Pharmacy Practice, College of Pharmacy and Pharmaceutical Sciences, The University of Toledo, Toledo, OH 43614

\*Corresponding author: [kesser@rockets.utoledo.edu](mailto:kesser@rockets.utoledo.edu)

Published: 14 December 2023

**Introduction:** Non-occupational post-exposure prophylaxis (nPEP) to prevent HIV infection is highly effective and consists of initiation of antiretroviral medications (ART) ideally within 2 – 24 hours after HIV exposure and continued for 28 days: it is a medical emergency requiring rapid ART access. Rapid access problems have hindered its widespread usage. Pharmacy-initiated PEP access was first trialed in New York City in 2017, allowing pharmacists to prescribe a seven-day supply of PEP without a prescription for consumers at high risk for HIV infection. The provision of PEP by pharmacists – ie, pharmacy-driven PEP (PDP) – may improve access to this time-sensitive HIV prevention strategy in the US but the current status of PDP nationwide is not known. We assessed the current legal status of PDP nationally since its initiation in 2017.

**Objective:** To assess the current legislative status of pharmacy-driven PEP in the US.

**Methods:** A review of the status of current state legislation/guidance related to PDP was performed.

**Results:** As of July 31, 2023, 12 states allow pharmacists to furnish HIV PEP through specific legislative initiatives. The authority for pharmacist prescribing or furnishing nPEP is defined primarily through state government-defined protocols, standing orders, prescriptive authority or collaborative practice agreements (California, Colorado, Illinois, Maine, Missouri, New Mexico, New York, Nevada, North Carolina, Oregon, Utah, Virginia). Multiple states have legislation pending specifically for nPEP (Massachusetts, New Jersey, Florida, and Maryland).

**Conclusion:** The lifetime risk of contracting HIV among Black MSM (men who have sex with men) is 1 in 2. nPEP is currently rapidly accessible through pharmacies for patients at risk in 12 states but is accessible only through physicians and physician extenders in 38 states. Analysis of barriers to widespread implementation of pharmacy-driven PEP nationwide should be undertaken to improve rapid access to nPEP for communities at risk.

## References

1. *HIV Surveillance*. Volume 28(3). Centers for Disease Control and Prevention, May 23, 2023. Accessed June 6, 2023. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-28-no-3/index.html>.
2. *HIV declines among young people and drives overall decrease in new HIV infections*. Centers for Disease Control and Prevention, May 23, 2023. Accessed June 6, 2023. <https://www.cdc.gov/media/releases/2023/p0523-hiv-declines-among-young-people.html>.
3. Centers for Disease Control and Prevention. About Ending the HIV Epidemic Initiative, September 2021. <https://www.cdc.gov/endhiv/about.html>
4. “*Post-Exposure Prophylaxis*.” HIV.gov, [www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/post-exposure-prophylaxis](http://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/post-exposure-prophylaxis).
5. *Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis*. MMWR, May 15, 1998. 47(RR-7);1-28
6. Joyce MP, Kuhar D, Brooks JT. *Notes from the Field: Occupationally Acquired HIV Infection Among Health Care Workers — United States, 1985–2013*. MMWR, January 9, 2015. 63(53);1245-1246
7. Beymer MR, Kofron RM, Tseng CH, Bolan RK, Flynn RP, Sayles JM, Perez MJ, Jordan WC, Landovitz RJ. *Results from the post-exposure prophylaxis pilot program (P-QUAD) demonstration project in Los Angeles County*. Int J STD AIDS, 2018 May. 29(6): pp. 557-562.
8. *Unknown*. United States Office of Safety and Health Administration. <https://www.osha.gov/laws-regs/standardinterpretations/2020-08-19-1>
9. *Unknown*. United States Office of Safety and Health Administration. <https://www.osha.gov/laws-regs/standardinterpretations/2013-11-27-0>
10. John SA, Quinn KG, Pleuhs B, Walsh JL, Petroll AE. *HIV Post-Exposure Prophylaxis (PEP) Awareness and Non-Occupational PEP (nPEP) Prescribing History Among U.S. Healthcare Providers*. AIDS Behav, 2020 Nov. 24(11): pp. 3124-3131. doi:10.1007/s10461-020-02866-6.
11. “*HIV Diagnoses*.” Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 24 Oct. 2022, [www.cdc.gov/hiv/statistics/overview/diagnoses.html](http://www.cdc.gov/hiv/statistics/overview/diagnoses.html).
12. Reif S, Safley D, McAllaster C, Wilson E, Whetten K. *State of HIV in the US deep South*. 2017, 42: pp. 844-853.
13. Lewis, C.F., Lekas, H.M., Rivera, A. et al. *Pharmacy PEP Access Intervention Among Persons Who Use Drugs in New York City: iPEPcare Study—Rethinking Biomedical HIV Prevention Strategies*. AIDS Behav, 2020. 24: pp. 2101–2111. <https://doi.org/10.1007/s10461-019-02775-3>
14. Goode JV, Owen J, Page A, Gatewood S. *Community-Based Pharmacy Practice Innovation and the Role of the Community-Based Pharmacist Practitioner in the United States*. Pharmacy (Basel), 2019 Aug 4. 7(3): p.106. doi:10.3390/pharmacy7030106.

15. Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, et al. *Access to community pharmacies: a nationwide geographic information systems cross-sectional analysis*. Journal of the American Pharmacists Association, 2022. **62**: pp.1816-1822. <https://doi.org/10.1016/j.japh.2022.07.003>
16. Mitchell, Travis. “*Views of Problems Facing Urban, Suburban and Rural Communities.*” Pew Research Center's Social & Demographic Trends Project, Pew Research Center, 30 May 2020. [www.pewresearch.org/social-trends/2018/05/22/views-of-problems-facing-urban-suburban-and-rural-communities/](http://www.pewresearch.org/social-trends/2018/05/22/views-of-problems-facing-urban-suburban-and-rural-communities/)
17. National Alliance of State and Territorial AIDS Directors (NASTAD). “*Pharmacist- Initiated PrEP and PEP*” Information Sheet. NASTAD.org, 2021. <https://nastad.org/sites/default/files/2021-11/PDF-Pharmacist-Initiated-PrEP-PEP.pdf> Accessed June 15, 2023.
18. Tung EL, Thomas A, Eichner A, Shalit P. *Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care*. Sex Health, 2018 Nov. **15**(6): pp. 556-561.
19. Havens JP, Scarsi KK, Sayles H, Klepser DG, Swindells S, Bares SH. *Acceptability and feasibility of a pharmacist-led HIV pre-exposure prophylaxis (PrEP) program in the Midwestern United States*. Open Forum Infect Dis, 2019 Aug 14. pii: ofz365.
20. Lopez MI, Cocohoba J, Cohen SE, Trainor N, Levy MM, Dong BJ. *Implementation of pre-exposure prophylaxis at a community pharmacy through a collaborative practice agreement with San Francisco Department of Health*. J Amer Pharm Assoc, 2019. **60**: pp.138-144.
21. SB 159. *HIV: pre-exposure and post-exposure prophylaxis*. California Legislative Information. [https://leginfo.ca.gov/faces/billTextClient.xhtml?bill\\_id=201920200SB159](https://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB159). Accessed August 1, 2023.
22. HBj20-1061. *Human Immunodeficiency Virus Infection Prevention Medications*. Colorado General Assembly. [https://leg.colorado.gov/sites/default/files/2020a\\_1061\\_signed.pdf](https://leg.colorado.gov/sites/default/files/2020a_1061_signed.pdf). Accessed August 1, 2023.
23. CCR 719-1 Appendix C. *Colorado State Board of Pharmacy Statewide Protocol. Pre-Exposure and Post-Exposure Prophylaxis of HIV*. Code of Colorado Regulations. <https://drive.google.com/file/d/10vcW8Pq-1rjBjQ3Uvm1ZZPGmHiEOPgWB/view>. Accessed August 1, 2023.
24. Full Text of HB4430. 102nd general assembly. Illinois General Assembly. <https://www.ilga.gov/legislation/fulltext.asp?DocName=&SessionId=110&GA=102&DocTypeId=HB&DocNum=4430&GAID=16&LegID=&SpecSess=&Session=>. Accessed August 1, 2023.
25. LD 1115. *An Act to improve access to HIV prevention medications*. Maine Legislature. <https://legislature.maine.gov/bills/getPDF.asp?paper=SP0378&item=1&snum=130>. Accessed August 1, 2023.
26. HB 476. Missouri General Assembly. <https://house.mo.gov/billtracking/bills191/hlrbillspdf/1034H.01I.pdf>. Accessed August 1, 2023.

27. Missouri Department of Commerce and Insurance. Division State Board of Pharmacy. *20 CSR 2220-6.025 HIV Post-Exposure Prophylaxis*. <https://dci.mo.gov/proposed-rule/20CSR2220-6.025.pdf>. Accessed August 1, 2023.
28. New Mexico Administrative Code. *NMAC 16.19.26. Occupational and Professional Licensing Pharmacist Prescriptive Authority*. <https://www.srca.nm.gov/parts/title16/16.019.0026.html>. Accessed August 1, 2023.
29. New Mexico Regulation and Licensing Department. *Protocol for pharmacist prescribing HIV post-exposure prophylaxis (PEP) therapy in conjunction with point-of-care testing (POCT)*. <https://www.rld.nm.gov/uploads/files/PEPProtocolALONE.pdf>. Accessed August 1, 2023.
30. New York State Department of Health. *The licensed pharmacist's role in initiating HIV post-exposure prophylaxis: overview and frequently asked questions*. Published August 2022. [https://www.health.ny.gov/diseases/aids/general/pep/docs/pharmacists\\_role.pdf](https://www.health.ny.gov/diseases/aids/general/pep/docs/pharmacists_role.pdf). Accessed August 1, 2023.
31. Nevada Electronic Legislative Information System. *SB 325*. <https://www.leg.state.nv.us/App/NELIS/REL/81st2021/Bill/7959/Text>. Accessed August 1, 2023.
32. Nevada State Board of Pharmacy. *LCB File No. R039-21*. <https://www.leg.state.nv.us/Register/2021Register/R039-21AP.pdf>. Accessed August 1, 2023.
33. North Carolina General Assembly. *HB 96*. <https://www.ncleg.gov/Sessions/2021/Bills/House/PDF/H96v5.pdf>. Accessed August 1, 2023.
34. *North Carolina State Health Director's Standing Order for Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus*. North Carolina Department of Health and Human Services, March 28, 2022. <https://www.dph.ncdhhs.gov/docs/PEP-StandingOrder-March2022.pdf>. Accessed August 1, 2023.
35. Oregon State Legislature. *HB 2958*. 2021. Accessed August 1, 2023. <https://legiscan.com/OR/text/HB2958/2021>
36. Oregon Secretary of State. *OAR 855-020-0110: Prescribing Practices*. Pharmacist Prescriptive Authority. [https://oregon.public.law/rules/oar\\_855-020-0110](https://oregon.public.law/rules/oar_855-020-0110). Accessed August 1, 2023.
37. Oregon Board of Pharmacy. *Preventative Care: HIV Post-Exposure Prophylaxis. Statewide drug therapy management protocol for Oregon pharmacists*. [https://www.oregon.gov/pharmacy/Documents/PrevCare\\_PEP\\_Protocol\\_v.6.2023.pdf](https://www.oregon.gov/pharmacy/Documents/PrevCare_PEP_Protocol_v.6.2023.pdf). Accessed August 1, 2023.
38. Utah State Legislature. *HB 178*. Pharmacy practice modifications. <https://le.utah.gov/~2021/bills/hbillenr/HB0178.pdf>. Accessed August 1, 2023.
39. Utah Division of Occupational Professional Licensing. *Utah guidance for pre-exposure and post-exposure prophylaxis of HIV*. Published September 2021. <https://www.dopl.utah.gov/wp-content/uploads/2022/09/utah-guidance-for-pre-exposure-and-post-exposure-prophylaxis-of-hiv.pdf>. Accessed August 1, 2023.

40. Virginia General Assembly. *HB 2079. Pharmacists: initiation of treatment with and dispensing and administering drugs and devices*. <http://leg1.state.va.us/cgi-bin/legp504.exe?212+ful+HB2079ER>. Accessed August 1, 2023.
41. Virginia Department of Health Professionals. *Virginia Board of Pharmacy. HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol*. <https://www.dhp.virginia.gov/pharmacy/docs/protocols/PEPCombinedProtocol12-22-2021.pdf>. Accessed August 1, 2023.
42. Bellman R, Mohebbi S, Nobahar N, Parizher J, Apollonio DE. An observational survey assessing the extent of PrEP and PEP furnishing in San Francisco Bay Area pharmacies. *J Am Pharm Assoc*, 2022 Jan-Feb. **62**(1): pp. 370-377.e3. doi: 10.1016/j.japh.2021.08.001. Epub 2021 Aug