

TESTIMONY OF GLBTQ LEGAL ADVOCATES & DEFENDERS LD 1115 – OUGHT TO PASS

COMMITTEE ON HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES April 8, 2021

Senator Sanborn, Representative Tepler, and Honorable Members of the Committee on Health Coverage, Insurance and Financial Services: Good Morning. My name is Anthony Lombardi, and I am a legal fellow at GLBTQ Legal Advocates & Defenders (GLAD) and a lobbyist associate of Mary Bonauto, who lives in Portland. GLAD is a legal rights organization that works throughout New England to create a just society free of discrimination based on gender identity and expression, HIV status, and sexual orientation.

GLAD strongly supports LD 1115 because it expands access to a simple, safe and effective medication known as HIV pre-exposure Prophylaxis (PrEP) that reduces the risk of HIV transmission by close to 100% and provides our best opportunity to end the HIV epidemic. The bill, which authorizes pharmacists to dispense PrEP without a prescription on a short-term basis, will: (1) allow the most vulnerable populations, including rural communities, to obtain PrEP quickly; (2) remove cost barriers to PrEP consistent with federal directives; and (3) improve access to care by requiring pharmacists to link customers to medical care for ongoing PrEP oversight and other vital health needs.

The HIV epidemic continues despite multiple breakthroughs in treatment and prevention. According to the Centers for Disease Control and Prevention (CDC), an estimated 1.2 million Americans are living with HIV, and one in seven of these individuals are unaware of their HIV-positive status. The most recent data available shows that there were nearly 38,000 new diagnoses in the United States in 2018, the majority of which were among gay and bisexual men, as well as people who inject drugs. As the National Advisory Committee on Rural Health and Human Services (NACRHHS) reported to the U.S. Department of Health and Human Services, the "decrease in new HIV infections has plateaued because effective HIV treatment and prevention services are not adequately reaching the populations most disproportionately affected such as people who inject drugs, LGBTQ+ people, Black people, Latinx people, and members of Tribal communities." Consistent with national data, people of color and members of the LGBTQ+ community are disproportionately and consistently overrepresented in these confirmed diagnoses.

-

¹ CTRS. FOR DISEASE CONTROL & PREVENTION, *HIV in the United States and Dependent Areas* (Nov. 2020), https://www.cdc.gov/hiv/statistics/overview/ataglance.html.

² CTRS. FOR DISEASE CONTROL & PREVENTION, *HIV In the United States and Dependent Areas* (Nov. 2020), https://www.cdc.gov/hiv/statistics/overview/ataglance.html.

³ NAT'L ADVISORY COMM. ON RURAL HEALTH AND HUM. SERV., *HIV Prevention and Treatment Challenges in Rural America* 1, 4 (May 2020), https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2020-rural-hiv-prev-treat-call.pdf.

⁴ ME. DEP'T OF HEALTH & HUM. SERV., *HIV Maine Surveillance Report* – 2019 (2019), https://www.maine.gov/dhhs/mecdc/infectious-disease/hiv-std/documents/pdf/HIV-Surveillance-Report-2019.pdf



Cases per 100,000 individuals are also higher in some of Maine's most rural counties, including Piscataguis and Franklin.⁵

PrEP reduces the risk of acquiring HIV via sex by about 99%. 6 PrEP is a highly effective medication. There are currently only two FDA-approved daily oral medications for PrEP: Truvada, which was approved by the FDA in 2012, and Descovy, a similar medication approved by the FDA in 2019.8 They are taken as a single pill once a day with a fixed dosage. Patient monitoring is straightforward; it consists of quarterly HIV testing and standard kidney function bloodwork. PrEP, therefore, represents an extremely effective tool for eliminating the dissemination of HIV in the United States.

PEP is a similarly revolutionary medication for post-exposure treatment. Post-Exposure Prophylaxis (PEP) is an antiretroviral medication used to prevent HIV infection in an HIV-negative person who has had an exposure to blood or bodily fluids that, although low risk, is a potential route of HIV exposure and involves a 28-day course of a 3-drug antiretroviral regimen. PEP must be started as soon as possible to be effective—and always within 72 hours of a possible exposure. Decades of studies have proven that PEP further reduces the already low risk of HIV transmission when there has been a potential exposure. PEP is a vital tool for treating cases of sexual assault and similar medical emergencies. 10

PrEP is underutilized, especially in rural areas and due to racial disparities.

PrEP, underutilized generally, is critical in underserved rural communities. Evidence shows that PrEP is underutilized. For example, PrEP is indicated for nearly 492,000 gay and bisexual men aged 18-59.11 However, Gilead, the manufacturer of these drugs, estimated filling approximately 140,000 Truvada prescriptions in 2018. 12 This underutilization is consistent in rural

⁵ *Id*.

⁶ CTR. FOR DISEASE CONTROL & PREVENTION, *PrEP Effectiveness* (Nov. 3, 2020)

https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html. PrEP is also highly effective (74%) in reducing the risk of HIV transmission via injectable drugs.

⁷ ME. CTRS. FOR DISEASE CONTROL & PREVENTION, Pre-Exposure Prophylaxis (PrEP) Against HIV-1 Infection General Information (2021), https://www.maine.gov/dhhs/mecdc/infectious-disease/hiv-std/index.shtml

⁸ HIV.GOV, Pre-Exposure Prophylaxis (March 23, 2021), https://www.hiv.gov/hiv-basics/hiv-prevention/using-hivmedication-to-reduce-risk/pre-exposure-prophylaxis.

⁹ CTRS. FOR DISEASE CONTROL & PREVENTION, Post-Exposure Prophylaxis (PEP) (May 13, 2020), https://www.cdc.gov/hiv/clinicians/prevention/pep.html.

¹⁰ CTRS. FOR DISEASE CONTROL & PREVENTION, Post-Exposure Prophylaxis (PEP) (May 13, 2020), https://www.cdc.gov/hiv/clinicians/prevention/pep.html.

¹¹ Dawn K. Smith, et al., Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition — United States, 2015, 64 MORBIDITY AND MORTALITY WEEKLY REPORT 1292 (Nov. 27, 2015).

¹² Ian W. Holloway et al, Longitudinal trend in PrEP familiarity, attitudes, use and discontinuation among a national probability sample of gay and bisexual men, 2016-2018, 15 PLoS ONE 1, 2, 5 (Dec. 31, 2020). Recent estimates suggest that there may be as many as approximately 200,000-205,000 current PrEP users. PrEPWatch, United States (Dec. 31, 2020), https://www.prepwatch.org/country/united-states/.



areas. In 2020, the NACRHHS submitted a policy brief on HIV prevention to the U.S. Department of Health and Human Services. ¹³ The committee found that rural counties were among the highest in the nation in terms of HIV prevalence. ¹⁴ The brief suggested that stigma, social factors, and public health infrastructure were impeding the prevention efforts in rural areas, noting that:

. . . [t]he lack of public health infrastructure investment lead to barriers and challenges complicating access to HIV prevention and treatment efforts in rural communities. In addition, compared to their urban counterparts, rural residents have higher rates of poverty, less access to health care and transportation, and are less likely to have health insurance. ¹⁵

The report pointed to the small, close-knit social networks of rural communities, which could make it difficult to privately seek HIV-related care, as well as a lack of education among physicians and care providers in rural areas, given that many as one in three rural providers have not heard of PrEP.¹⁶

Several studies substantiate the findings of the committee. A geographic survey of PrEP access among men who have sex with men (MSM) found that one in eight PrEP eligible MSM lived in a "30-minute drive desert," and a sizable minority lived in a "60-minute desert," denoting the length of time it would take for an individual to access a physician that prescribed PrEP. The majority of PrEP eligible persons living in these PrEP deserts resided in rural census tracts, indicating to the study's authors a "need to target service availability to remote areas." Notably, several of Maine's counties would fit these desert definitions, including Franklin, Somerset, Piscataquis, as well as parts of Oxford, Penobscot, and Hancock counties. The study pointed to alternative venue models such as pharmacies as a "promising approach" to alleviating this rural need. Another study of MSM in the midwestern U.S. found that individuals taking PrEP faced multiple barriers, including lack of rural dissemination of PrEP information, costs and lack of access to quality PrEP care.

¹³ See NAT'L ADVISORY COMM. ON RURAL HEALTH AND HUM. SERV., supra note 5.

¹⁴ *Id*. at 4.

¹⁵ *Id.* at 5.

¹⁶ *Id.* at 7.

¹⁷ Aaron J. Siegler, Anna Bratcher & Kevin M. Weiss, *Geographic Access to Preexposure Prophylaxis Clinics Among Men Who Have Sex With Men in the United States*, 1216 Am. J. OF Pub. Health 1216 (May 6, 2019). ¹⁸ *Id. at 1220*.

¹⁹ See id. at fig. 1.

²⁰ *Id.* at 1219.

²¹ Christopher Owens et al., Facilitators and Barriers of Pre-exposure Prophylaxis (PrEP) Uptake Among Rural Men who have Sex with Men Living in the Midwestern U.S., 2179 ARCHIVES OF SEXUAL BEHAVIOR 2179 (March 26, 2020). Further, two thirds of the survey participants received PrEP from another provider because their PCP was unwilling to prescribe it or referred them to an LGBTQ+ or infectious disease clinic for it, and the study suggested that one reason for this was due to a lack of knowledge among rural PCPs. The men in the study reported driving anywhere from thirty minutes to two and a half hours to obtain PrEP. The survey population of 32 participants, though small, roughly mirrors the number of new HIV diagnoses in Maine annually.



There are significant racial disparities in HIV diagnoses and PrEP utilization. Of the nearly 38,000 new HIV diagnoses in the United States in 2018, approximately 58% were among Black and Latinx individuals.²² Maine is no exception; the Maine Department of Health and Human Services' most recent available data states that 30% and 41% of new HIV diagnoses were among people of color in 2018 and 2019, respectively, despite representing only about 7% of the general population.²³

The discrepancies also exist with PrEP utilization. During 2010-2015, racial/ethnic disparities in HIV incidence increased among MSM.²⁴ In 2015, rates among black and Hispanic MSM were 10.5 and 4.9 times as high, respectively, as the rate among white MSM (compared with 9.2 and 3.8 times as high, respectively, in 2010.)²⁵ Further, Black and Hispanic MSM were significantly less likely than were white MSM to be aware of PrEP, to have discussed PrEP with a health care provider, or to have used PrEP within the past year.²⁶ The study concluded that "Social, structural, and epidemiologic factors are the underlying determinants of racial/ethnic health disparities. Therefore, prevention efforts that address these factors have the potential to decrease disparities along the HIV PrEP continuum of care."²⁷ Increasing access to providers that can dispense PrEP and connect individuals to competent health care professionals that can provide long term care and prescriptions, is a vital step in dismantling these health disparities.

LD 1115 is a simple and innovative bill to expand critical access and connect individuals to the healthcare system in Maine. Maine would be a national leader in expanding access to PrEP/PEP by allowing pharmacists to dispense medications on an over-the-counter basis, in small supplies. Doing so can open up pharmacies across the state to individuals that are seeking care, especially in rural areas. Notably, this bill requires participating pharmacists to follow several important requirements. First, pharmacists would need to complete a training program, approved by the pharmacy board, regarding testing, adherence, and best practices to counsel patients. This will help expand the community's knowledge about HIV prevention and mitigate concerns regarding proper adherence and ongoing testing. Second, in dispensing PrEP, pharmacists must notify a patient's PCP, or provide a list of physicians, clinics, or other health care providers to contact regarding follow-up care. This is a crucial and welcome inclusion in the bill, as it will provide a point of access for individuals to enter the system and find caregivers that can assist

²² CTRS. FOR DISEASE CONTROL & PREVENTION, *HIV In the United States and Dependent Areas* (Nov. 2020), https://www.cdc.gov/hiv/statistics/overview/ataglance.html.

²³ See generally, Me. Dep't of Health & Hum. Serv., HIV Maine Surveillance Report – 2018 (2018) https://www.maine.gov/dhhs/mecdc/infectious-disease/hiv-std/documents/pdf/HIV-Surveillance-Report-2018.pdf; Me. Dep't of Health & Hum. Serv., HIV Maine Surveillance Report – 2019 (2019),

https://www.maine.gov/dhhs/mecdc/infectious-disease/hiv-std/documents/pdf/HIV-Surveillance-Report-2019.pdf; U.S. CENSUS BUR., *QuickFacts: Maine (last accessed Apr. 6, 2021)*,

https://www.census.gov/quickfacts/fact/table/ME/RHI125219#RHI125219.

²⁴ Dafna Kanny et al., *Racial/Ethnic Disparities in HIV Preexposure Prophylaxis Among Men who have sex with men – 23 urban areas*, 2017, 68 MORBIDITY AND MORTALITY WEEKLY REPORT 801 (Sept 20, 2019). ²⁵ *Id.*

²⁶ *Id.* at 803.

²⁷ *Id.* at 802.



patients with best practices, ongoing prescriptions, and establishing a healthy patient/physician relationship.

LD 1115 remedies cost and coverage barriers to PrEP. Requiring carriers to cover HIV-prevention drugs without prior authorization or step therapy can remove a potential barrier to treatment for otherwise eligible individuals. GLAD welcomes this legislation and would note that the federal requirements will soon prohibit any cost sharing for PrEP.

GLAD would like to bring the current federal framework regarding cost-sharing to the Committee's attention as the basis for a proposed amendment to LD 1115. Section 2713 of the ACA incorporates evidence-based services that have a rating of "A" or "B" in the requirement that non-exempt private health plans must provide coverage for a range of preventive services and may not impose cost-sharing (such as copayments, deductibles, or co-insurance) on patients receiving these services. ²⁸ In June of 2019 the U.S. Preventive Services Task Force issued a "Grade A" recommendation for PrEP, which means that it "recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition." As such, PrEP medications must be provided at a zero-cost basis for plans covered by Section 2713 of the ACA, which includes most private plans and all plans in the ACA marketplace. With this ruling, nearly all private plans will be required to provide PrEP free of patient cost sharing in 2021. ³⁰

GLAD would therefore, in keeping with federal guidelines, recommend amending §4317-D.2, requiring that medications be offered at a no cost-sharing basis, rather than the lowest available cost-sharing tier.

Conclusion. LD 1115 is an opportunity for Maine to lead the nation in providing innovative and accessible healthcare. This bill is modeled on similar statutes that were recently enacted in Colorado and California, and this Committee joins its neighbors in Massachusetts in taking up the possibility of pharmacy access to PrEP/PEP. GLAD would also refer the Committee to the community position statement submitted alongside this testimony, in which over thirty organizations, public health advocates, constituents, and individuals that are, work with, care for,

²⁹ U.S. Preventive Serv. Task Force, Final Recommendation Statement, Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis (June 11, 2019),

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

³⁰ Sean Bland, *USPSTF RECOMMENDATION FOR PREP: REFLECTIONS ON INSURANCE COVERAGE AND HIV PREVENTION FOR OLDER ADULTS*, O'Neill Inst. For Nat'l & Glob. Health L. (June 12, 2019), https://oneill.law.georgetown.edu/uspstf-recommendation-for-prep-reflections-on-insurance-coverage-and-hiv-prevention-for-older-adults/. *See also* HIV Medicine Ass'n., *Statement of HIVMA Chair Dr. W. David Hardy on USPSTF final PrEP recommendation*, (June 11, 2019),

 $https://www.hivma.org/news_and_publications/hivma_news_releases/2019/statement-of-hivma-chair-dr.-w.-david-hardy-on-uspstf-final-prep-recommendation/.$

²⁸ 29 C.F.R. § 2590.715-2713.



love, and/or support Mainers living with or at a heightened risk to contract HIV urge this Committee to pass LD 1115.

Thank you for your consideration, and we hope that you will unanimously vote ought to pass on LD 1115.

Submitted by:

Anthony Lombardi, Esq. Legal Fellow GLBTQ Legal Advocates & Defenders alombardi@glad.org

Bennet Klein, Esq. AIDS Law Project Director GLBTQ Legal Advocates & Defenders bklein@glad.org

Mary L. Bonauto, Esq. Civil Rights Project Director GLBTQ Legal Advocates & Defenders mbonauto@glad.org 257 Deering Ave., #203 Portland ME 04103