TESTIMONY OF GLBTQ LEGAL ADVOCATES & DEFENDERS, YOUTH PRIDE, INC., SHIP, AND LGBTQ ACTION RI IN SUPPORT OF H 6150 (INSURANCE COVERAGE FOR PREVENTION OF HIV INFECTION) AND PROPOSED AMENDMENTS[1]

House Committee on Health and Human Services
March 21, 2023

INTRODUCTION AND SUMMARY

GLBTQ Legal Advocates & Defenders (GLAD), Youth Pride, INC., SHIP, and LGBTQ Action RI applaud the sponsors of this bill for their commitment to expanding access to HIV pre-exposure prophylaxis (PrEP), an extraordinary medication first approved by the FDA in 2012 that reduces the risk of HIV infection by close to 100 percent. PrEP provides our best opportunity to end the HIV epidemic. The promise of PrEP, however, has not been realized because it has been significantly underutilized, particularly in communities of color.

This Committee and the Legislature should do everything possible to:

- expand the ways people access PrEP and increase utilization by those most at risk for HIV.
- protect Rhode Island from a recent federal court decision threatening to abolish current federal cost protections for PrEP.
- realize the full promise of new forms of PrEP such as long-acting injectables that will be a game-changer in HIV prevention if access is not impeded.
- reduce the glaring racial disparities in PrEP use.

H 6150 contains two substantive components:

(1) The bill will allow people to obtain PrEP quickly by permitting pharmacists to dispense a 60-day supply once every two years without a prescription. The bill also allows pharmacists to dispense HIV post-exposure prophylaxis (PEP), a one-time 30- day regimen of antiviral medication taken after a person has had a potential exposure to HIV.[2] **We support the pharmacy access component of H 6150 without qualification or need for amendment.**

(2) The bill provides that insurers must cover one HIV prevention drug for each method of administration (daily oral pill or long-acting injectable) without cost-sharing or prior

[1] This Committee is also hearing testimony on H 5744 (Relating to Insurance- Accident and Sickness Policies) and H 5876 (Relating to Health and Safety- Prevention and Suppression of Contagious Diseases). These bills, while positive, do not contain all of the components necessary to ensure access to HIV prevention medications. Because H 6150 is the more comprehensive bill, GLAD focuses its testimony on that bill and will note the differences with the other bills, as appropriate, in this testimony.

[2] H 5876 authorizes pharmacists to dispense PrEP, but does not include PEP.

authorization. We strongly recommend that the provisions of the bill related to insurance practices be amended as follows:

> First, the bill should prohibit cost-sharing or prior authorization for all HIV prevention medications.
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> Second, the bill's prohibition on cost-sharing for ancillary services related to PrEP use (bill lines 21-23) should be more comprehensive in order to meet federal guidelines.
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> Proposed new language for these amendments is included in the discussion below.
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> Third, the bill's provisions requiring healthcare providers to submit records and data after a person has initiated PrEP, or else risk termination of PrEP for a patient, must be removed. This provision will take Rhode Island in the wrong direction in HIV prevention and, contrary to the goal of this bill, result in unnecessary HIV transmissions.

BACKGROUND ON PrEP

Simply put, HIV pre-exposure prophylaxis (PrEP) is a game changer in HIV prevention. It reduces the risk of HIV transmission by close to 100 percent.[3]

There are currently two FDA-approved daily oral pills for PrEP: Truvada, which was approved by the FDA in 2012, and Descovy, a similar medication approved by the FDA in 2019 which is indicated for some patients who cannot tolerate Truvada. They are taken as a single pill once a day with a fixed dosage. Truvada is now available as a generic. In addition, a long-acting injectable form of PrEP, Cabotegravir, was approved by the FDA in December, 2021. Cabotegravir provides a two-month duration of PrEP coverage in a single shot. A six-month long-acting injectable is expected to be approved by the FDA soon. Additional innovative ways to deliver PrEP are also in development.

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.[4] 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

[3] Ctrs. 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.
[4] Ctrs. for Disease Control & Prevention, HIV in the United States and Dependent Areas (Nov. 2020), https://www.cdc.gov/hiv/statistics/overview/ataglance.html.

men, as well as people who inject drugs.[5] While Rhode Island has been unusually successful in reducing new HIV infections, the most recent Rhode Island HIV/AIDS epidemiological profile indicates there is continued HIV transmission in the state making the provision of PrEP critical.[6] Significant racial disparities in HIV diagnoses continue.

PrEP reduces the risk of acquiring HIV via sex by about 99%.[7] PrEP, therefore, represents an extraordinary tool for eliminating the transmission of HIV in the United States. We need to expand every possible option for people to obtain PrEP. Studies have demonstrated that long-acting injectable medication is more effective at preventing HIV transmission than daily oral medication because of better adherence for people who cannot be compliant to a daily pill regimen.

PrEP is underutilized, particularly in communities of color. Evidence shows that PrEP is underutilized. For example, PrEP is indicated for nearly 492,000 gay and bisexual men aged 18-59.[8] However, Gilead, the manufacturer of these drugs, estimated filling approximately 140,000 Truvada prescriptions in 2018.[9] Most recently, the CDC reported that in 2019 only 23% of people eligible for PrEP were prescribed it.[10] The CDC also reported that only 8% of Black people and 14% of Latinx people eligible for PrEP received it compared to 63% of white people who were eligible for PrEP.[11]

Similarly, an earlier study found that 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.[12] The study concluded that "[s]ocial, 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

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[5] Id.
[6] Rhode Island Department of Health, *Rhode Island: HIV, Sexually Transmitted Infections, Viral Hepatitis, and Tuberculosis Surveillance Report* (2021), https://health.ri.gov/publications/surveillance/2021/HIVSTI.pdf.
[7] Ctrs. 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.
[8] 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).
[9] 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/.
[10] Ctrs. for Disease Control & Prevention, *2019 National HIV Surveillance System Reports* (May 27, 2021), https://www.cdc.gov/nchhstp/newsroom/2021/2019-national-hiv-surveillance-system-reports.html.
[11] Ctrs. for Disease Control & Prevention, *Monitoring Selected National HIV Prevention and Care Objectives by Using Surveillance Data* 35 (2021).
[12] 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 80*1 (Sept. 20, 2019).

disparities along the HIV PrEP continuum of care."[13] 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.

THE PHARMACY ACCESS PROVISION IN H 6150

H 6150 authorizes pharmacists to prescribe, dispense, and administer a short-term supply (60 days once in a two-year period) of PrEP to a single patient without a prescription. The bill requires pharmacists to provide counseling regarding the ongoing use of PrEP. Further, it requires pharmacists to connect patients without a primary care provider with health care providers for ongoing medication and care.

The bill similarly authorizes pharmacists to dispense PEP, a protocol first approved by the CDC more than 20 years ago, to be administered after a person has had a potential exposure to HIV. It consists of a 30-day course of antiviral medication. This provision will not only make PEP more readily accessible but will relieve burdened and crowded emergency rooms and primary care offices for this critical one-time intervention which must be administered within 72 hours of exposure.

The bill authorizes the pharmacy board to issue regulations and protocols for dispensing PrEP and PEP.

Similar pharmacy access bills have been passed in California, Colorado, Maine, Nevada, Oregon, Utah and Virginia.

We unequivocally support pharmacy access for PrEP and PEP as a vital tool to expand access to HIV prevention medication and also to increase access to health care more generally by requiring that pharmacists link patients to healthcare providers for further PrEP therapy.

THE INSURANCE PRACTICE PROVISIONS IN H 6150

H 6150 requires that insurers cover one type of PrEP within each method of administration without cost-sharing or prior authorization. These provisions are critical, but should go further in order to remove obstacles to PrEP.

Cost-sharing and prior authorization impede health care access and utilization. *See* Norris HC, Richardson HM, Benoit M-AC, Shrosbree B, Smith JE, Fendrick AM. Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review. Medical Care Research and Review. 2022;79(2):175-197. doi:10.1177/10775587211027372 ("There is significant evidence that the presence of cost-sharing, even if the amount is relatively modest, deters patients from receiving care," especially low socio-economic groups); American Medical

[13] *Id.* at 802.

Association. (2021). Prior authorization and step therapy. Retrieved from https://www.ama-assn.org/system/files/prior-authorization-survey.pdf (91% of physicians reported that prior authorization requirements negatively impacted clinical outcomes for their patients); Lauffenburger JC, Stults CD, Mudiganti S, Yan X, Dean-Gilley LM, He M, Tong A, Fischer MA. Impact of implementing electronic prior authorization on medication filling in an electronic health record system in a large healthcare system. J Am Med Inform Assoc. 2021 Sep 18;28(10):2233-2240. doi: 10.1093/jamia/ocab119. PMID: 34279657; PMCID: PMC8449617.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8449617/#ocab119-B23 (prior authorization requirements further exacerbated medical nonadherence, resulting in patients **abandoning prescriptions almost 40% of the time**).

We must reduce all barriers to PrEP. A requirement that insurers cover all HIV prevention medications and a prohibition on cost-sharing and prior authorization for any HIV prevention medication is necessary both to cover patients who cannot tolerate Truvada and need Descovy as a daily pill, and also to realize the potential of new long-acting injectables.

In particular, a state-based prohibition on cost-sharing and prior authorization is critical now because of a nationwide threat to PrEP access from a lawsuit in Texas that affects a critical protection under the Affordable Care Act (ACA).

The ACA requires commercial insurers and Medicaid expansion programs to cover without cost-sharing (e.g., co-pays, deductibles) select preventive services given a Grade A recommendation by the United States Preventive Services Task Force (USPSTF). In June 2019, the USPSTF gave PrEP an "A" rating which was updated in December 2022 to cover new PrEP medications, including long-acting injectable medication. A robust body of medical literature demonstrates that cost-sharing substantially reduces access to medical care, especially prevention.

A lawsuit brought by plaintiffs who are hostile to the ACA specifically challenging the USPFT's PrEP recommendation threatens this critical cost-sharing prohibition. In September 2022, a federal district judge in Texas ruled that the members of the USPSTF are unconstitutionally appointed. **The judge's further order implementing his decision is expected in early 2023 and could result in a nationwide injunction against the PreP mandate**.

In addition, the advent of long-acting injectables brings us into a new era in the quest to end the HIV epidemic. Studies have demonstrated that long-acting injectable medication is more effective at preventing HIV transmission than daily oral medication because of better adherence for people who cannot be compliant with a daily pill regimen. A long-acting injectable medication can also be administered immediately in a clinical or mobile setting. Studies have shown that utilization review has generally been associated with delayed or denied access to

care; and PrEP cannot be administered in any of these settings if healthcare providers must first obtain prior authorization from an insurer.

For these reasons, H 6150 should be amended to read:

A health insurer shall provider coverage for any HIV prevention drug. Coverage for any HIV prevention drug shall not require: (A) any cost-sharing, including co-payments or co-insurance or any deductible; and (B) prior authorization, step therapy or any other protocol that could restrict or delay the dispensing of any HIV prevention drug.

The Committee should address two additional aspects of H 6150. The federal Department of Health and Human Services has issued a directive that the ACA's prohibition on cost-sharing for PrEP include ancillary health and monitoring services necessary to determine eligibility for and ensure the safety of PrEP.[14] **The bill language relating to coverage for laboratory testing related to HIV prevention drugs should be amended as follows to reflect the scope of the federal directive:**

> **A health insurer offering a health plan in this state shall provide coverage with no out-of-pocket cost for any including any ancillary or support health service determined by the Department of Health that is necessary to: (1) ensure that such a drug is prescribed or administered to a person who is not infected with HIV and has no medical contraindications to the use of such a drug; and (2) monitor such a person to ensure the safe and effective ongoing use of such a drug through: (A) an office visit; (B) laboratory testing; (C) testing for a sexually transmitted infection; (D) medication self-management and adherence counseling; (E) or any other health service specified as part of comprehensive HIV prevention drug services by the United States Department of Health and Human Services, the United States Centers for Disease Control and Prevention or the United States Preventive Services Task Force.**

Finally, H 6150 requires that providers of HIV prevention medication must, after the initiation of treatment, furnish records or data to an insurer. It further provides that failure of a provider to do so will result in the loss of reimbursement for the patient.

It should be obvious from the previous discussion here that this provision is contrary to the goals of the bill. In order to end the HIV epidemic we need to remove obstacles and barriers to PrEP, not erect new requirements. This provision places an undue burden on overworked primary care providers who are already stretched too far in getting patients the care they need. It

[14] U.S. Department of Health and Human Services, *FAQs about Affordable Care act Implementation Part 47* (Jul. 19, 2021), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf.

will also require that a person at risk for HIV terminate PrEP in the event that the requirements of this section are not met. This is not the right policy to address a public health emergency.

For these reasons, we strongly recommend that the provision on "Medical necessity and appropriateness of treatment" be removed from the bill.

We appreciate the opportunity to comment on this important legislation. Passing H 6150, with the proposed amendments, will ensure that Rhode Island is implementing the best practices to address, and finally end, the decades-long HIV epidemic.

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