

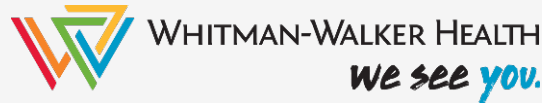
PrEP, TelePrEP, and Long-Acting PrEP: Legal and Policy Issues in the Current and Future HIV Landscape

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Ben Klein: GLBTO Legal Advocates and Defenders receives donations to support its litigation and advocacy work from Gilead, Pfizer, Sanofi and Abbott Labs.

Goals of This Presentation

We hope to assist participants to:

- Understand legal and policy obstacles to PrEP access and efforts to overcome those obstacles
- Appreciate how to advocate more effectively for increased access to PrEP
- Better understand the education and legal and policy actions needed to implement telehealth models for PrEP and prepare for innovative long-acting formulations of PrEP

We Are Not Yet Realizing PrEP's Potential

- Pre-exposure prophylaxis (PrEP) involves persons at risk of HIV infection taking a daily pill to prevent HIV.
- Current estimates are that 1,144,500 have an indication for PrEP.
- In 2017, 158,183 people were taking PrEP, meaning only about 15% of those with a PrEP indication were on PrEP.
- Racial disparities in PrEP utilization: While PrEP use increased by 500% from 2013 to 2015, Black people accounted for only 10% of PrEP users.
- PrEP use is too low among Black and Latinx men who have sex with men (MSM), transgender people, women, people who inject drugs, and young people.

Smith DK et al. Estimates of adults with indications for HIV pre-exposure prophylaxis by jurisdiction, transmission risk group, and race/ethnicity, United States, 2015. *Ann Epidem* 2018;28(12):850-857.

Nguyen C et al. Utilization of emtricitabine/ tenofovir disoproxil fumarate (FTC/TDF) for HIV pre-exposure prophylaxis (PrEP) in the United States by Age, Gender, and Race/ Ethnicity (2014-2017). Presented at: International AIDS Society Conference on HIV Science; July 21-24, 2019; Mexico City.

Bush S et al. Racial characteristics of FTC/TDF for pre-exposure prophylaxis users in the US. Presented at American Society for Microbiology Microbe 2016; June 16–20, 2016; Boston, MA.

One Promising Development: US Preventive Services Task Force Has Rated PrEP As “A”

- In June 2019, the US Preventive Services Task Force issued a final “Grade A” recommendation for PrEP, urging that health care providers offer PrEP to people at high risk for HIV.
- The Grade A rating means that nearly all private insurance plans, including employer plans and those offering coverage through Affordable Care Act (ACA) marketplaces, will have to cover PrEP without cost-sharing for those individuals by 2021. The recommendation also means that, for Medicaid expansion enrollees, any cost sharing be lowered to zero.
- Still questions about what this means legally and what the implications are:
 - Coverage of medical monitoring or just the drug?
 - Self-executing?
 - Notice?
- Additional advocacy is needed.

Another Potentially Promising Development: TelePrEP

- Telehealth services – clinical services offered where the patient and the practitioner are communicating in real time over a telecommunication systems – offer a way to expand access to PrEP.
 - For example, PrEPtech is a program piloted in San Francisco targeting young MSM of color with telemedicine medical visits, home delivery of PrEP, and sexually transmitted infection (STI) testing kits. This can reduce the burden of regular screenings and visits recommended for PrEP users.
- **Policy change may be needed:** In total, 49 states and DC provide for Medicaid reimbursement of some form of live video telehealth services. While about half of states specify a specific set of facilities that can serve as “originating sites” where the patient may be, only ten states permit a patient’s home to be the originating site. This can be a barrier to financing telehealth PrEP-related clinical visits if providers cannot bill Medicaid for visits originating at a patient’s home.

Another Potentially Promising Development: The Administration's "End the Epidemic" Initiative

- Earlier this year, the Trump Administration launched its Ending the HIV Epidemic (EHE) Initiative, setting a goal of reducing HIV transmission in the US by 90% within ten year.
- The President's FY 2020 Budget Request proposed \$291 million of new funding for the EHE Initiative, including \$140 million to the CDC for improved testing, prevention and referral to medical care, including PrEP.
- In May, Gilead Sciences announced that over the next 10 years it would give free Truvada pills for use as PrEP to 200,000 uninsured people. This would amount to a donation of 2.4 million free bottles annually to the CDC for the 11-year period.
 - Descovy, a new PrEP drug from Gilead Sciences, is currently being reviewed by the Food and Drug Administration. Descovy contains tenofovir alafenamide (TAF)—an updated formulation of tenofovir that is easier on the kidneys and bones—and emtricitabine.

Another Potentially Promising Development: Bills Recently Introduced in the Senate and House

PrEP Access and Coverage Act, S. 1926, introduced June 20, 2019, would

- Require all public and private health insurance plans to cover the drug—as well as all required tests and follow-up visits—without a copay, just as the Affordable Care Act requires insurance to cover contraception and other preventive services.
- Fund a grant program to assist states, territories, and tribal communities in facilitating access to PrEP for people who lack insurance and reducing disparities in access to PrEP. The bill authorizes grants to cover the cost of the drug, as well as all associated tests and follow-up visits. The grants will also support outreach to physicians and other providers designed to increase understanding of PrEP and the recommended clinical practices for providing care.
- Prohibit companies selling life insurance, disability insurance, and long-term care insurance from denying coverage to customers who take PrEP or charging them higher premiums.
- Fund a public education campaign to reduce disparities in access to and use of PrEP by educating the public—particularly high-need communities in which PrEP is underutilized—about the safety and efficacy of the drug and to combat stigma associated with using PrEP.

Press Release, “Harris Introduces Bill to Dramatically Expand Access to PrEP” (June 20, 2019), <https://www.harris.senate.gov/news/press-releases/harris-introduces-bill-to-dramatically-expand-access-to-prep>.

Companion bill, H.R. 3815, introduced in the House July 17, 2019.



Insurance Company Restrictions on PrEP Coverage

- A number of health insurance carriers require pre-authorization for PrEP prescriptions. Some also require use of specified mail-order pharmacies for the drug. Protests of the resulting delays and unnecessary burdens have met with varying degrees of success.
- Gilead's Truvada Co-Pay Coupon program currently covers up to \$7,200/year of co-pays for eligible patients, with no monthly cap. However, an increasing number of insurers are adopting "co-pay accumulator" programs. These policies do not credit amounts paid by a pharmaceutical company for the patient's drug towards the patient's annual deductible, which forces the patient to bear substantial additional costs and discourages the patient from starting or continuing on PrEP. (Drug co-pay coupons are prohibited by Medicare and Medicaid as kickbacks, but permitted under commercial health plans.)
- The issues raised by this insurance practice are getting increasing public attention. They pit insurers' concerns over pharmaceutical company incentives that may encourage unnecessary use of costly drugs, against patient advocate and public health concerns over disincentives to engage in PrEP and other beneficial therapies.

Emily Turturici, *Manufacturer Drug Coupons and Copay Accumulator Adjustments*, Feb. 27, 2019, <https://www.highpointsolutions.com/manufacturer-drug-coupons-and-copay-accumulator-adjustments>.

Bob Herman & Caitlin Owens, *Pharmacy Sticker Shock is Here*, Axios Vitals, July 9, 2018. Available at <https://www.axios.com/newsletters/axios-vitals-b2afd56f-b6f4-497a-8b6a-37e347c2ba50.html>. Accessed Sept. 21, 2018.

Michelle Andrews, *Benefit Change Could Raise Costs for Patients Getting Drug Copay Assistance*, Kaiser Health News May 29, 2018.

Bob Herman, *The Drug Pricing Issue That Could Erupt This Year*, Axios Vitals, Feb. 8, 2018. Available at <https://www.axios.com/newsletters/axios-vitals-c6830c75-a952-481c-b711-3bdccc2dd755.html>. Accessed Sept. 21, 2018.



Addressing Lack of Patient and Provider Information

There is still widespread lack of accurate information about PrEP in many communities that could benefit, and among many providers. Providers have a wide range of attitudes about when PrEP is indicated, based on their (often imperfect) knowledge and sometimes on their own (implicit or explicit) biases.

- Smith DK et al. PrEP awareness and attitudes in a national survey of primary care clinicians in the United States, 2009–2015. PLOS One 2016. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0156592>.
- Pinto RM et al. Improving PrEP implementation through multilevel interventions: A synthesis of the literature. AIDS and Behavior 2018. <https://link.springer.com/article/10.1007%2Fs10461-018-2184-4>.
- Patel RR et al. Missed opportunities to prescribe HIV pre-exposure prophylaxis by primary care providers in Saint Louis, Missouri. LGBT Health 2018, 5(4): 250-256.

One response: California law enacted in 2016 on HIV Testing:

“...If the patient tests negative for HIV infection and is determined to be at high risk for HIV infection by the medical provider or person administering the test, the medical provider or the person who administers the test shall ... provide information about methods that prevent or reduce the risk of contracting HIV, including, but not limited to, pre-exposure prophylaxis and post-exposure prophylaxis, consistent with guidance of the federal Centers for Disease Control and Prevention, and may offer prevention counseling or a referral to prevention counseling.”

Calif. Health & Safety Code, Section 120990(h).



Addressing Lack of Patient and Provider Information

In *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018), the Supreme Court, by a vote of 5-4, struck down two California laws as violations of the First Amendment's right to free speech:

- A law requiring certain licensed "pregnancy crisis centers" (religiously-based and anti-abortion) to provide standardized, written information to patients about the availability of low-cost or no-cost abortions in California; and
- A law requiring unlicensed "pregnancy crisis centers" to provide written disclosures to patients that they are not licensed to provide medical services.

The majority concluded that the laws in question were motivated by a "pro-choice" agenda – targeting entities and services providers who are opposed to abortion and requiring them to "speak" in ways that contradicted their beliefs and/or undermined their credibility. However, some of the majority opinion's language is quite broad and might be used by opponents of any law requiring health care providers to provide virtually any specified information to patients.

Discrimination Based on PrEP Use

Numerous reported cases where applicants for life, disability or long-term care insurance have been denied as “high risk” because they were on PrEP.

Some insurance companies appear to have a standard policy to this effect.

Advocacy Options

1. Education
2. Legislation
3. Public Policy and Regulatory Directives
4. Litigation

Litigation to Address Barriers to PrEP: Two Examples

- I. Denials of Life, Disability and Long-term Care Insurance to Qualified Applicants Solely due to PrEP Usage.

- II. Physician Refusals to Prescribe PrEP

Case I: Life, Long-Term Care, Disability Insurance Denials

Insurance Industry Rationales:

- People who take PrEP are by definition at higher risk for HIV, and therefore have a higher risk of claims.
- People might not adhere to medication/monitoring.
- PrEP is new and long-term side effects of Truvada in HIV-negative individuals are unknown.

Legal Claims

- Sexual Orientation Discrimination:
80% of PrEP users are gay men.
- Disability Discrimination:
Unscientific beliefs that PrEP users are at higher risk to get HIV in the future than are non-PrEP users.

Case II: Physician Refusal To Prescribe

- Negligence?
- Discrimination?

Physician Refusal To Prescribe: The Facts

1. Pt. to PCP (2017) – dx. syphilis, chlamydia, HIV exposure.
[no discussion of PrEP]
2. 8 Months Later – Pt. requests PrEP. PCP indicates that he “does not do that” and Pt. must go to an STD clinic.
[Pt. does not go to STD clinic]
3. 4 Months Later – Pt. seroconverts.

An Additional Challenge: HHS' "Conscience Protection" Rule

Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23170 (May 21, 2019):

- Covers any health care provider or health insurer receiving federal funding.
- Purports to enforce federal laws that protect the "conscience" of health care providers and health insurers. Most of these laws focus on abortion and sterilization, but one statute – the Church Amendments – allegedly protects the right to opt out of participating in any health program or activity or research project that is funded by HHS.
- Very broad notion of "participation", including refusal to provide information or referrals.

Currently being challenged in lawsuits in multiple federal courts, brought by multiple state, county and municipal governments, by LGBTQ and reproductive health and advocacy groups, and individual providers. Decision on motions for summary judgment expected by Nov. 22, 2019.

PrEP for Youth: State Laws on Minor Consent

- In May 2018, the FDA approved changes to the labeling of Truvada to include PrEP for adolescents as well as adults weighing at least 35 kg (77 lbs.) who are at risk of HIV infection. (Note: 35 kg is significantly lower than the average weight of a 13-year old.) This has eliminated a major impediment to providing PrEP for young people at significant risk of HIV. (Prior to the FDA's change, PrEP could still be prescribed off-label for adolescents, but many providers were hesitant to do so.)
- However, the general legal requirement of parental consent for medical care for minors is an obstacle for minors whose sexual behavior is not known to, or approved of, by their parents: gay and bisexual boys and young men and transgender individuals, as well as heterosexual young people of all genders who are sexually active.
- State laws generally provide for testing and treatment of minors for sexually transmitted diseases, including HIV, without parental notice or consent. But many state laws authorize *testing and treatment*, but do not specifically authorize *prevention* of sexually transmitted disease.

Burda JP. PrEP and our youth: Implications in law and policy. Colum. J. Gender & L. 2016; 30(2): 295-363.

Culp L and Carducci L. State adolescent consent laws and implications for HIV pre-exposure prophylaxis. Am J Prev Med 2013; 44(1S2):S119-S124.

PrEP for Youth: Confidentiality When on a Parent's Insurance Plan

- A significant concern of many young people who are on their parents' health insurance is the standard practice of providing notice to the primary insured party of any coverage decision (an "Explanation of Benefits"). Many young people are reluctant for their parent to receive notice of their usage of a drug related to sexual activity – particularly if they are gay or bisexual.
- The importance of the issue has increased after the passage of the ACA – which allows children to remain on their parents' health plans until age 26.
- Some states have enacted laws that authorize an insured individual to instruct the insurer, in writing, to provide all notices only to that individual – or to another specified individual (or, e.g., a post office box).

Michelle Andrews, *States Offer Privacy Protections To Young Adults On Their Parents' Health Plan*, Kaiser Health News June 28, 2016. <https://khn.org/news/states-offer-privacy-protections-to-young-adults-on-their-parents-health-plan>.

English A & Lewis J. Privacy protection in billing and health insurance communications. *AMA J Ethics* 2016; 18(3): 279-287.

- The PrEP Access and Coverage Act recently introduced in the Senate (S. 1926) and House (H.R. 3815) would require HHS to amend the HIPAA Privacy Rule to specify an insured person's right to restrict notices about claims and coverage decisions.

Long-Acting PrEP

- Several long-acting products for HIV treatment and prevention that do not require daily dosing are in various stages of the research pipeline. These include injections, implants, and oral medications, and intravaginal rings.
- For individuals to benefit from these products, the products will be subject to a complex maze of policy decisions.
- Long-acting PrEP raises questions related to the Food and Drug Administration review and approval process for these products, the payer landscape, and consumer and provider acceptability.

Crowley JS and Bland SE. Long-Acting HIV Treatment and Prevention Are Coming: Preparing for Potential Game Changers. amfAR. July 2018.
<https://www.amfar.org/long-acting-arv/>

Long-Acting PrEP

- **Food and Drug Administration**
 - Drugs and devices are regulated by different centers within the FDA. Long-acting products may be regulated by different or multiple parts of the FDA.
- **Payer Landscape**
 - Medicaid, Medicare, private insurance and other programs have various levels of discretion to determine whether and when to make new products available.
 - Different payers operate under different provisions of laws and have different rules regarding pharmaceutical coverage and cost-sharing. For example, different long-acting products could be covered by different parts of Medicare and could have different access rules.
 - Medicare Part B program: Covers physician-administered drugs, consumers pay 20% of the Medicare cost, and there is no low-income subsidy program
 - Medicare Part D program: Covers most outpatient prescription drugs, significant cost sharing is possible, and there is a low-income subsidy program
- **Consumer and Provider Acceptance**
 - More research is needed to understand whether infrequent dosing actually strengthens adherence. Other considerations include discontinuance, side effects, injection site pain, affordability, privacy, and convenience.