

LEGAL ISSUES AFFECTING PREP UTILIZATION

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GLMA Annual Conference on LGBTQ Health
Las Vegas, Nevada
October 11, 2018



Conflict of Interest Disclosures

- Sean Bland

The O'Neill Institute for National and Global Health has received funding from Gilead Sciences for its Ryan White Policy Project and for a separate HIV Prevention Project. Sean Bland received an honorarium from Gilead Sciences for participating in a community advisory board in April 2017.

- Daniel Bruner

Whitman-Walker Health has received funding from Gilead Sciences for a Mobile Outreach Retention and Engagement project, focusing on patients who have fallen out of care or who encounter significant barriers to engagement in care. Gilead Sciences is also a sponsor of a National LGBT Cultural Competency Summit, organized by Whitman-Walker and the National LGBT Cancer Network.

- Scott Schoettes

None.

GOALS OF THIS PRESENTATION

We hope to assist participants to:

- Advise their patients of potential obstacles to PrEP coverage and assist them in overcoming those obstacles.
- Advocate more effectively for increased PrEP utilization when appropriate.
- Participate more effectively in professional and public debates over initiatives to encourage PrEP utilization.

CURRENT PREP UTILIZATION IN THE UNITED STATES

PrEP use is growing, and has been linked to declining new HIV infections.

- Liz Highleyman, PrEP use linked to fewer new HIV infections in US states. NAM Aidsmap July 26, 2018. <http://www.aidsmap.com/PrEP-use-linked-to-fewer-new-HIV-infections-in-US-states/page/3313879>.
- Gilead Sciences, *Gilead Announces New Data on the Impact of Truvada® (Emtricitabine and Tenofovir Disoproxil Fumarate) for Pre-Exposure Prophylaxis (PrEP) on the Number of HIV Diagnoses in the United States*, July 24, 2018. <https://www.gilead.com/news/press-releases/2018/7/gilead-announces-new-data-on-the-impact-of-truvada-emtricitabine-and-tenofovir-disoproxil-fumarate-for-preexposure-prophylaxis-prep-on-the-number-of-hiv-diagnoses-in-the-united-states>.

But PrEP is reaching only a small percentage of the approximately 1.2 million individuals in the US who the CDC estimates would benefit from PrEP because of higher-risk sexual activity. And PrEP is still dramatically underutilized by populations that remain disproportionately affected by HIV: Black and Latino gay and bisexual men; women of color; and young people.

- Centers for Disease Control and Prevention, *March 6, 2018 – A new CDC analysis suggests HIV prevention pill is not reaching most Americans who could benefit – especially people of color*. <https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018.html>.
- Liz Highleyman, *Most adolescent PrEP users in US are young women*. NAM Aidsmap July 31, 2018, <http://www.aidsmap.com/Most-adolescent-PrEP-users-in-US-are-young-women/page/3316220>.
- Goldstein RH, Streed Jr. CG, Cahill SR. *Being PrEPared – Preexposure prophylaxis and HIV disparities*. NE J Med Sept. 19, 2018. <https://www.nejm.org/doi/full/10.1056/NEJMp1804306?query=TOC>.

Moreover, there are indications that current guidelines for recommending PrEP do not identify everyone who is at risk, including young Black gay and bisexual men.

- Lanki N. et al. *Preexposure prophylaxis guidelines have low sensitivity for identifying seroconverters in a sample of young Black MSM in Chicago*. AIDS 2018, 32(3): 383-392.
- Beymer M.R. et. al. *Are CDC guidelines for pre-exposure prophylaxis specific enough? Formulation of a personalized HIV risk score for pre-exposure prophylaxis initiation*. Sex Transm Dis. 2017, 44(1): 48-56. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5145736>.

PROVIDER AND PATIENT KNOWLEDGE OF AND ATTITUDES ABOUT PREP

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>.
- Goparaju L. et al. Women want pre-exposure prophylaxis but are advised against it by their HIV-positive counterparts. J AIDS Clin Res 2015, 6(11). <https://www.omicsonline.org/open-access/women-want-preexposure-prophylaxis-but-are-advised-against-it-by-theirhivpositive-counterparts-2155-6113-1000522.php?aid=64479>.
- 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.
- Hammack PL et al. HIV testing and pre-exposure prophylaxis (PrEP) use, familiarity, and attitudes among gay and bisexual men in the United States: A national probability sample of three birth cohorts. PLOS One 2018, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0202806>.

California has enacted a law providing that providers and others administering HIV tests “shall” provide information about PrEP and PEP, and other protective measures, to individuals testing HIV-negative and “determined to be at high risk for HIV.”

- California Assembly Bill 2640, http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB2640 (enacted 2016, effective January 1, 2017).

Other jurisdictions are considering similar measures. However, a recent Supreme Court case may limit the power of governments to mandate provision of PrEP-related information.

- [*Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 \(2018\).](#)

DISCRIMINATION AGAINST PEOPLE TAKING PREP

Some insurance companies have denied disability, life or long-term care insurance to individuals who are on PrEP on the basis that this indicates their “high risk” for HIV. GLAD in Boston has challenged Mutual of Omaha in court; and several state insurance regulators have initiated investigations or issued rulings banning such discrimination. The District of Columbia Council is considering a bill that would outlaw such practices.

- For the Mutual of Omaha litigation, see GLAD's web site: <https://www.glad.org/cases/doe-v-mutual-of-omaha>.
- For other instances, see Donald G. McNeil Jr., *He Took a Drug to Prevent AIDS. Then He Couldn't Get Disability Insurance*, New York Times Feb. 12, 2018. <https://www.nytimes.com/2018/02/12/health/truvada-hiv-insurance.html>.

Actions of state insurance regulators

- California Department of Insurance, *Insurance Commissioner Jones opens investigation into alleged denials of life insurance policies for gay men taking HIV/AIDS prevention medications*, Feb. 15, 2018. <http://www.insurance.ca.gov/0400-news/0100-press-releases/2018/statement018-18.cfm>.
- New York State Department of Financial Services, *Insurance Circular Letter No. 8, Underwriting in life insurance, disability income insurance, and long term care insurance for the use of antiretroviral pre-exposure prophylaxis (“PrEP”) to reduce the risk of contracting human immunodeficiency virus (“HIV”) infection*, June 22, 2018. https://www.dfs.ny.gov/insurance/circltr/2018/cl2018_08.htm.

Legislation pending before the Council of the District of Columbia

- Bill 22-699, *Pre-exposure Prophylaxis Insurance Discrimination Act of 2018*, introduced Feb. 20, 2018. <http://lims.dccouncil.us/Legislation/B22-0699?FromSearchResults=true>.

DISCRIMINATORY DENIALS OF HEALTH INSURANCE COVERAGE OF PREP

In June 2017, United Healthcare sent a letter to a policyholder denying coverage of PrEP because the man was engaging in ‘high-risk homosexual behavior.’ After negative publicity, UHC reversed the decision and apologized.

- Kristina Marusic, *Insurer Apologizes For Shaming Man's "High Risk Homosexual Behavior" In PrEP Coverage Denial Letter*, Logo August 8, 2017. <http://www.newnownext.com/insurer-apologizes-for-shaming-mans-high-risk-homosexual-behavior-in-prep-coverage-denial-letter/08/2017>.

In late 2017 and early 2018, it was reported that the Florida-based grocery store chain Publix, with stores in 7 states in the South and approximately 188,000 employees, was denying coverage of PrEP in its employee health plan. The company declined repeated requests for an explanation. After significant adverse publicity, the company reversed its position. The incident highlighted uncertainties about the legal rights of businesses to restrict health insurance coverage provided to employees for religious reasons, in the wake of the Supreme Court's decision in [*Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 \(2014\)](#).

- Ryan Lee, *Publix Grocery Chain Denies PrEP Coverage to Its Employees*, The Body Jan. 29, 2018. <http://www.thebody.com/content/80784/publix-grocery-chain-denies-prep-coverage-to-its-e.html>.
- Martin Vassolo & David J. Neal, *Publix Reverses Policy Denying Coverage for HIV-Prevention Drug*, Miami Herald Feb. 6, 2018. <https://www.miamiherald.com/news/politics-government/article198652559.html>.

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.

- 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.
- AIDS Foundation of Chicago, *News: This New Insurance Loophole Could Affect People on HIV Meds, Including PrEP*, May 2, 2018, <https://www.aidschicago.org/page/news/this-new-insurance-loophole-could-affect-people-on-hiv-meds-including-prep>.

PREP FOR YOUTH: STATE LAWS ON STI PREVENTION AND 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 who are at risk of HIV infection. (Note: 35 kg is significantly lower than the average weight of a 13-year old.)

- FDA, HIV Email Update, May 15, 2018.
- National Institutes of Health, *Item of Interest: FDA Approves PrEP Therapy for Adolescents at Risk of HIV*, May 16, 2018. <https://www.nichd.nih.gov/newsroom/releases/051618-PrEP>.

FDA approval 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 OF INDIVIDUALS ON A PARENT'S INSURANCE PLAN

A significant concern of many young people who are on their parents' health insurance is the standard practice (required under many state laws) 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.
- The issue is also relevant for persons of any age who are on a spouse's (or other family member's) health plan.

Some states have enacted laws – statutes or insurance regulations – 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.
- English A et al. Confidentiality for individuals insured as dependents: A review of state laws and policies. Guttmacher Institute July 2012. https://www.guttmacher.org/sites/default/files/report_pdf/confidentiality-review.pdf.

US PREVENTIVE SERVICES TASK FORCE CLASSIFICATION OF PREP: IMPLICATIONS FOR NO-COST COVERAGE

The Affordable Care Act requires covered health plans to provide cost-free coverage of certain preventive health services: “[e]vidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States Preventive Services Task Force.” [42 U.S.C. 300gg-13\(a\)\(1\)](#).

Efforts have been underway for several years to persuade the USPSTF to rate PrEP as A (“There is high certainty that the net benefit is substantial”) or B (“There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial”). Those efforts have not yet succeeded.

In August 2017, the USPSTF issued its PrEP Research Plan. The timetable for issuance of the USPSTF’s conclusions is uncertain.

- *Final Research Plan: Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis*. U.S. Preventive Services Task Force. August 2017.
<https://www.uspreventiveservicestaskforce.org/Page/Document/final-research-plan/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

QUESTIONS?