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December 21, 2018

Dr. Susan J. Curry, Chair  
U.S. Preventive Services Task Force  
USPSTF Program Office  
5600 Fishers Lane, Mail Stop 06E53A  
Rockville, MD 20857

**RE: Draft Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis**

Dear Dr. Curry and Task Force Members,

Thank you for the opportunity to comment on the Draft Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis (PrEP). The National Health Law Program, founded in 1969, protects and advances health rights of low-income and underserved individuals and families by advocating, educating, and litigating at the federal and state levels.

We strongly support the USPSTF draft recommendation designating PrEP as an “A” recommended preventive service. This recommendation would make PrEP more widely and readily accessible to help prevent HIV infection. However, we have concerns regarding the criteria used for determining who is at “high risk” for HIV infection and urge the USPSTF to expand access to this potentially life-saving preventive service. We also suggest that USPSTF clarify that the ancillary services associated with PrEP use, including HIV testing and counseling, are included in the PrEP access under this recommendation.

**1. Background**

The Affordable Care Act (ACA) recognizes that even small investments in preventive screenings and services can yield significant cost savings and improve health outcomes. The ACA requires non-grandfathered individual and small group plans to provide certain preventive services and screenings without cost

sharing.<sup>1</sup> The ACA also allows state Medicaid programs to receive a one percent increase in their federal match for covering the USPSTF recommended screenings and adult vaccines without charge to enrollees.<sup>2</sup>

## 2. High cost of PrEP impedes access

Truvada® is the only medication approved and available for PrEP to prevent HIV infection.<sup>3</sup> According to the Centers for Disease Control and Prevention (CDC), PrEP can reduce the risk of HIV infection in people who are at high risk by up to 92 percent.<sup>4</sup> Yet more than six years since the Food and Drug Administration (FDA) approved Truvada for use as PrEP, and more than four years since CDC recommended PrEP as a proven HIV prevention strategy, few people can access this potentially life-saving treatment.

In February 2016, the drug's manufacturer, Gilead Sciences, estimated that only 98,732 U.S. residents had started Truvada for PrEP since 2012, which accounts for less than 10 percent of the 1.2 million people for whom the CDC estimates PrEP is indicated.<sup>5</sup>

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<sup>1</sup> 42 U.S.C. § 300gg–13. See also Julia Quinn and Wayne Turner, NAT'L HEALTH LAW PROGRAM, *Health Advocate: The ACA and Preventive Screenings and Services* (July 13, 2016),

<https://healthlaw.org/resource/health-advocate-the-aca-and-preventive-screenings-and-services/>.

<sup>2</sup> 42 U.S.C. 1396d (note). See also CMS, Questions & Answers on ACA Section 4106: Improving Access to Preventive Services for Eligible Adults in Medicaid, <https://www.medicaid.gov/affordable-care-act/provisions/downloads/4106-faqs-clean.pdf>.

<sup>3</sup> Press Release, FDA Approves First Drug for Reducing the Risk of Sexually Acquired HIV Infection, FOOD & DRUG ADMIN. (July 16, 2012), <https://wayback.archive-it.org/7993/20170112032741/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm>. *Pre-exposure Prophylaxis (PrEP) for HIV Prevention*, CTRS. FOR DISEASE CONTROL AND PREVENTION 1 (May 2014), [https://www.cdc.gov/hiv/pdf/PrEP\\_fact\\_sheet\\_final.pdf](https://www.cdc.gov/hiv/pdf/PrEP_fact_sheet_final.pdf); *PrEP*, CTRS. FOR DISEASE CONTROL AND PREVENTION (March 23, 2018), <https://www.cdc.gov/hiv/basics/prep.html>. While a generic version of Truvada was approved by the FDA in 2017, it appears likely that it will not become commercially available until 2021, when Gilead's patent on emtricitabine (one of the two HIV antiretroviral drugs Truvada is composed of) expires. See *The FDA Has Approved Generic PrEP – but Access May Remain Difficult*, PROJECT INFORM (June 16, 2017), <https://www.projectinform.org/hiv-news/the-fda-has-approved-generic-prep-but-access-may-remain-difficult/>.

<sup>4</sup> *Pre-Exposure Prophylaxis (PrEP)*, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 15, 2018), <https://www.cdc.gov/hiv/risk/prep/index.html>.

<sup>5</sup> Robertino M. Giler et al., *Changes in Truvada for Hiv pre-exposure prophylaxis utilization in the USA: 2012-2016*, 9<sup>th</sup> International AIDS Society Conference on HIV Science (July 2017), <http://programme.ias2017.org/Abstract/Abstract/1614>; *Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Pre-exposure Prophylaxis to Prevent HIV Acquisition – United States, 2015*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Nov. 27, 2015), [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a4.htm?s\\_cid=mm6446a4\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a4.htm?s_cid=mm6446a4_w).



One of the main reasons for this underuse is cost. For the uninsured, the cost for PrEP can be as high as \$1,250 per month or \$15,000 per year.<sup>6</sup> For those with insurance, PrEP can still be prohibitively expensive, with out-of-pocket costs estimated at \$6,000 annually.<sup>7</sup>

Research shows that for those most at-risk for HIV infection, the cost associated with PrEP is one of the most significant barriers to PrEP utilization. One study conducted among high-risk gay men having sex with men (MSM) found that 80% of respondents would be likely to use PrEP if it were provided without cost sharing.<sup>8</sup> Another study found that the most commonly reported barrier to PrEP use among study participants who did not take PrEP after completion of the study's project was cost or lack of health insurance.<sup>9</sup> Yet another study found that higher income was significantly associated with PrEP usage.<sup>10</sup>

Additionally, financial barriers can be even more acute for people experiencing intimate partner violence ("IPV").<sup>11</sup> In many violent relationships, the abusive partner maintains control over household finances. This may make it difficult for a person experiencing IPV to pay for PrEP. The "A" rating from the Task Force ensures no cost-sharing for PrEP in applicable health plans, but does not eliminate the cost barrier altogether. A person experiencing IPV may not be able to utilize insurance coverage if they wish to use PrEP covertly and are covered under the abusive partner's plan. Providers should be trained on confidentiality best practices, and future research is needed to develop strategies and policies that ensure confidentiality of PrEP services so that people experiencing IPV can fully benefit from them.

Low-income communities and communities of color disproportionately bear the burden of HIV and are at the highest risk of infection.<sup>12</sup> A recent analysis by the CDC found that, while

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<sup>6</sup> Jason Ervin & Carolyn McAllaster, *We Have the Tools to End HIV: Benefits, Barriers, and Solutions to Expanded Utilization of Pre-Exposure Prophylaxis (PrEP) in the US Deep South*, SOUTHERN HIV/AIDS STRATEGY INITIATIVE, 1, 9 (June 2016); *Are You PrEP Skeptical?*, PREP FACTS, <http://men.prepfacts.org/the-questions/> (last visited June 26, 2018); Kimberly A. Koester et al., *Financial Assistance for PrEP: Best Practices & Recommendations for the California State Office of AIDS' PrEP Assistance Program*, FACTS CAL. HIV/AIDS POLICY RESEARCH CENTERS 1 (2017), [http://www.chprc.org/wp-content/uploads/2017/09/PrEP-Benefits-Report\\_September\\_2017\\_FINAL.pdf](http://www.chprc.org/wp-content/uploads/2017/09/PrEP-Benefits-Report_September_2017_FINAL.pdf)

<sup>7</sup> *Id.*

<sup>8</sup> Jason Ervin & Carolyn McAllaster, *We Have the Tools to End HIV: Benefits, Barriers, and Solutions to Expanded Utilization of Pre-Exposure Prophylaxis (PrEP) in the US Deep South*, SOUTHERN HIV/AIDS STRATEGY INITIATIVE at 9-10 (June 2016).

<sup>9</sup> Susan Doblecki-Lewis et al., *Healthcare Access and PrEP Continuation in San Francisco and Miami after the US PrEP Demo Project*, JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROME 531, 534 (Apr. 15, 2017).

<sup>10</sup> Ian Holloway et al., *PrEP Uptake, Adherence, and Discontinuation among California YMSM Using Geosocial Networking Applications* 1, 5 (Jan. 1, 2018).

<sup>11</sup> Amy Braksmajer et al., *The Potential of Pre-Exposure Prophylaxis for Women in Violent Relationships*, AIDS PATIENT CARE & STDs 274 (June 1, 2016).

<sup>12</sup> *HIV Prevention Pill Not Reaching Most Americans Who Could Benefit*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Mar. 6, 2018), <https://www.cdc.gov/nchstp/newsroom/2018/croi-2018-PrEP-press-release.html>.



two-thirds of people who could potentially benefit from PrEP are Black or Latino, they account for the smallest percentage of prescriptions to date.<sup>13</sup> What this means practically is that PrEP is not being used by the very people who are at highest risk for contracting HIV.

The USPSTF recommendation of “A” will help remove the cost barrier by requiring applicable health plans to provide this potentially life-saving preventive service with no cost sharing. For these reasons, we strongly support expanded access to PrEP for persons at risk for HIV infection.

### 3. Recommendations for the USPSTF

#### a. Expand criteria for who is “high risk”

NHeLP agrees with USPSTF that “[T]he first step in implementing PrEP is identifying persons at high risk of HIV acquisition who may benefit from PrEP.”<sup>14</sup> NHeLP recommends that the USPSTF expand the criteria for identifying persons at “high risk” for HIV infection who may access PrEP without cost sharing.

The draft recommendation links access to PrEP to effective screening and diagnosis of specific sexually transmitted infections (STIs). However, STIs may be undetected in significant numbers of MSM due to shortcomings in the USPSTF’s recommendation for STI screenings.

Currently, the USPSTF recommends gonorrhea and chlamydia screenings for sexually active women, but not men.<sup>15</sup> The difference, according to the USPSTF, is because urethral infections in men are symptomatic, unlike gonorrhea and chlamydia in women that is asymptomatic and might otherwise go undetected.

However, not all gonorrhea infections in men are urethral. A 2010 study of MSM found that rectal gonorrhea also fails to produce symptoms.<sup>16</sup> The study also notes a “dearth of research on rectal immunology” and its correlation to HIV transmission.<sup>17</sup> In 2014, the USPSTF called more research on MSM and sexually active males younger than 24 years old when it declined to extend STI screenings to men. However, research in this area continues to be limited.

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<sup>13</sup> *Id.*

<sup>14</sup> U.S. Preventive Health Services Task Force, Draft Recommendation Statement Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis (Nov. 20, 2018).

<sup>15</sup> U.S. Preventive Health Services Task Force, Chlamydia and Gonorrhea: Screening (Sept. 2014).

<sup>16</sup> Bernstein, Kyle T PhD, et al., *Rectal Gonorrhea and Chlamydia Reinfection Is Associated With Increased Risk of HIV Seroconversion*, JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES: April 1st, 2010 - Volume 53 - Issue 4 - p 537-543

<sup>17</sup> *Id.*



We are concerned that the ongoing deficiencies in STI screenings for men, particularly MSM, will unduly restrict PrEP access. In the absence of an effective and efficient tool for assessing risk, we urge USPSTF to note that patients who request PrEP should be assumed to be at higher risk and should be able to access PrEP with no cost sharing.

*b. Clarify what services are included in the PrEP recommendation*

Utilization of PrEP requires a number of actions beyond simply taking the daily medication (e.g. frequent clinician visits, regular HIV tests, other lab tests, etc.), all of which involve additional expenses that might not be covered by insurance or other financial assistance programs.<sup>18</sup> The USPSTF should clarify that these services are included within the USPSTF recommendation for PrEP.

Lack of clarity on USPSTF recommended services has allowed health plans to charge for key components of A or B preventive services. For example, colonoscopies and other screening tools for colorectal cancer receive an “A” level recommendation from USPSTF for all adults beginning at age 50. However, some insurers have charged patients for anesthesia and bowel preparation medications prescribed for the procedure. HHS, along with the Departments of Labor (DOL) and Treasury, issued joint guidance reiterating insurers’ obligation to cover the entire costs of colonoscopies without charge to the patient, including anesthesia, bowel preparation medication, and polyp removal incidental to a screening.<sup>19</sup>

We suggest USPSTF clarify that HIV testing and counseling are included in the provision of PrEP services. Although USPSTF currently designates routine HIV testing and counseling for adults between ages 15-65 as an “A” preventive service, the scope and frequency of such screening may not align with protocols for HIV testing pursuant to PrEP.<sup>20</sup> The draft recommendation for PrEP use does not include such age restrictions, and we do not support including such limits. Sexually active youth and older adults who are at risk for HIV infection should not be arbitrarily excluded from PrEP access.

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<sup>18</sup> Jason Ervin & Carolyn McAllaster, *We Have the Tools to End HIV: Benefits, Barriers, and Solutions to Expanded Utilization of Pre-Exposure Prophylaxis (PrEP) in the US Deep South*, SOUTHERN HIV/AIDS STRATEGY INITIATIVE at 9-10 (June 2016).

<sup>19</sup> CTRS. FOR MEDICARE & MEDICAID SERVICES, FAQs about Affordable Care Act Implementation (PART XXVI) (May 11, 2015), [https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca\\_implementation\\_faqs26.pdf](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf); CTRS. FOR MEDICARE & MEDICAID SERVICES, FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women’s Health and Cancer Rights Act Implementation (April 20, 2016), [https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31\\_Final-4-20-16.pdf](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf).

<sup>20</sup> The USPSTF stated that evidence is insufficient to establish time intervals for HIV screening, but suggested that annually could be “reasonable.” U.S. Preventive Health Services Task Force, Final Recommendation Statement Human Immunodeficiency Virus (HIV) Infection: Screening, <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/human-immunodeficiency-virus-hiv-infection-screening>.





*c. Prohibit unnecessary prior authorization requirements*

Persons in need of PrEP should be able to access this important preventive service without unnecessary or burdensome prior authorization requirements. Some health plans currently require HIV testing and counseling on safe sex practices and HIV infection risk reduction as a pre-requisite for PrEP and impose a three month authorization period.<sup>21</sup> For some persons at high risk for HIV infection, such as those who report inconsistent condom use, repeated safe sex counseling may be warranted. However, for a person in a sero-discordant relationship, safe sex counseling may be unwarranted and overly burdensome. The three-month authorization period and ongoing follow-up may also create a barrier for people experiencing IPV who need to use PrEP covertly. We urge the USPSTF to expressly proscribe plans from implementing onerous prior authorization requirements for PrEP.

*d. Recognize the intersecting threats of HIV and gender-based violence*

We appreciate the USPSTF's note "that the risk of acquisition of HIV infection lies on a continuum."<sup>22</sup> A successful HIV response must consider where and how HIV enters people's lives: at the intersection of poverty, gender-based violence, sexual and reproductive health, power dynamics in relationships, denial of bodily autonomy, and a fragmented healthcare system.<sup>23</sup> We believe this draft Recommendation Statement could benefit from explicit recognition of the intersecting threats of HIV and gender-based violence.

People who are abused or fear violence may not be comfortable asking their partner to use traditional prevention methods (e.g., a barrier method) during sex, or may not be comfortable saying no to sex if their partner refuses to use prevention. PrEP holds such considerable promise for risk reduction because it can be used covertly, without a partner's cooperation and independent of sexual activity. PrEP is also uniquely promising because it protects against HIV transmitted through both sexual contact and injection drug use. Violence, HIV, and substance use frequently co-occur, and when the co-occurring substance use involves injection drug use, people experiencing IPV may additionally be at risk of HIV through shared needles.

In September 2013, a working group convened by President Obama released a report of federal policy recommendations and action steps to address the intersection of HIV and

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<sup>21</sup> E.g., Letter from the National Coalition for LGBT Health, et al., to Stephen J. Hemsley, CEO United Healthcare and David S. Wichmann, President, United Healthcare (Aug. 4, 2017), <http://healthhiv.org/wp-content/uploads/2017/08/UHC-PrEP-Discriminatory-PA-Requirement-Sign-On-Letter-8-4.pdf>.

<sup>22</sup> U.S. Preventive Health Services Task Force, Draft Recommendation Statement Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis (Nov. 20, 2018).

<sup>23</sup> Positive Women's Network, *Bringing Gender Justice to HIV Prevention: A Blueprint for Women's Action* (July 2012), [https://pwnusa.files.wordpress.com/2013/12/pwn\\_policy\\_brief\\_blueprint\\_final.pdf](https://pwnusa.files.wordpress.com/2013/12/pwn_policy_brief_blueprint_final.pdf).



gender-based violence, including increased, concurrent screening for intimate partner violence and HIV.<sup>24</sup> We believe it is important to acknowledge that screening for PrEP takes place within this broader context.

The report also highlights opportunities for additional action by USPSTF, including evaluation and assessment of whether strategies that reduce risk for sexual and intimate partner violence are also effective at reducing risk for HIV; engaging men and boys to prevent violence and promote healthy relationships; focusing on structural factors that contribute to violence and HIV risk; and addressing how substance use and mental health issues may synergistically contribute to HIV risk and gender-based violence.<sup>25</sup>

## Conclusion

We strongly support the USPSTF draft recommendation to make PrEP an “A” recommended preventive service to help prevent the transmission of HIV. If you have further questions, please feel free to contact Staff Attorney Liz McCaman at [mccaman@healthlaw.org](mailto:mccaman@healthlaw.org); or Senior Attorney Wayne Turner at [turner@healthlaw.org](mailto:turner@healthlaw.org).

Thank you,

Elizabeth G. Taylor  
Executive Director

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<sup>24</sup> Addressing the Intersection of HIV/AIDS, Violence against Women and Girls, & Gender-Related Health Disparities: Interagency Federal Working Group Report (Sep. 2013), [https://files.hiv.gov/s3fs-public/vaw\\_master\\_report.pdf](https://files.hiv.gov/s3fs-public/vaw_master_report.pdf).

<sup>25</sup> Id.

