



December 20, 2024

*Submitted via the Regulations.gov Portal*

ATTN: 1210-AC25  
U.S. Department of Labor  
Employee Benefits Security Administration  
Office of Health Plan Standards and Compliance Assistance  
200 Constitution Ave NW  
Room N-5653  
Washington, DC 20210

**Re: Enhancing Coverage of Preventive Services Under the Affordable Care Act**

Dear Acting Secretary Su, Secretary Yellen, and Secretary Becerra:

We are writing on behalf of the Federal AIDS Policy Partnership – HIV Health Care Access Working Group (HHCAGW). HHCAGW is a coalition of national and community-based organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV- and hepatitis C-related health care and support services. Our organizations serve and work on behalf of people with serious, complex chronic illness who rely heavily on the patient protections in the Affordable Care Act (ACA) to ensure that they have access to the services and treatments needed to prevent disease, cure illness, and manage chronic health conditions.

As organizations committed to ending the national HIV epidemic, we support efforts to ensure and enhance coverage of preventive services under the ACA and applaud the proposed rule. Preventive services that are required to be covered under the ACA include HIV pre-exposure prophylaxis (PrEP) medication and ancillary care,<sup>1</sup> which can reduce the risk of acquiring HIV through sex by about 99%.<sup>2</sup> Increasing access to and use of PrEP is a key strategy of the “Ending the HIV Epidemic in the U.S.” campaign, an effort launched by the first Trump Administration.<sup>3</sup>

We therefore write to (1) express support for codifying prior guidance on medical exceptions requirements under the ACA preventive services rule and (2) urge the Departments to expand coverage of recommended preventive services without cost-sharing or prescription requirements to other over-the-counter (OTC) products, including services critical to accessing PrEP such as HIV and sexually transmitted infection (STI) self-tests.

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<sup>1</sup> *FAQs About Affordable Care Act Implementation Part 47*, CMS (July 19, 2021), <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/faqs-part-47.pdf>.

<sup>2</sup> *Let's Stop HIV Together*, CENTERS FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/stophivtogether/hiv-prevention/prep.html> (last visited Nov. 22, 2024).

<sup>3</sup> *EHE Overview*, HIV.GOV (Dec. 4, 2023), <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview#:~:text=The%20Ending%20the%20HIV%20Epidemic%20initiative%20focuses%20on%20four%20key,Treat%2C%20Prevent%2C%20and%20Respond.>

## **1. The Departments should codify prior guidance on reasonable medical management techniques for recommended preventive services.**

We support the proposed rule establishing that health plans and insurers must provide an “easily accessible, transparent and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider.” This will help ensure that individuals can access medically recommended preventive services at the “frequency, method, treatment, or setting determined to be medically necessary” for them by their provider without cost-sharing.

This rule would help address improper use of medical management that creates barriers to access for preventive services. As HIV advocates, we are well aware that despite clear guidance to the contrary, some insurers and plans have continued to impose burdensome medical management processes on PrEP medication and ancillary services.<sup>4</sup> A CDC study found that 20 to 30 percent of PrEP users with commercial insurance were charged for PrEP-related services in 2021 and 2022, even though plans were required to cover these services without cost-sharing at that time.<sup>5</sup> Moreover, some plans have improperly implemented step therapy requirements for PrEP, obliging patients to endure months of painful side effects before they can access a more suitable PrEP option—or worse, to “fail” on their PrEP regimen and acquire HIV, defeating the purpose of PrEP.<sup>6</sup> Other plans do not provide or publicize the availability of exceptions processes for PrEP regimens that a provider may deem medically necessary, such as off-label use of emtricitabine/tenofovir alafenamide in cisgender women.<sup>7</sup> Without clear guidance on the clinical criteria for zero-cost coverage of PrEP and ancillary services—including cases of medical necessity—patients do not know when they can and should appeal coverage denials. By explicitly requiring plans and insurers to clarify and streamline their exceptions processes, the Departments can reduce improper medical management techniques and improve uptake of preventive services.

## **2. The Departments should expand coverage of OTC preventive services without cost-sharing or prescription requirements to other recommended preventive services, including those associated with PrEP.**

We commend the Departments for expanding coverage of recommended OTC contraceptives without cost-sharing or prescription requirements. This will facilitate increased use of contraceptives by eliminating costs and reducing administrative and other barriers for individuals of reproductive age. For example, a large percentage of reproductive age females have expressed interest in using OTC contraceptives due to their convenience, faster access, and greater confidentiality as compared to prescription contraceptives.<sup>8</sup> As HIV advocacy organizations, we support efforts to improve access to

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<sup>4</sup> Jessica Bartlett, *Despite Federal Rules, HIV Prevention Drug Still Comes With Costs*, THE BOSTON GLOBE (Jan. 8, 2023), <https://www.bostonglobe.com/2023/01/08/metro/despite-federal-rules-hiv-prevention-drug-still-comes-with-costs>.

<sup>5</sup> Ya-Lin A. Huang et al., *Out-of-Pocket Payments for PrEP Ancillary Services Among US Commercially Insured Persons, 2017-2022*, CONFERENCE ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS, <https://www.croiconference.org/wp-content/uploads/sites/2/posters/2024/1117.pdf>

<sup>6</sup> *TAI Letter to Florida Office of Insurance Regulation*, THE AIDS INSTITUTE (Mar. 31, 2021), <https://www.theaidsinstitute.org/eliminating-hiv/tai-letter-to-fl-office-of-insurance-regulation-on-prep-compliance>.

<sup>7</sup> *Id.*; see also *Preventive Services Coverage and Cost-Sharing Protections Are Inconsistently and Inequitably Implemented*, NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS (Aug. 13, 2023).

<sup>8</sup> Michelle Long, Brittini Frederiksen, Usha Ranji, Karen Diep, and Alina Salganicoff, *Interest in Using Over-the-Counter Oral Contraceptive Pills: Findings from the 2022 KFF Women’s Health Survey*, KFF (Nov. 3, 2022), <https://www.kff.org/womens-health-policy/issue-brief/interest-using-over-the-counter-oral-contraceptive-pills-findings-2022-kff-womens-health-survey>.

products and services that help individuals maintain their bodily autonomy and sexual and reproductive health.

Moreover, as the next step in the Departments' proposed "incremental" approach to "expanding the scope of coverage without cost sharing for all recommended preventive services," we encourage the Departments to require coverage of other OTC preventive services, such as HIV and STI self-tests, without cost-sharing or prescription requirements. Access to HIV testing is important, because patients must stop taking PrEP immediately if they have acquired HIV. This is because PrEP alone is not an effective medication for HIV, and if a person with HIV takes PrEP alone it can lead to drug resistance. Periodic STI screenings—including HIV, hepatitis B, gonorrhea, syphilis, and chlamydia tests—are also critical ancillary care services for PrEP. Other STIs correlate strongly with high risk of HIV acquisition or are common co-infections; testing allows providers to intervene early with sexual risk-reduction counseling.<sup>9</sup> Although most patients taking PrEP are tested for HIV and other STIs in clinical settings, individuals accessing PrEP through telehealth may self-test, especially those who live in rural areas or are not able to access a healthcare provider in-person due to fear of HIV stigma.<sup>10</sup>

Patients taking PrEP face similar barriers as those using contraceptives and would likewise benefit from coverage of OTC services. Stigma surrounding PrEP use and limited access to medical care remain key barriers to PrEP uptake.<sup>11</sup> Coverage of OTC HIV and STI self-tests would simplify compliance with PrEP testing requirements by offering a more discreet, convenient, and accessible alternative to lab appointments. Given the benefit to consumers of being able to access coverage of both OTC contraceptives and PrEP ancillary services, we strongly urge the Departments to finalize the proposed rule and extend coverage of OTC preventive services to other products such as HIV and STI self-tests.

## **Conclusion**

Thank you for the opportunity to provide feedback and for your thoughtful consideration of these comments. If you have further questions, please reach out to HHCAWG co-chairs Liz Kaplan (ekaplan@law.harvard.edu) with the Center for Health Law and Policy Innovation; Rachel Klein (rklein@tmail.org) with The AIDS Institute; and Leslie McGorman (LMcGorman@aidsunited.org).

Respectfully submitted by the undersigned organizations:

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<sup>9</sup> *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States — 2021 Update*, CENTERS FOR DISEASE CONTROL AND PREVENTION 1, 31–32, 34 (2021), <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>.

<sup>10</sup> *Telehealth for HIV Care*, HEALTH RESOURCES AND SERVICES ADMINISTRATION, <https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-for-hiv-care/preventing-hiv-with-telehealth> (last visited Nov. 22, 2024).

<sup>11</sup> Kenneth H. Mayer, Allison Agwu, and David Malebranche, *Barriers to the Wider Use of Pre-Exposure Prophylaxis in the United States: A Narrative Review*, 37 *ADVANCES IN THERAPY*, 1778, 1781(2020).

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