

QUICK TAKE

ENSURING COMPLIANCE WITH NEW FEDERAL USPSTF PrEP GUIDANCE

PRE-EXPOSURE PROPHYLAXIS (PrEP) IS A CRITICAL COMPONENT OF COMPREHENSIVE HIV PREVENTION.

Achieving widespread and sustained use of PrEP by individuals for whom it is recommended is critical to preventing new HIV infections, providing both individual and public health benefits. As such, PrEP has the potential to protect communities from HIV infection and strengthen them with lifelong benefits. Delivering PrEP effectively, however, requires overcoming multiple obstacles, not the least of which is ensuring affordable and hassle-free access to PrEP medications and related care.

In 2019, following an evidence-based review, the United States Preventive Services Task Force (USPSTF) issued a [final recommendation](#) and gave daily oral PrEP its strongest rating, an A. Pursuant to the Affordable Care Act (ACA), most private health plans and all Medicaid-expansion programs must cover USPSTF grade A and B-recommended services free-of-charge for the plan year beginning one year after the issue date of the recommendation. State

REQUIRED PrEP SERVICES

Effective PrEP involves more than taking medication. Per federal guidance, most private plans and all Medicaid expansion plans **must provide the following care, without cost-sharing**, to insured persons. These standards reflect CDC clinical practice guidelines and help ensure safe and effective prescribing.

Office Visits: Office visits associated with each recommended preventive service when the primary purpose of the office visit is the delivery of the preventive service.

HIV Testing: Individuals must be tested to confirm that they are HIV negative before starting PrEP, and current guidelines call for repeat testing every 3 months while on PrEP.

Hepatitis B and C Testing: Individuals should be tested for Hepatitis B and C when initiating PrEP. Persons with an ongoing risk for Hepatitis C should be screened regularly.

Creatinine Testing and Calculated Estimated Creatine Clearance (eCrCl) or Glomerular Filtration Rate (eGFR): These tests of kidney function must be performed before starting PrEP and should be checked periodically.

Pregnancy Testing: Persons with childbearing potential must be tested before enrolling in PrEP and should be tested again periodically.

Sexually Transmitted Infection (STI) Screening and Counseling: All persons must be tested for STIs when starting PrEP and should be retested periodically. This includes testing for all symptomatic individuals. Sexually active adults and adolescents should be screened every six months. Asymptomatic gay and bisexual men at high risk for STIs should be screened every 3 months with 3-site specimen collection (i.e. pharyngeal, rectal, and genital/urine specimens).

Adherence Counseling: Individuals on PrEP must be offered regular behavioral counseling and adherence support.

CRITICAL COMPONENTS OF THE FEDERAL PrEP GUIDANCE

Coverage of PrEP-related ancillary services without cost-sharing

See text box above for details.

Frequency of services must follow CDC guidelines and no restrictions on restarting PrEP

Plans must cover, free-of-charge, baseline and monitoring services that includes HIV testing every three months and sexually transmitted infection (STI) screening consistent with CDC guidelines.

Plans cannot restrict individuals from continuing or re-starting PrEP as long as their own health care provider determines that PrEP is medically indicated.

Access to medically appropriate PrEP medication without cost sharing, as determined by the individual's health care provider

Reasonable medical management is permitted to give preference to a specific PrEP medication, such as by offering one product without cost-sharing and imposing cost-sharing for other products. Plans are required, however, to accommodate any individual for whom a particular PrEP medication (generic or brand name) would be medically inappropriate, *as determined by the individual's own health care provider*. This requires plans to have a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version.

Easy and timely exceptions process if plans limit PrEP services

If plans use medical management techniques to limit access to specific PrEP products or services, they must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual (or authorized representative) or provider. The FAQs provide the example of an exceptions process that allows for prescribing and accessing PrEP medications on the same day that an individual receives a negative HIV test and decides to start a PrEP regimen.

ACTIONS NEEDED TO SUPPORT COMPLIANCE AND ENFORCE THE LAW

PrEP USERS AND PROVIDERS

If patients or providers observe that a plan is not complying, they should bring the federal guidance to the attention of the plan or plan sponsor. In addition, they can contact the state and federal regulators indicated below.

Private-Employer Group Health/ERISA Plans: Persons with private employer group health plans can file a complaint with the Department of Labor Employee Benefits Security Administration (EBSA) at <https://www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa> or 1-866-444-EBSA (3272).

Non-ERISA Group Plans and Individual Plans: Persons with these kinds of plans (including persons with ACA marketplace plans) should contact their state insurance regulator. A directory is available from the National Association of Insurance Commissioners (NAIC) at <https://content.naic.org/state-insurance-departments>.

State and Local Government Employee Plans: In addition to state and local government oversight, HHS enforces federal requirements. Complaints can be emailed to NonFed@cms.hhs.gov.

Federal Government Employee Plans: The federal Office of Personnel Management (OPM) requires plans in the Federal Employees Health Benefits Program (FEHB) to provide ACA-required preventive services. Complaints can be made at 202.606.1800 or FEHB@opm.gov.

HEALTH DEPARTMENTS AND INSURANCE REGULATORS

State and local health departments and state and federal insurance regulators should develop compliance tools, conduct audits, and monitor activities to ensure plan compliance with federal rules. As regulators may be less familiar with the complexities of HIV prevention and clinical practices in PrEP services delivery, HIV experts in health departments can be an important resource for regulators in ensuring compliance with these requirements.

Audits, assessments, and enforcement actions should be released to the public, including any enforcement actions taken.

FEDERAL AGENCIES

The Centers for Medicare and Medicaid Services (CMS) should issue a State Health Officials Letter describing the critical importance of PrEP, available federal resources, and describing compliance obligations of Medicaid programs and ACA marketplace health plans.

The FAQs rely heavily on Centers for Disease Control and Prevention (CDC) clinical practice guidelines. CDC should write to all health plans describing their clinical practice guidelines and how to use them to comply with federal requirements. This could help to greatly increase the public health impact of PrEP.

Medicaid programs also can extend this coverage to all non-expansion Medicaid beneficiaries. Fifteen states and the District of Columbia currently do (NASTAD, July 2021). This recommendation does not apply to a small set of private “grandfathered plans.” While the recommendation also does not apply to Medicare, most Medicare plans cover PrEP, but with applicable cost sharing.

In July 2021, the US Departments of Health and Human Services (HHS), Labor, and Treasury jointly issued [frequently asked questions \(FAQs\)](#) to clarify coverage obligations without cost sharing for PrEP medications and services. Enforcement actions may be taken by state and federal regulators starting on September 17, 2021 to ensure compliance with these requirements.

WHILE THESE FAQs PROVIDE HELPFUL CLARIFICATION, THEY ARE ONLY MEANINGFUL TO THE EXTENT THAT HEALTH PLANS UNDERSTAND AND COMPLY WITH THEM. Individuals, PrEP providers and care teams, health departments, insurance regulators, advocacy groups, and others must take action to support compliance with these requirements. Improving the health of communities and preventing new HIV infections is a large and complex undertaking. Enforcement of this clarifying guidance will benefit individuals by helping to address barriers to PrEP uptake and will move us closer to ending the HIV epidemic in the United States.

TO LEARN MORE

The new guidance, *FAQs About Affordable Care Act Implementation Part 47*, was released on July 19, 2021. It can be accessed at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf> and at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf>.

The USPSTF’s Final Recommendation Statement for PrEP is available at <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

For clinical practice guidelines, see the US Public Health Service/CDC Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update, available at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>. NOTE: CDC is updating its guidelines. New guidelines are anticipated to be published before the end of 2021.

For additional background information, please read our Quick Take, *The USPSTF PrEP Recommendation, March 2020*, and our Big Ideas Brief, *Achieving Sufficient Scale of PrEP Use is Critical to Ending the HIV Epidemic*, August 2019, at the link below.