



Patient Advocacy Toolkit: Enforcement of USPSTF Patient Protections

Ensure Plans Comply with USPSTF Patient Protections for HIV Prevention Drugs

In 2019, the U.S. Preventive Services Task Force (USPSTF) gave the Pre-exposure Prophylaxis (PrEP) for HIV prevention an “A” grade, recommending that clinicians offer the drug to individuals at high-risk of infection.

The USPSTF determination was crucial, because the Affordable Care Act (ACA) requires all non-grandfathered private health insurance plans and Medicaid expansion plans to provide coverage for USPSTF “A” (or “B”) graded recommendations with no cost-sharing to patients.

Simply put, plans must now cover PrEP – and its associated services – at no out-of-pocket cost to patients. Insurers must comply with the new federal PrEP coverage mandate, or they risk penalties under the ACA.

There is a critical need to raise awareness amongst patients and providers to challenge issues of non-compliance with their plans and engage with federal and state regulators to ensure proper enforcement of patient protections for HIV prevention drugs and services.

Please consider customizing, distributing, and sharing the following resources with your professional and personal networks and with partners to urge individual state insurance commissioners to adequately enforce patient protections for HIV prevention drugs and services.

Patient Resources: Enforcement of USPSTF Patient Protections

Click to view individual resources below.

- **BACKGROUND:** [Consumer Challenges of Non-Compliance & Sample Letter](#)
- **CONSUMER PORTAL:** [How to File Coverage Complaints in Your State](#)
- **SOCIAL MEDIA:** [Urge State Insurance Commissioners to Enforce Patient Protections](#)
- **GRAPHICS:** [Urge State Insurance Commissioners to Enforce Patient Protections](#)
- **STATE ACTIVITY:** [Insurance Bulletins to Support USPSTF PrEP Coverage Guidelines](#)
- **APPENDIX:** [Key Educational Resources on PrEP Coverage Requirements](#)

**PRIVATE PLANS MUST COVER PREP DRUGS
& ASSOCIATED SERVICES FOR FREE.**





BACKGROUND: Consumer Challenges of Non-Compliance & Sample Letter

What Consumers Need to Know About PrEP Coverage Compliance

Coverage of PrEP Services

- PrEP-related ancillary tests and services must be covered with no cost-sharing to patients.

Patient-Provider Choice

- Patients must have access with no-cost sharing to the PrEP medication that is medically appropriate for them, as determined by the individual's health care provider.

Continued Access Protections

- Plans cannot restrict the number of times a patient may start PrEP or the frequency of services.

Provide Easy Exceptions Process

- Plans must have an easily accessible, transparent, and sufficiently expedient exceptions process for individuals to access the PrEP medication that is medically appropriate for them.

Sample Letter: Letter Challenging Issues of Non-compliance with Insurer

Dear _____,

We are writing to ensure [ENTITY] will not charge patients for PrEP or its related services under an existing federal coverage mandate. If [ENTITY] does not comply, they risk facing penalties under the Affordable Care Act. The coverage requirements for PrEP are based on existing guidance from the U.S. Departments of Labor, Health and Human Services, and Treasury.

Federal guidance clarifies the coverage requirements for PrEP for patients at high-risk of acquiring HIV based on its grade "A" recommendation by the United States Preventive Services Task Force (USPSTF). Under the federal guidance, PrEP-related treatment and services, such as screening tests for HIV and sexually transmitted infections, must be covered at no-out-of-pocket cost to patients.

Patients must have free access to the PrEP medication that is medically appropriate for them, as determined by their provider.

Additionally, plans must provide an easily accessible, transparent, and expedient exemptions process in the face of utilization management barriers that limited patient access to PrEP, such as step therapy. The number of times an individual may start PrEP or the frequency of services, such as HIV and STI screenings must also not be limited.

Compliance with this mandate ensures that at-risk individuals are able to access the care they need to help prevent the spread of HIV and help reach the ultimate goal of HIV elimination.

Sincerely,





CONSUMER PORTAL: How to File Coverage Complaints in Your State

[What Should Consumers Do If a Health Plan Is Not Complying with The Federal Guidelines?](#)

Enforcement of the federally mandated guidance for private insurers to cover PrEP with no-cost sharing depends on the type of plan involved. If patients or providers observe that a plan is not complying with the guidance, they should bring the federal guidance to the attention of the health plan or plan sponsor. Additionally, patients and their providers can contact federal and state regulators to file a coverage complaint. When contacting regulators, it is important that patients provide plan documents, drug formularies, and other documentation regarding the coverage that is offered (or denied) by the plan.

In four states (Missouri, Oklahoma, Texas, Wyoming), HHS is directly responsible for enforcing Affordable Care Act health insurance rules, including the requirement to cover PrEP. Complaints about health insurance coverage in those states should be sent to MarketConduct@cms.hhs.gov.

[Consumer Portal: How to File Coverage Complaints in Your State](#)

Click to view state-by-state consumer complaint portals and resources.

STATE	STATE-LEVEL DOI CONSUMER COMPLAINT RESOURCES
ALABAMA	Alabama Department of Insurance
ALASKA	Department of Commerce, Community, and Economic Development
ARIZONA	Department of Insurance and Financial Institutions
ARKANSAS	Arkansas Insurance Department
CALIFORNIA	California Department of Insurance/Department of Managed Health Care
COLORADO	Colorado Department of Regulatory Agencies
CONNECTICUT	Connecticut Insurance Department
DELAWARE	Delaware Department of Insurance
FLORIDA	Florida Department of Financial Services
GEORGIA	Office of Commissioner of Insurance and Safety Fire
HAWAII	State of Hawaii Department of Commerce and Consumer Affairs
IDAHO	Idaho Department of Insurance
ILLINOIS	Illinois Department of Insurance
INDIANA	Indiana Department of Insurance
IOWA	Iowa Insurance Division
KANSAS	Kansas Insurance Department



KNOW YOUR RIGHTS:

Patient Coverage of PrEP with No Cost-Sharing



KENTUCKY	Kentucky Public Protection Cabinet
LOUISIANA	Louisiana Department of Insurance
MAINE	Maine Bureau of Insurance
MARYLAND	Maryland Insurance Administration
MASSACHUSETTS	Massachusetts Division of Insurance
MICHIGAN	Michigan Department of Insurance and Financial Services
MINNESOTA	Minnesota Department of Commerce
MISSISSIPPI	Mississippi Insurance Department
MISSOURI*	Missouri Department of Insurance
MONTANA	Montana Commissioner of Securities and Insurance
NEBRASKA	Nebraska Department of Insurance
NEVADA	Nevada Division of Insurance
NEW HAMPSHIRE	The State of New Hampshire Insurance Department
NEW JERSEY	State of New Jersey Department of Banking & Insurance
NEW MEXICO	New Mexico Office of Superintendent of Insurance
NEW YORK	New York State Department of Financial Services
NORTH CAROLINA	North Carolina Department of Insurance
NORTH DAKOTA	North Dakota Insurance Department
OHIO	Ohio Department of Insurance
OKLAHOMA*	Oklahoma Insurance Department
OREGON	Oregon Division of Financial Regulation
PENNSYLVANIA	Pennsylvania Insurance Department
RHODE ISLAND	State of Rhode Island Department of Business Regulation
SOUTH CAROLINA	South Carolina Department of Insurance Office of Consumer Services
SOUTH DAKOTA	South Dakota Department of Labor & Regulation
TENNESSEE	Tennessee Department of Commerce and Insurance
TEXAS*	Texas Department of Insurance
UTAH	Utah Insurance Department
VERMONT	State of Vermont Department of Financial Regulation

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KNOW YOUR RIGHTS:

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VIRGINIA	Commonwealth of Virginia State Corporation Commission
WASHINGTON	Office of Insurance Commissioner Washington State
WEST VIRGINIA	West Virginia Offices of The Insurance Commissioner
WISCONSIN	Wisconsin Office of the Commissioner of Insurance
WYOMING*	Wyoming Department of Insurance
DISTRICT OF COLUMBIA	DC Department of Insurance Securities and Banking
PUERTO RICO	Office of The Commissioner of Insurance of Puerto Rico
U.S. VIRGIN ISLANDS	U.S. Virgin Islands Division of Banking, Insurance & Financial Regulation

****Indicates states that must also direct complaints about health insurance coverage to MarketConduct@cms.hhs.gov***

[Example Comments for Complaint Form](#)

Details Of Complaint:

- My insurer is charging for PrEP and tests related to its services. They continue to limit my access to treatment that I need to prevent the transmission of HIV, even though the federal government mandated that these services need to be free. I have provided documents as proof of my insurer's actions.
- I began the process of taking PrEP but a short time later discontinued use. I then decided to restart the process, but my insurer has told me I am not able to restart again because I decided to pause taking PrEP. According to the federal government, insurance plans can't restrict the number of times I start and stop taking PrEP.

What do you consider to be a fair solution?

- I would like to receive the PrEP treatment as determined by my health care provider for free. My insurer should face penalties for not following the federal guidelines and recommendations by the United States Preventive Services Task Force.
- I want to be reassured that if I make lifestyle changes, I will be able to restart PrEP if necessary or access the services related to PrEP including HIV screening. I would like my insurer to face penalty, so no other beneficiary feels as if they are restricted to a certain number of times, they can start PrEP.

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SOCIAL MEDIA: Urge State Insurance Commissioners to Enforce Patient Protections

NOTE: Posts are customized for Twitter character limits.

For Patient Advocates

- **CLICK TO TWEET:** “If federal and state regulators don’t hold plans accountable for covering #PrEP, people at risk of HIV will continue to face unnecessary financial and coverage barriers.” Read more from @HIVHep’s Carl Schmid in @statnews <https://bit.ly/prepcoverage> **[IMAGE: See Options Below]**
- **CLICK TO TWEET:** “Lack of timely enforcement and penalties puts people at risk of contracting and spreading #HIV.” Read more from @HIVHep’s Carl Schmid in @statnews on the need for enforcement of #PrEP coverage guidelines <https://bit.ly/prepcoverage> **[IMAGE: See Options Below]**
- **CLICK TO TWEET:** PrEP has the potential to protect communities from HIV infection. It is crucial that patients know their rights to receive #PrEP for free. Read more on the impact of insurer compliance with federal guidance: <https://bit.ly/PrEPCompliance> **[IMAGE: See Options Below]**

For Consumers

- Act now! Call on **[INSERT STATE]** to enforce coverage protections for HIV prevention treatments for patients. Ensure health plans are meeting their legal requirement under the ACA to cover #PrEP – and its associated services for free. Learn more: <https://bit.ly/USPSTFFAQs> **[IMAGE: See Options Below]**
- In all states, patients can file complaints when health plans don’t provide coverage for #PrEP at no cost. Take action NOW to hold non-compliant insurers accountable. Tell **[INSERT STATE]** to enforce coverage protections for HIV prevention. Read more: <https://bit.ly/covenforcement> **[IMAGE: See Options Below]**
- Know Your Rights! Ensuring compliance with new federal USPSTF #PrEP guidance allows patients in **[INSERT STATE]** who have run into roadblocks to receive the proper care they need to help stop the spread of #HIV. Read FAQs here: <https://bit.ly/USPSTFFAQs> **[IMAGE: See Options Below]**

For State Authorities

- **CLICK TO TWEET:** Private insurers must now comply with the new federal #PrEP coverage mandate, or they risk penalties under the #ACA. Learn more: <https://bit.ly/PrEPguide> **[IMAGE: See Options Below]**
- **CLICK TO TWEET:** There must be a unified effort to make sure health plans are abiding by the federally mandated #PrEP coverage requirements. State insurance commissioners must continue to remind insurers what they are legally required to do. Learn more: <https://bit.ly/USPSTFFAQs> **[IMAGE: See Options Below]**



KNOW YOUR RIGHTS:

Patient Coverage of PrEP with No Cost-Sharing



GRAPHICS: Urge State Insurance Commissioners to Enforce Patient Protections

NOTE: Right click and select "Save as picture" to save locally to your computer.

Across all 50 states, patients have the ability to file complaints when health plans don't provide coverage for PrEP at no cost.

State Insurance Commissioners Must Enforce Patient Protections for HIV Prevention Drugs & Services

Private insurers and Medicaid expansion plans must now comply with the new federal PrEP coverage mandate, or they risk penalties under the ACA.

State Insurance Commissioners Must Enforce Patient Protections for HIV Prevention Drugs & Services

Private insurers and Medicaid expansion plans must now cover PrEP – and its associated services – at no out-of-pocket cost to patients.


State Insurance Commissioners Must Enforce Patient Protections for HIV Prevention Drugs & Services

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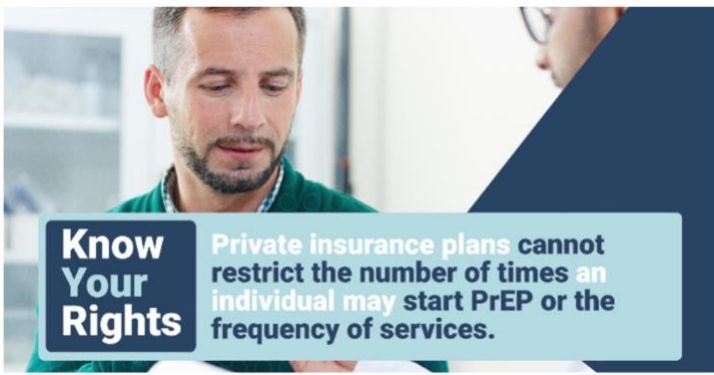


KNOW YOUR RIGHTS:

Patient Coverage of PrEP with No Cost-Sharing



Know Your Rights All non-grandfathered private plans and Medicaid expansion plans must provide coverage for PrEP with no cost-sharing to patients.



Know Your Rights Private insurance plans cannot restrict the number of times an individual may start PrEP or the frequency of services.

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STATE ACTIVITY: Insurance Bulletins Raise Awareness of PrEP Coverage Guidelines

It is critical that federal and state regulators hold non-compliant insurers accountable for not abiding by the legal requirements under the Affordable Care Act (ACA) to offer PrEP and its services to patients for free. Several states have released bulletins to all health insurers reminding them of their legal obligation.

CALIFORNIA	<p><u>Letter by Insurance Commissioner Ricardo Lara</u> <i>June 10, 2020</i></p> <p><i>“Insurers are encouraged to uniformly implement coverage of the PrEP recommendation for all insured by June 11, 2020, rather than on a rolling basis at renewal.”</i></p> <p><u>Letter by Department of Managed Health Care</u> <i>July 8, 2020</i></p> <p><i>“On June 11, 2019, the USPSTF recommended that clinicians offer PrEP to persons who are at high risk of contracting HIV and issued a Grade “A” rating. As a result, all plans must cover preventive health services for HIV PrEP to any individual who is determined to be at high risk of contracting HIV by the attending health care provider and must do so without cost sharing.”</i></p>
COLORADO	<p><u>Policy Directives for Coverage of HIV Prevention Ancillary Services</u> <i>December 2020</i></p> <p><i>“Ensuring that people who may benefit from PrEP are able to access and afford testing and related services is vital.”</i></p>
ILLINOIS	<p><u>Notice Regarding Implementation of the Affordable Care Act Part 47</u> <i>July 29, 2021</i></p> <p><i>“On July 19, 2021, the U.S. Departments of Health and Human Services, Labor, and the Treasury jointly released Part 47 of their FAQs on the implementation of the Affordable Care Act (ACA), which pertains to the coverage of services integral to pre-exposure prophylaxis (PrEP) as a preventive health service not subject to cost-sharing.”</i></p>



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MASSACHUSETTS	<p><u>HIV PrEP Preventive Health Service Bulletin</u> September 7, 2021</p> <p><i>“The Division expects that Carriers are in compliance with federal guidance regarding preventive health services and bring health plans into compliance with the required coverage and cost-sharing requirements as set forth in the federal clarifying guidance by no later than 60 days from the date of the July 19, 2021, clarifying federal guidance.”</i></p>
NEW YORK	<p><u>Letter by State Health Bureau Chief Lisette Johnson</u> October 8, 2020</p> <p><i>“Ensuring that people who may benefit from PrEP are able to access and afford testing and related services is vital, and the Department of Financial Services will continue to ensure full compliance with this circular letter, Insurance Circular Letter No. 21 (2017), and Supplement No.1 to Insurance Circular Letter No. 21 (2019).”</i></p>

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APPENDIX: Key Educational Resources on PrEP Coverage Requirements

Federal Guidance

- Centers for Medicare and Medicaid Services: [FAQS About Affordable Care Act Implementation Part 47](#)
- O'Neill Institute for National & Global Health Law: [Ensuring Compliance With New Federal USPSTF PrEP Guidance](#)

Media

- STAT: [Hold insurers accountable for covering HIV prevention drugs at no cost to patients](#)
September 2, 2021

Additional Resources

- HIV+ HEP Policy Institute: [Federal Government Issues Guidance to Insurers on Coverage of HIV Prevention Drugs](#)
- NASTAD: [PrEP Services Covered with No Cost Sharing](#)
- Educational Handout: Know Your Rights: Patient Coverage of PrEP with No Cost-Sharing

