



Policy Updates

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Presentation Outline

- President's Budget Proposal
- Congressional Proposals and Action
- U.S. Preventive Services Task Force
- *Braidwood Management, Inc. v. Becerra*



President's Budget Proposal



PrEP in the President's FY2023 Budget

- Called for a national PrEP program
- \$9.8 billion in mandatory funding over 10 years
- “Provide essential wraparound services through States, IHS and tribal entities, and localities”
- “Establish a network of community providers to reach underserved areas and populations.”
- Also called for expanded access to PrEP under Medicaid
 - Ensure coverage the drug and associated services without cost sharing
 - Remove “utilization management practices that may limit access”



Congressional Proposals



PrEP Access and Coverage Act

History

- Introduced in 116th Congress by then Sen. Kamala Harris (S. 1926)
- House companion introduced by Rep. Schiff, 13 original co-sponsors (H.R. 3815)

Current status

- Sen. Tina Smith introduced bill, but may update

Summary

- Requires private insurance, Medicaid, Medicare, CHIP, VA, DoD, IHS to cover PrEP and ancillary services without cost-sharing
- Prohibits prior authorization for PrEP services
- Prohibits denial or limiting life insurance benefits, disability insurance, long-term care insurance for PrEP users
- Creates public and provider education campaigns for PrEP
- Creates a grant program through HHS for states, territories, Tribes and “eligible entities” to establish and support PrEP and PEP programs
 - Authorized at \$60 m for the first five fiscal years



PrEP Assistance Program Act

History

- Introduced in 116th Congress by Rep. Bonnie Watson-Coleman (H.R. 1643)
- No Senate companion was introduced

Summary

- Creates a grant program through HHS to state, local and Tribal governments, FQHCs, rural health clinics, and community-based organizations to establish and support PrEP programs
- Grant funds can be used for:
 - Clinic and lab fees
 - Office visits
 - PrEP medications
 - Blood testing
 - STI testing
 - Adherence counseling
 - Outreach activities for health professionals and physicians
- Grantees must match 10% of grant amount, unless waived
- Authorized at \$400 m each fiscal year for five years
- Individual grants may not exceed \$5 m



Ryan White PrEP Availability Act

- Introduced by Sens. Rick Scott (FL) and Ben Ray Lujan (NM)
- Allows for use of Ryan White Program program income for PrEP



Congressional FY2023 PrEP Funding Request

- **Included Language:** *Access to PrEP—The Committee notes the importance of expanding HIV pre-exposure prophylaxis (PrEP) nationally to improve access to medications and essential support services, community and provider outreach, to make progress towards ending the HIV epidemic.*
- **Requested Language:** *Access to PrEP—In support of the vision of ending the HIV epidemic, the Committee includes an increase of \$30 million to the Centers for Disease Control and Prevention (CDC) Division of HIV Prevention to increase equitable access to pre-exposure prophylaxis (PrEP) nationwide. Additionally, the Division should use existing funding to increase access to PrEP. The committee is concerned that only 25% of people who could benefit from PrEP, an effective HIV prevention medication, received a prescription in 2020, with only 9.7% of women, 9% of Black and 16% of Hispanic/Latino people in need of PrEP having access compared to 66% of their White counterparts. This funding should support planning and launching a national program to increase access to PrEP medications; laboratory services; essential support and wrap around services, such as case management, counseling, linkage, and adherence services; robust PrEP outreach and education activities; and PrEP provider capacity expansion. The Committee further directs CDC to examine and remove limitations on grantees' abilities to use HIV prevention grants and cooperative agreements on PrEP medications, laboratory services, and clinic visits for people who are uninsured or underinsured. CDC shall submit a report to the Committee within 180 days of enactment of final FY23 appropriations on the status of a national PrEP initiative.*



U.S. Preventive Services Task Force



USPSTF

- In January 2022, the U.S. Preventive Services Task Force (USPSTF) published its final research plan on PrEP
 - *Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis*
- The research plan will look at new PrEP modalities, including long acting injectables
- The final research plan is the third step in a five-step process that the task force follows when developing all recommendations



*Braidwood Management, Inc.
v. Becerra*



Why was the suit filed?

- Plaintiffs (complaining parties):
 - 6 individuals and 2 businesses
 - Purchasers of health care insurance
- Plaintiffs are contesting the legality of the Affordable Care Act's mandatory coverage of preventative health care services – specifically PrEP



What are the key issues?

1. Plaintiffs argue that the U.S. Preventive Services Task Force (“USPSTF”) violates the Appointments Clause.
2. Plaintiffs argue that mandatory coverage of PrEP violates the Religious Freedom Restoration Act (RFRA).



First Key Issue – Background

USPSTF:

- Independent, volunteer panel of experts in disease prevention and evidence-based medicine
- Makes health care recommendations, which are either issued as “A” or “B” Recommendations classed as “A” have the legal effect of requiring health insurance plans to cover that drug. The USPSTF has issued PrEP as an “A” recommendation.

Appointments Clause:

- Constitutional provision that lays out the appointment process for “Officers of the United States”
- Requires Principal Officer to be nominated by the President and confirmed by the Senate



Second Key Issue – Background

RFRA

- Federal law that prohibits government from substantially burdening a person’s exercise of religion
- Exception: A compelling state interest outweighs the religious “burden”



What are the key holdings?

1. USPSTF violates Appointments Clause

- Reasoning: Members of the USPSTF are Principal Officers that were unconstitutionally appointed as they were not nominated by the President and confirmed by the Senate.

2. PrEP mandate violates RFRA

- Reasoning: Provision of PrEP substantially burdens Plaintiffs' Christian beliefs, and Defendants did not "show a compelling interest in forcing private, religious corporations to cover PrEP drugs with no cost-sharing and no religious exemptions."



What is the impact of this case?

- Court has yet to give a remedy
- Limited jurisdictional authority
 - Northern District of Texas currently has federal jurisdiction (depicted by brown in Figure 1)
 - Case was heard by the Fort Worth Division within the Northern District (depicted by orange in Figure 2)

Figure 1

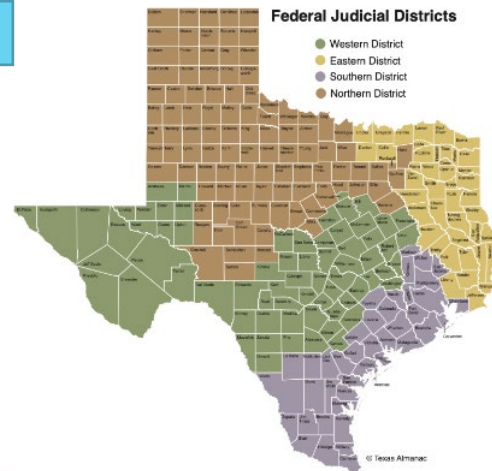


Figure 2



What is the impact of this case?

- For now, the actual legal impact of this case is extremely limited.
- Highly likely to be appealed
- Holdings of this case are currently not mandatory law for the general public in any jurisdiction, including Fort Worth





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