CENTER *for* HEALTH LAW *and* POLICY INNOVATION
HARVARD LAW SCHOOL

Braidwood Management v. Becerra: Frequently Asked Questions for Health Care Advocates and Providers

The FAQs below are intended to help health care advocates, providers, and individuals understand key issues at stake in *Braidwood Management v. Becerra*, a case in which the plaintiffs seek to undermine a critical portion of the Affordable Care Act (ACA). This part of the ACA is intended to guarantee the accessibility and affordability of certain preventive services. Since this is active litigation and legal analysis is ongoing, these FAQs will be updated periodically to reflect new developments (last updated July 12, 2024).

Contents

1. **What is the ACA's preventive services mandate and who does it cover?**

The Affordable Care Act (ACA) requires most private health insurance plans and all Medicaid expansion programs to cover certain preventive services without cost sharing (meaning plan members do not need to pay a copay or coinsurance amount to receive these services). The specific services that must be covered without cost sharing are defined in formal recommendations or guidelines from government and independent bodies based on clinical evidence. These guidelines and recommendations cover four categories:

- **Services recommended by the U.S. Preventive Services Task Force (USPSTF):** The USPSTF is an independent group of experts in prevention, evidence-based medicine, and primary care. The USPSTF reviews the evidence in support of preventive services and, through a transparent process with opportunity for public comment, issues grades that indicate the degree to which the service provides a net benefit to patients. Preventive services with a USPSTF Grade A or B must be covered without cost sharing.
- **Services recommended by the Advisory Committee for Immunization Practices (ACIP) and adopted by the CDC**: ACIP is composed of subject matter experts and one consumer representative and makes recommendations to the Director of the Centers for Disease Control and Prevention (CDC) regarding vaccination to control the spread of diseases within the U.S. ACIP-recommended services adopted by the CDC must be covered without cost sharing.
- **Additional women's preventive health services recommended by the Health Resources and Services Administration (HRSA):** Through the Women's Preventive Services Initiative, HRSA convenes a body of experts to make evidence-based recommendations for preventive services for women that are not already covered by the USPSTF recommendations. Services recommended by HRSA must be covered without cost sharing.
- **Preventive services for children and youth recommended by HRSA:** HRSA also runs the Bright Futures Program, which makes evidence-based recommendations regarding preventive services for infants, children, and adolescents. These services must also be covered without cost sharing.

2. **What are the arguments in *Braidwood Management v. Becerra*, and what did the federal district court decide?**

In 2020, a Christian-owned business called Braidwood Management, Inc. (Braidwood) filed a lawsuit in a Texas federal court seeking to prevent the federal government from enforcing the ACA preventive services requirements. Braidwood is self-insured and provides health insurance to its employees. Braidwood, along with other plaintiffs, argued that the ACA preventive services requirements are unconstitutional for several reasons, including because they violate the Appointments Clause of the U.S. Constitution by empowering people who are not properly appointed government officials to make rules regarding services that must be covered. Braidwood also argued that the ACA's requirement to cover pre-exposure prophylaxis (PrEP) – a

medication that prevents acquisition of HIV and that has a Grade A from the USPSTF – without cost sharing violates Braidwood's religious freedom under the Religious Freedom and Restoration Act (RFRA).

In September 2022, Judge Reed O'Connor ruled that the requirement to cover PrEP in contravention of Braidwood's owner's religious beliefs violated Braidwood's rights under RFRA. Judge O'Connor also ruled that the requirement that plans cover USPSTF Grade A or B recommended services without cost sharing was unconstitutional. The judge agreed with Braidwood's argument that Congress improperly delegated authority to issue coverage mandates to a body whose members were not appointed consistent with the Appointments Clause. Judge O'Connor, however, upheld the ACA's coverage and cost sharing requirements with regard to the ACIP- and HRSA-recommended services, since the CDC Director and HRSA Administrator—two officials who answer to the Secretary of Health and Human Services (HHS)—must sign off on those services before they become mandates. Judge O'Connor also rejected other constitutional arguments the plaintiffs had raised, including a different constitutional attack on the ACA's preventive services mandate arising from the way that Congress grants power to administrative agencies.

On March 30, 2023, Judge O'Connor issued an order vacating any federal agency action that has occurred since the ACA's passage to implement the USPSTF-related part of the preventive services mandate. This order, had it gone into effect, would have forbidden the federal government from enforcing no-cost coverage of USPSTF recommendations published since March 23, 2010. However, private health plans and Medicaid expansion programs would have still been required to cover preventive services with pre-existing USPSTF recommendations. This ruling could have impacted coverage of a wide range of preventive services across the United States, caused widespread uncertainty, accelerated health disparities, and degraded public health efforts.

In addition, Judge O'Connor ruled that Braidwood and some of the other plaintiffs in the case need not comply with the mandate to cover PrEP based on their claim under RFRA that coverage of PrEP runs counter to their religious beliefs. This order was limited to certain parties in the *Braidwood* lawsuit, and the federal government chose not to appeal it. Because it is a district court decision, and not a decision by an appellate court, other courts are not required to follow it. However, it established legal authority that other plaintiffs will likely point to as justification for why they should also be allowed to discriminate in this way.

3. Appeal to the Fifth Circuit: What did the Fifth Circuit decide?

The federal government appealed the district court's Appointments Clause ruling to the United States Court of Appeals for the Fifth Circuit. Braidwood and its allies also filed a cross-appeal, indicating that they planned to ask the higher court to issue even broader judgments than they had already received. On June 13, 2023, the Fifth Circuit issued a stay of enforcement of the district court's ruling while the Fifth Circuit considered the case. This meant that preventive care recommended by USPSTF remained covered without cost sharing by most private insurers

as required by the ACA preventive care mandate throughout the appeal.

On June 21, 2024, the Fifth Circuit ruled on the appeal, describing its own decision as a "mixed bag." The Fifth Circuit agreed with Judge O'Connor that the USPSTF's role in determining which services must be covered under the ACA preventive care mandate is unconstitutional under the Appointments Clause because of the limited authority that the Secretary of Health and Human Services (HHS) may exert over USPSTF and because USPSTF members are not appointed by the President and confirmed by the Senate. But the Fifth Circuit stopped short affirming Judge O'Connor's nationwide injunction, which would have made USPSTF's recommendations unenforceable under the preventive care mandate. Instead, the court cabined the remedy to the plaintiffs in the case and their employees. This outcome was due to a procedural error committed by the plaintiffs, who had not brought timely claims under the federal Administrative Procedure Act (APA). If they had, the Fifth Circuit indicated that it would have found a basis for a nationwide injunction.

The Fifth Circuit also held that, unlike USPSTF, the Secretary of HHS has sufficient authority over ACIP and HRSA that he may, at least in theory, cure any Appointments Clause defect with respect to those agencies by ratifying their recommendations. However, the Fifth Circuit remanded (meaning it sent back) the case to the district court to consider arguments that the parties had not yet briefed as to whether the Secretary has legally ratified ACIP's and HRSA's existing recommendations.

The end result of the Fifth Circuit's ruling is that, for the time being, all preventive services recommended by USPSTF, ACIP, and HRSA must still be covered without cost sharing for most people with private insurance. However, it is important for patients, providers, and health care access advocates to remain vigilant about this case. The Fifth Circuit punted the case back the federal district court in Texas with a roadmap that lays out how these or similar plaintiffs could successfully seek a nationwide injunction against the ACA preventive care mandate as it applies to USPSTF-recommended services, and potentially to ACIP- and HRSA-recommended services as well. Given this decision, it is likely only a matter of time until the Fifth Circuit will have another opportunity to undermine the ACA preventive services mandate.

4. What will happen next?

Given that the Fifth Circuit limited its order on remedy to the current plaintiffs, and that there is no nationwide injunction currently at stake, the federal government is unlikely to appeal the Fifth Circuit's decision. However, the plaintiffs may decide to try to seek review by the U.S. Supreme Court of the parts of the case on which they lost. Alternatively, they may return to the district court to litigate the issues for which the Fifth Circuit ordered a remand. They may also try to amend their complaint before the district court to raise the APA claim that the Fifth Circuit said they should have raised before.

Even if they do not seek to amend their complaint, or even attempt to continue the litigation at all, they are represented by a well-known conservative attorney who will likely find other

plaintiffs interested in continuing the litigation and pursuing a nationwide injunction that undermines the ACA preventive care mandate.

Consumers who have been denied continued coverage of preventive services to which they believe they are entitled should review FAQ 7 below.

5. What preventive services could still be impacted by this lawsuit?

As discussed above, the Fifth Circuit's decision laid out a roadmap as to how other plaintiffs could bring a case that would lead to an injunction against enforcement of the mandate as to recommendations from USPSTF, and possibly ACIP and HRSA as well. If that occurs, the ruling would eliminate the federal government's ability to require private insurance companies to cover without cost sharing all services that have received a Grade A or B from USPSTF or have been recommended by either HRSA or ACIP since March 23, 2010.

Removing the mandate to cover all recommended preventive services that have been added since March 23, 2010, could ultimately have a big impact. These services include a range of important interventions with extensive clinical evidence indicating safety and efficacy. The following are some examples:

Examples of services with USPSTF Grade A or B since March 23, 2010
Lung cancer screening
Hepatitis C screenings
HIV pre-exposure prophylaxis (PrEP)
HIV screenings
Drugs that reduce the risk of breast cancer
Statins for individuals at risk for cardiovascular disease
Flouride varnish for children provided in primary care offices
Examples of vaccines recommended by ACIP since March 23, 2010
COVID-19
Haemophilus Influenza Type b (HiB)
Human Papillomavirus (HPV)
Examples of services recommended by HRSA since March 23, 2010
Screening for Diabetes during pregnancy
Screening for Diabetes after pregnancy
Screening for urinary incontinence

The complete list of USPSTF published recommendations is available here, HRSA's recommendations are here, and ACIP's are here. Note that for many services, even if the agency issued a recommendation for the service prior to March 23, 2010, the recommendation may have been updated to clarify specific aspects (such as to whom the service should be provided, how often, etc.) based on the most up-to-date medical evidence. Also, some services covered under the USPSTF recommendations, such as HIV screening, also have a similar recommendation from HRSA.

6. **What other laws protect access to preventive services?**

At least 17 states have passed laws that require private health plans sold to individuals to cover the same categories of preventive services that the ACA covers. Some of these state laws also cover the state-regulated, fully insured group market (although states do not have the power to regulate ERISA-governed plans). Other states are currently considering ACA-like legislation for state-regulated plans.

Some states also have statutes, regulations, or guidance to ensure coverage of specific preventive services without cost sharing. For example, Colorado has regulations requiring plans to cover PrEP without cost sharing. New York also has PrEP-specific legislation.

7. **What should people do if they think someone with private health insurance has been wrongly denied coverage of a preventive service?**

If someone with private health insurance has been wrongly denied coverage or charged for a preventive service, there are a number of ways to appeal. First, most plans have an internal appeals process to challenge the plan's coverage determinations. This is often the first step beneficiaries can take. If the internal appeals process does not correct the issue, there are different ways to elevate the complaint depending on what type of plan it is. For example:

- For individual health plans, and small and large group fully insured plans, consumers may file complaints with their state department of insurance. The National Association of Insurance Commissioners provides helpful resources about the complaint process along with links to each state's complaint submission process.

- For self-insured plans, which are usually offered by larger employers and unions, the federal Department of Labor is charged with accepting complaints. Direct advocacy with the employer or union may also be effective.

For concerns that a plan may have engaged in illegal discrimination against a consumer, the consumer may file a complaint with the Department of Health and Human Services Office for Civil Rights.

As noted above, there are very few people whose insurance plans are allowed to change as a result of the Fifth Circuit's decision in Braidwood (only the plaintiffs, their families, and their employees). Advocates, providers, and consumers with questions about the above FAQs, or who believe that a consumer has been wrongly denied coverage of a preventive service, and the consumer's health plan has denied the appeal, are welcome to contact CHLPI at chlpi@law.harvard.edu.

8. **If I do not have insurance or my insurance is not comprehensive, what options are there to help me access PrEP at low or no cost?**

There are several programs that help uninsured or underinsured people afford PrEP. Individuals with insurance can apply for assistance through private programs that help cover cost sharing amounts for PrEP. In addition, some state health departments operate PrEP assistance programs that can help cover cost sharing amounts for PrEP medications and associated labs and clinic visits.

If you believe your health insurance plan has unlawfully dropped coverage for PrEP, please contact CHLPI at chlpi@law.harvard.edu.

9. **I have Medicaid. Does the *Braidwood Management v. Becerra* decision affect my access to preventive services?**

Not at this time. The ACA requires states to offer essential health benefits (EHB) to the ACA's Medicaid expansion group. (Medicaid expansion, in states that have adopted it, generally covers non-disabled, non-pregnant adults up to age 65 with incomes up to 138% of federal poverty level.) EHB includes preventive services, which has been defined to include coverage of USPSTF-, ACIP- and HRSA-recommended services without cost sharing. Although future iterations of this case may address the interplay between the EHB regulations and the constitutionality of the ACA's preventive care mandate for private insurers, nothing in the Fifth Circuit's 2024 decision undermines the requirement that states with Medicaid expansion offer preventive services for this group.

A separate provision of the ACA also offers states access to additional federal funding if they cover in Medicaid without cost sharing all adult preventive services recommended by USPSTF and ACIP. The Fifth Circuit's 2024 decision also does not impact interpretation or enforcement of this statute.

10. **I have Medicare. Does the *Braidwood Management v. Becerra* decision affect my access to preventive services?**

No. Since 2009, the Secretary of HHS has had the authority, through a process called a National Coverage Determination (NCD), to identify preventive services with a USPSTF Grade A or B recommendation that should be covered under Medicare. To make these services more affordable, the ACA added the requirement that USPSTF-recommended services with an NCD must be covered without cost sharing. However, the *Braidwood* litigation did not challenge any Medicare statutes or regulations, and the Fifth Circuit's decision does not touch on Medicare.

Check here for information about the preventive services that Medicare covers.