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 a single federal district court judge in Texas has ruled that the federal government cannot enforce 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 May 16, 2023).

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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 did the federal district court in *Braidwood Management v. Becerra* 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. Note that if the case is appealed to the Supreme Court, that issue may reappear, as certain members of the Court have announced that they want to limit agency powers in this way.

On March 30, 2023, Judge O'Connor followed up on his earlier ruling after considering arguments from both sides about the remedies to which the Plaintiffs are entitled. Most importantly, the judge 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 forbids the federal government from enforcing no-cost coverage of USPSTF recommendations published since March 23, 2010, meaning that private health plans and Medicaid expansion programs are still required to cover preventive services with pre-existing USPSTF recommendations. This ruling could affect coverage of a wide range of preventive services across the United States and has the potential to cause widespread uncertainty, accelerate health disparities, and degrade 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 that coverage of PrEP runs counter to their religious beliefs. While this order is limited to certain parties in the *Braidwood* lawsuit and is subsumed under the court's more sweeping order, it establishes a legal authority that will likely be cited by others seeking a license to discriminate.

3. What will happen next? Will there be an appeal from the federal district court ruling?

On March 31, 2023, the federal government appealed to the United States Court of Appeals for the Fifth Circuit to review Judge O'Connor's legal rulings in this case. Braidwood and its allies have also filed a cross-appeal of Judge O'Connor's rulings, indicating that they plan to ask the higher court to issue even broader judgments than they have already received.

Since there are thousands of cases pending before this court, it is very difficult to predict how long it will take to resolve the appeal. Recent statistics from the federal government show that the median time from filing an appeal to issuance of the Fifth Circuit's opinion is more than nine months. In the meantime, the federal government filed a motion for a stay asking Judge O'Connor to temporarily limit his ruling to Braidwood and the other plaintiffs, thereby avoiding unnecessary disruptions to care for millions of people while the case is appealed. On May 15, 2023, the Fifth Circuit issued an administrative order that grants the stay temporarily while the court considers the motion for stay.

4. What preventive services could be affected by the court's ruling?

As discussed above, the court's ruling affects the federal government's ability to enforce the ACA's mandate that private insurance companies cover without cost sharing all services that have received a USPSTF Grade A or B recommendation since March 23, 2010. The court's ruling does not affect coverage of ACIP- and HRSA-recommended services.

Removing the mandate to cover all USPSTF-recommended services 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:

Services with USPSTF Grade A or B since March 23, 2010[1] (non-exhaustive list)
Lung cancer screening
Hepatitis C screening
HIV pre-exposure prophylaxis (PrEP)
HIV screening
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

The complete list of USPSTF published recommendations is available here. Note that for many services, even if the USPSTF 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.

Although the plaintiffs in *Braidwood Management* challenged the entire ACA preventive services mandate, the federal district court rejected the plaintiffs' arguments regarding ACIP- and HRSA-recommended services. (See FAQs #1 and #2.) This means that the court's ruling

[1] Kaiser Family Foundation has released a more detailed chart analyzing the impact on some of the affected recommendations. American Lung Association also hosts a more detailed chart.

does not affect the ACA requirement to cover services recommended by those bodies. These services include a range of immunizations and preventive services for adults and children, including hepatitis b vaccinations, breast feeding services and supplies, well woman preventive visits, and childhood vaccines. The court also rejected arguments related to coverage of contraceptives, which are included under the HRSA recommendations.

5. **Can employers or private insurance plans change their coverage rules for preventive services immediately? What other rules protect people from mid-year plan changes? Do those rules still apply?**

Although the court has issued an order preventing the federal government from enforcing the preventive services mandate as it applies to USPSTF recommendations issued after March 23, 2010, most consumers with private insurance likely will not see immediate changes to their coverage for these services for a variety of reasons. First, the preventive services mandate is a popular provision of the ACA, and insurance plans have already incorporated coverage of these benefits without cost sharing into their plans for the 2023 plan year. Widespread, immediate changes to private insurance coverage of these services are thus not anticipated.

Second, the court may decide to stay the decision until the Fifth Circuit or the Supreme Court has ruled on any appeal. (See FAQ #3.) If that happens, insurance providers would have to continue to fully cover these services unless and until the stay is lifted.

And, other provisions of the ACA, the Employment Security Retirement Income Act (ERISA), and other laws and policies may provide protections for consumers from immediate or near-term changes to coverage of preventive services. For example:

ACA

The ACA and its implementing regulations include numerous protections that may be helpful to consumers at this time, including rules regarding when plans may change their coverage and notices that must be provided regarding certain types of coverage changes. For example, every private health plan must provide a Summary of Benefits and Coverage (SBC), which may include information about coverage of preventive care. Health insurance issuers are required to provide notice to plan members at least 60 days before any material modifications to a plan's SBC will become effective. And, there are other statutory provisions of the ACA besides the one being litigated in this case that mandate coverage of preventive services. Individual and small group plans must cover ten categories of essential health benefits (EHB), including "preventive and wellness services," which has been defined to include USPSTF-recommended services. Given the court's sweeping ruling, the full impact on some of these rules is not yet clear. However, these rules may continue to offer important protections for consumers. CHLPI is continuing to monitor and analyze the impact of the court's decision, and will provide more information as it becomes available.

ERISA

Self-insured employer and union plans governed by ERISA are required to operate "in accordance with the documents and instruments governing the plan." Those documents and instruments are generally negotiated prior to each plan year and may include rules that limit mid-year plan changes. ERISA plans are also subject to notice protections regarding, for example, changes to a plan's SBC.

State Laws

At least fifteen states have passed laws that require private health plans sold to individuals to cover the same categories of preventive services that the ACA covers, including USPSTF-recommended services. 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). Some states also have existing 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. Other states are currently considering ACA-like legislation that would require coverage of all USPSTF-recommended services without cost sharing and/or service-specific legislation.

Some states also have laws or regulations that limit the types of changes plans are able to make to their formularies mid-year.

Consumers who have been denied continued coverage of preventive services to which they believe they are entitled, or who are seeking an exception to their plan's coverage limitations, should begin by initiating their plan's internal appeals or exception process. (See FAQ #11.)

6. **If my employer or insurance plan stops covering PrEP without cost sharing or drops coverage for PrEP altogether, 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.

See FAQ 5 for discussion of protections that may prohibit or discourage insurance companies from immediately dropping coverage for PrEP or imposing cost sharing requirements despite the *Braidwood Management* decision. If you believe your health insurance plan has dropped coverage for PrEP, please contact CHLPI at chlpi@law.harvard.edu.

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

Possibly, but any impact on Medicaid remains ambiguous at this time and would likely vary state-by-state. This is because 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-recommended services without cost sharing. Given the court's sweeping ruling, this case may impact the EHB rules as they apply to Medicaid expansion. However, this case did not challenge any Medicaid statutes, and nothing in the court's decision undermines a state's authority to continue offering all USPSTF-recommended services to Medicaid beneficiaries. States also continue to have access to extra federal funding if they provide all USPSTF- and ACIP-recommended services without cost sharing to Medicaid beneficiaries. In light of these factors—and the long-term cost-saving advantage of preventive care—many states may maintain robust coverage of these services in their Medicaid programs. CHLPI is continuing to monitor and analyze the impact of the court's decision, and will provide more information as it becomes available.

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

Probably not. 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. Because the NCD process requires the Secretary's approval, the Appointments Clause argument that the court accepted in *Braidwood Management* does not apply to Medicare coverage of preventive services. (See FAQ #2.) Also, Medicare is generally governed by a different statutory and regulatory structure than applies to private health insurance plans, so the court's order vacating agency actions to implement the statute challenged in this case should not affect Medicare.

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

9. **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.

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.