



Preventive Services Access on the Docket in *Braidwood v. Becerra*

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Preventive care benefits for millions of privately insured individuals may be impacted by *Braidwood Management Inc. et al. v. Becerra (Braidwood)*, an ongoing legal challenge to a federal requirement for coverage of clinical preventive services. Established by the Patient Protection and Affordable Care Act (ACA), this requirement generally compels most private-sector health plans and insurers to cover certain preventive services without cost-sharing (i.e., out-of-pocket costs) to their enrollees. A central issue in *Braidwood* is whether the preventive services requirement violates certain separation-of-powers principles of the U.S. Constitution, particularly the nondelegation doctrine and the Appointments Clause. In September 2022, a Texas district court dismissed most of the plaintiffs' constitutional claims, but concluded in part that covered services based on certain U.S. Preventive Service Task Force (PSTF or Task Force) recommendations were invalid. The district court's decision is stayed while the litigation proceeds in the U.S. Court of Appeals for the Fifth Circuit (Fifth Circuit). This Legal Sidebar provides background on the preventive services requirement, examines the *Braidwood* case, and discusses legal considerations for Congress.

Background

Clinical preventive care generally consists of routine medical services and items, such as immunizations, screening tests, and patient counseling, intended for promoting patient health and preventing illness. The ACA compels most private-sector, employment-based group health plans and health insurers offering insurance in the group and individual insurance markets to cover certain preventive health services with no out-of-pocket costs (such as a deductible or a co-pay) to plan participants. While the ACA does not specify each service that must be covered, the law directs plans and insurers to cover the following categories of services:

- Evidence-based items or services with a rating of "A" or "B" in the current PSTF recommendations
- Vaccines recommended by the Advisory Committee on Immunization Practices (ACIP)

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- Pediatric preventive care and screenings identified in guidelines supported by the Health Resources and Services Administration (HRSA), an agency of the Department of Health and Human Services (HHS)
- Women's preventive care and screenings (in addition to the PSTF recommendations) as specified in guidelines supported by HRSA

Since the ACA's enactment, the preventive services requirement has been the subject of voluminous litigation. Earlier litigation primarily concerned the requirement to provide contraceptive coverage pursuant to HRSA's Women's Preventive Services Guidelines, and employers or other groups' religious or moral objections to offering this coverage in their health plans. Current regulations, which have been amended several times, contain regulatory exemptions or accommodations for those who oppose this coverage. The Supreme Court upheld these regulations in 2019 in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania (Little Sisters)*. (However, a new proposed rule would, if finalized, expand access to contraceptive coverage and may provoke new legal action). Unlike the contraceptive coverage litigation, plaintiffs in the *Braidwood* case are largely seeking to invalidate the preventive services requirement as a whole. Currently, there are more than 60 types of required covered services, ranging from those related to diabetes, lung cancer, and depression screenings, to breastfeeding support and counseling.

District Court Decision

In *Braidwood*, a group of individuals and businesses with financial or religious objections to insurance coverage of some or all currently-required preventive services sued the HHS Secretary and other federal officials, generally asking the U.S. District Court for the Northern District of Texas to declare the preventive services requirement unconstitutional and unenforceable. Among their claims, plaintiffs in *Braidwood* asserted that the manner in which covered benefits are "unilaterally determined" based on PSTF, ACIP, and HRSA recommendations or guidelines violates the Appointments Clause and the nondelegation doctrine. (Plaintiffs also challenged a requirement for insurers to offer pre-exposure prophylaxis drugs to prevent HIV infection as a violation of the Religious Freedom Restoration Act, and discussion of this claim is beyond the scope of this Legal Sidebar.)

Appointments Clause

Pursuant to the Appointments Clause, certain significant government functions must be performed by "Officers of the United States" that are appointed in particular manners. As interpreted by the Supreme Court, "principal officers" must be appointed by the President and confirmed by the Senate while "inferior officers" must be appointed by the President, courts of law, or heads of Departments. As the Supreme Court has indicated, a basic purpose of the Clause is to ensure political accountability to elected officials for appointees' actions. The plaintiffs in *Braidwood* argued that the preventive services requirement violates the Constitution's Appointments Clause in part because the provision authorizes members of PSTF, ACIP, and HRSA to make binding determinations as to which preventive services must be covered by private health insurers. According to plaintiffs, these determinations constitute "significant authority" that can only be exercised by properly appointed Officers of the United States, and the members are not properly appointed. Plaintiffs also argued that this defect could not have been remedied through the ratification of these determinations by the HHS Secretary, a properly appointed official.

The district court in *Braidwood* analyzed whether the PSTF, ACIP, and HRSA recommendations and guidelines had been ratified. As the court noted, based on several appellate court rulings, in some circumstances, a properly appointed official can ratify an improperly appointed official's decision and remedy an unconstitutional appointment. The court explained that ACIP and HRSA, both part of the

Public Health Service, are "under the supervision and direction of the [HHS] Secretary," and that the Secretary may direct ACIP and HRSA to include (or exclude) particular preventive care or screenings on the covered services list. Accordingly, the court concluded that ACIP and HRSA's actions with respect to the preventive services requirement were properly ratified by the HHS Secretary, and this ratification cured any Appointments Clause violation.

By contrast, the court determined that the HHS Secretary lacks the ability to ratify PSTF recommendations. The court explained that under the Task Force's authorizing statute, the HHS Secretary cannot decide which services receive an A or B rating (and thus, which services are covered under the preventive services requirement). The court also declared that PSTF panel members meet hallmarks of "officer" status as recognized by the Supreme Court, including the exercise of significant authority in making preventive service recommendations. As the court observed, the Task Force's recommendations constitute "legal directives" that dictate which preventive services an insurer must cover and have the force and effect of law. Moreover, the court concluded that PSTF panel members, neither directed nor supervised at some level by others who were presidentially appointed and senate confirmed, are "principal officers" who must be presidentially appointed and senate confirmed. Because Task Force members are merely "convene[d]" by the Director of the Agency for Healthcare Research and Quality, an agency within HHS, the court concluded that the members have not been properly appointed and that the preventive services requirement based on PSTF recommendations violates the Appointment Clause.

Nondelegation Doctrine

Additionally, plaintiffs in *Braidwood* alleged that the preventive services requirement runs afoul of the nondelegation doctrine, which generally restricts Congress's ability to transfer legislative power to other government branches or private actors. Although the Supreme Court has upheld broad delegations of authority to governmental entities, plaintiffs argued that the preventive services requirements are an unconstitutional delegation of legislative authority because the ACA does not provide the necessary "intelligible principle" to govern and guide PSTF, ACIP, and HRSA on the selection of preventive services requirement active services. Federal government defendants, on the other hand, maintained that the preventive services requirement articulates "clear standards" regarding the categories of services that should be covered, as well as the particular body responsible for recommending the relevant services.

The district court rejected the plaintiffs' nondelegation claims. Relying on earlier Fifth Circuit precedent, the court determined that the delegation of authority to PSTF, ACIP, and HRSA passed constitutional muster for three interrelated reasons, namely that Congress set: (1) a "general policy" in the preventive services requirement to expand coverage for preventive services; (2) the specific agencies to apply such policy; and (3) the limits of the delegated authority, including that PSTF-recommended services must be "evidence-based," that ACIP's authority is only for "immunizations," and HRSA's guidelines must be "evidence-informed" and applicable only to specified populations, such as women. While the district court acknowledged certain Supreme Court statements in the *Little Sisters* decision that arguably suggest a violation of the nondelegation doctrine with respect to HRSA (for instance, that HRSA has "virtually unbridled discretion to decide what counts as preventive care and screenings"), the district court indicated that the Supreme Court in *Little Sisters* did not rule on the scope of HRSA's delegation, and that it could not "read the tea leaves" to predict how the Court could address this issue in the future.

Remedy

In a subsequent March 2023 order, the district court vacated *all* agency action to implement or enforce the preventive care coverage requirements in response to an "A" or "B" PSTF rating for services recommended on or after March 23, 2010, the date of the ACA's enactment, as the remedy for the

Appointments Clause violation. The Fifth Circuit stayed the district court's judgment in light of a stipulation between the parties agreeing to a stay as the litigation proceeds. As part of the stipulation, the federal defendants have agreed not to take enforcement action against the plaintiffs related to the preventive services requirement while the Fifth Circuit case is pending. The case is currently being briefed in the appeals court, and oral arguments have yet to be scheduled.

Considerations for Congress

The *Braidwood* lawsuit has captured congressional court watchers' attention because it could potentially affect coverage of preventive health benefits not just for the litigating parties, but for all individuals that have health insurance subject to the preventive services requirement (approximately 150 million individuals, according to a recent estimate). Should the preventive services requirement ultimately be invalidated in whole or in part, it is possible that health plans may be able to impose cost-sharing amounts on enrollees with respect to these services, or may not be required to offer certain preventive services. The scope of preventive coverage could differ by plan or insurer (although some of the ACA's essential health benefits requirements may compel the provision of at least some services for applicable plans).

Congress may also choose to enact legislation that could affect the outcome in the *Braidwood* case. Among possible legislative options, to address the Appointments Clause violation as determined by the district court in *Braidwood*, Congress could amend the preventive services requirement to indicate further that all preventive services, or at least those recommended by PTSF, must be approved by the HHS Secretary, or another official that has been nominated by the President and confirmed by the Senate.

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