NO RIGHT TO DENY CARE:

THE IMPORTANCE OF PRESERVING PREVENTIVE

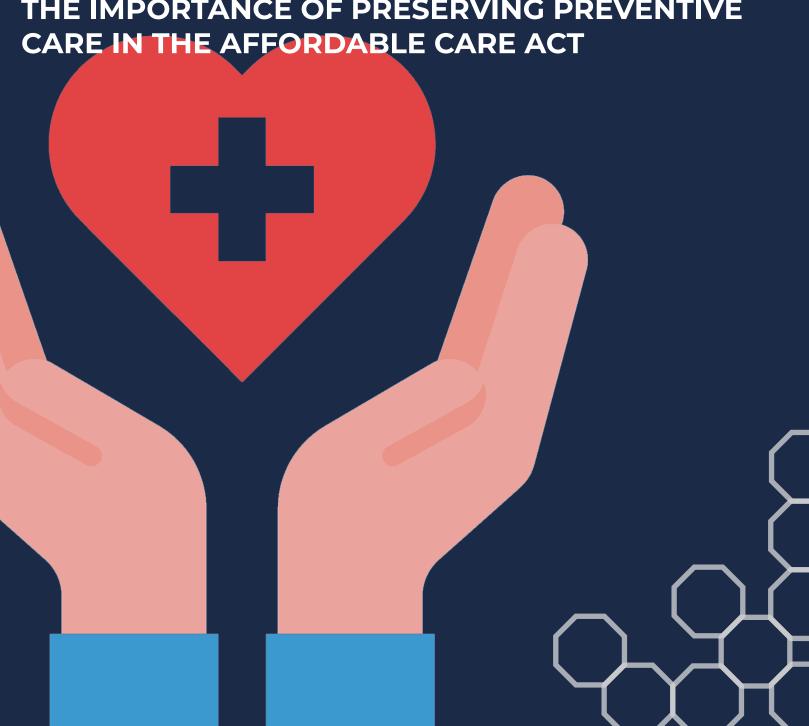


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INTRODUCTION

The Affordable Care Act (ACA) expanded Medicaid for low-income Americans, protected access to coverage for people with preexisting conditions, and created Healthcare.gov and state-based exchanges where individuals can purchase quality, affordable coverage. Additionally, the ACA included another major reform that affected nearly everyone with private health insurance - the requirement for coverage of preventive care without any cost-sharing, such as deductibles or copays.¹ This requirement has not only helped the more than 14 million enrollees in coverage through the ACA exchanges,² but also the vast majority of the approximately 155 million Americans who have coverage through their job.³

A recent decision by a very conservative court, issued by a very conservative judge, jeopardizes the future of these critical reforms for millions of individual consumers, small business owners, workers, and their families. In the case Braidwood v. Becerra, the judge ruled that the Constitution does not allow a requirement for plans to cover certain preventive services.⁴ The decision also found that the mandate to cover certain preventive service items, such as medication that can prevent HIV transmission, substantially burdens the religious exercise of one of the plaintiffs. ⁵ The ruling did not address every issue in the case, but the court indicated that it may also allow certain employers to limit coverage for other vital preventive services.⁶

This case is ongoing, and the decision will hopefully be overturned on appeal, but the stakes for American workers and families are high. Preventive service coverage has been enormously consequential in improving access to care for millions of Americans and it is critical that this protection be preserved.

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¹ Public Health Service Act § 2713 (grandfathered health plans and those offering limited scope benefits such as stand-alone dental and vision plans are exempt from this requirement, however).

 $^{^2}$ Press Release', Biden-Harris Ádministrátion Annóunces 14.5 Million Americans Signed Up for Affordable Health Care During Historic Open Enrollment Period (Jan. 27, 2022), https://www.hhs.gov/about/news/2022/01/27/biden-harris-administration-announces-14-5-million-

Enrollment Period (Jan. 27, 2022), https://www.hhs.gov/about/news/2022/01/27/biden-harris-administration-announces-I4-5-million-americans-signed-affordable-health-care-during-historic-open-enrollment-period.html.

3 Employer Health Benefits: 2021 Annual Survey, Kaiser Family Foundation, available at https://files.kff.org/attachment/Report-Employer-Health-Benefits-2021-Annual-Survey.pdf.

4 This case was formerly known as Kelley v. Becerra, but was later changed at the request of the plaintiffs. See Unopposed Motion to Amend Caption at 1, John Kelley, et al., v. Xavier Becerra, et al., No. 4:20-cv-00283-O (N.D. Texas, Aug. 10, 2022) ("The plaintiffs respectfully move to amend the caption so that Braidwood Management Incorporated is the first-listed plaintiff, and that the case be referred to as 'Braidwood Management Inc., et al. v. Xavier Becerra, et al.' going forward").

5 Braidwood Management Inc., et al. v. Xavier Becerra, et al., No. 4:20-cv-00283-O (N.D. Texas, Sept. 7, 2022), available at https://storage.courtlistener.com/recap/gov.uscourts.txnd.330381/gov.uscourts.txnd.330381.92.0.pdf.

6 In February 2021, the court dismissed plaintiffs' religious claims regarding the contraceptive mandate because the court had previously dealt with those claims by the same plaintiffs in a separate case, DeOtte v. Azar, DeOtte v. Azar, 393 F. Supp. 3d. 490 (N.D. Tex. 2019). However, the court's decision in DeOtte was recently reversed by the Fifth Circuit. The plaintiffs now contend that their religious claims regarding the contraceptive mandate are no longer precluded by the DeOtte case and as a result, have asked the court to reconsider those claims. The court signaled that it will further deliberate on the plaintiffs' claims regarding the contraceptive mandate issue. With regards to plaintiffs' objections t diseases (STDs), and substance use.



LOSING ACCESS TO COMPREHENSIVE PREVENTIVE CARE COULD HARM MILLIONS OF PEOPLE AND INCREASE HEALTH CARE COSTS

Before the ACA was enacted in 2010, there was no federal requirement for private health plans to cover preventive services. Further, there were no limits on how much Americans might be forced to pay out-of-pocket to get preventive care. As a result, coverage for preventive services varied considerably across the country. Some states required certain types of plans to cover certain preventive services, but the requirements were generally narrow and often did not cap out-ofpocket expenses.

Access to preventive care is essential to long-term health. Through preventive care, doctors and other health care providers can detect problems early when they are more treatable. Preventive services provide tremendous value by reducing the risk for developing a long-term, chronic disease. For example, preventive measures have led to a more than 75 percent reduction in new HIV infections each year since they peaked in 1984.8 Research has shown that access to preventive care also reduces overall health care spending, as fewer people develop chronic conditions that require expensive treatment.9

THE AFFORDABLE CARE ACT ENSURES THAT WORKERS HAVE ACCESS TO PREVENTIVE CARE

The ACA included several reforms that improved the quality and affordability of health care coverage for millions of workers and their families. One of these reforms is a requirement for nearly all private health plans to cover a robust set of preventive services without patients having to pay anything out-of-pocket.¹⁰ This requirement generally applies to all people, regardless of whether an individual gets their coverage through their employer or in the individual market - a combined total of about 170 million people. 11 Studies show that the requirement is one of the most popular parts of the ACA and the majority of Americans say that it is "very important" that it be preserved.¹²

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⁷ The Departments of Health and Human Services, Labor, and the Treasury issued interim final regulations in 2010 to implement the Affordable Care Act's preventive service coverage requirement. The preamble to the regulations includes an impact analysis that summarizes preventive service coverage available prior to the enactment of the Affordable Care Act. See, Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41726, 41732 (July 19, 2010), available at <a href="https://www.federalregister.gov/documents/2010/07/19/2010-17242/interim-final-rules-for-group-bealth-plans and health-insurance issuers relating to coverage of the contraction of the Affordable Care Act. The Protection and Affordable Care Act, 75 Fed. Reg. 41726, 41732 (July 19, 2010), available at <a href="https://www.federalregister.gov/documents/2010/07/19/2010-17242/interim-final-rules-for-group-bealth-plans and health-insurance issuers relating to coverage of the Affordable Care Act. See, Interim Final Rules for Group Health Plans and Health Insurance Issuers and Affordable Care Act. The Affordable Care Act.

^{41/32 (}July 19, 2010), available at health-plans-and-health-insurance-issuers-relating-to-coverage-of.
8 Smith, Dawn K., Kirk, Henry D., Weidle, Paul, J., The Evidence for Initial Intervention Strategies for Ending the HIV Epidemic in the U.S., American Journal of Preventive Medicine, 2021 S1-S5, available at https://www.ajpmonline.org/article/S0749-3797(21)00390-1/fulltext.
9 Maciosek, Michael V., Coffield, Ashley B., Flottemesch, et al., Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost. Health Affairs 2010, 29(9) 1656-1660, available at https://pubmed.ncbi.nlm.nih.gov/20820022/.
10 Public Health Service Act section 2713 (grandfathered health plans and those offering limited scope benefits such as stand-alone dental and vision plans are exempt from this requirement, however.)

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See Data Note: Changes in Enrollment in the Individual Health Insurance Market through Early 2019, Kaiser Family Foundation, available at <a href="https://www.kff.org/private-insurance/issue-brief/data-note-changes-in-enrollment-in-the-individual-health-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-market-through-insurance-marketearly-2019/; see also Employer Health Benefits, supra note 3.

¹² Ashley Kirzinger, 5 Charts About Public Opinion on The Affordable Care Act, Kaiser Family Foundation (April 14, 2022), available at https://www.kff.org/health-reform/poll-finding/5-charts-about-public-opinion-on-the-affordable-care-act-and-the-supreme-court/.

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Specifically, under the ACA, health plans and insurance companies must cover - without any costsharing - the following four categories of items and services:

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved:13
- Immunizations for routine clinical use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and
- With respect to women, preventive care and screenings provided for in comprehensive quidelines supported by HRSA, to the extent not included in certain recommendations of the USPSTF.

The range of items and services that that must be covered under these four categories is broad and includes, for example, cancer screenings, contraception, well-woman visits, pre-exposure prophylaxis (PrEP) for HIV prevention, routine vaccinations, screening for sexually transmitted diseases, breastfeeding services and supplies, tobacco cessation interventions, and many others. In just the first category of services that must be covered - those recommended by the USPSTF there are 45 different types of preventive services. ¹⁴ Office visits to receive preventive care as well as services that are integral to receiving certain preventive services, such as specimen collection for recommended screenings, are generally also required to be covered. 15

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The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 223 of Division H of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2023. In July 2021, the Departments of Health and Human Services, Labor, and the Treasury issued new guidance clarifying that most health plans must include PrEP coverage without cost-sharing based on the U.S Preventive Services Task Force's "Grade A" recommendation of June 2019. See, The Departments of Health and Human Services, Labor, and the Treasury, FAQs about Affordable Care Act Implementation Part 47 (July 19, 2021), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf.

14 U.S. Preventive Service Task Force Published Recommendations, available at https://www.uspreventiveservicestaskforce.org/uspstf/topic.search.results?topic.status=P&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=R&grades%5R%5D=

https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P&grades%5B%5D=A&grades%5B%5D=B&searc

¹⁵ See 29 CFR 2590.715-2713; see also FAQs About Affordable Care Act Implementation, Part 54, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsg/our-activities/resource-center/fags/acg-part-54.pdf.

RECOMMENDATIONS FOR WHICH PREVENTIVE SERVICES MUST BE COVERED ARE DEVELOPED BY INDEPENDENT EXPERTS - NOT INSURANCE COMPANIES OR POLITICIANS

Although the preventive service coverage requirement is grounded in federal law and enforced by federal and state insurance regulators, the specific items and services that must be covered are recommended by experts in preventive medicine from several entities: the United States Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), and Health Resources and Services Administration (HRSA).

The USPSTF is an organization comprised of experts in disease prevention. Members are independent volunteers who seek to improve the health of people nationwide through evidence-based recommendations about preventive health services. The USPSTF has a rigorous process for the development of their recommendations that ensures they are not influenced by conflicts of interest. Additionally, stakeholders have an opportunity to submit comments on proposed recommendations before they are finalized.

ACIP is a Federal Advisory Committee established by law to offer advice to the Director of the CDC about disease prevention through the use of vaccines.¹⁶ ACIP's members are experts in the fields of immunization practices and public health. Similar to the USPSTF, ACIP adheres to strict procedures to ensure transparency in the development of their recommendations. They hold meetings that are open to the public and they publish their framework for evaluating evidence before voting on each recommendation.

HRSA is one of nine Public Health Service agencies under the Department of Health and Human Services. Since 2016, HRSA has awarded contracts to the American College of Obstetricians and Gynecologists (ACOG) to convene a panel of medical professionals and other health experts to develop and update its preventive service recommendations.¹⁷

¹⁷ Women's Preventive Service Guidelines, Health Resources and Services Administration, availabl https://www.hrsa.gov/womens-guidelines.

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¹⁶ ACIP Charter, Centers for Disease Control and Prevention, available at https://www.cdc.gov/vaccines/acip/committee/charter.html.

¹⁷ Women's Preventive Service Guidelines, Health Resources and Services Administration, available at



COVERAGE FOR PREVENTIVE SERVICES HAS IMPROVED THE HEALTH OF **MILLIONS OF AMERICANS**

Since the ACA's preventive service coverage requirement took effect, numerous studies have sought to measure its impact on consumer access to preventive care. The studies generally all show that the law has been an enormous success: utilization rates for preventive care are up, racial and ethnic disparities in accessing preventive care are down, people are spending less out-ofpocket, and better health and economic outcomes are being achieved. 18

Clinical guidelines suggest that a 58-year-old woman who is at risk for heart disease should receive a mammogram, a colon cancer screening, a Pap test, a diabetes test, a cholesterol test, and an annual flu shot. Under a typical insurance plan before the ACA was enacted, these tests could cost more than \$300 out of her own pocket.¹⁹ Now, under the ACA, she would not require any out-of-pocket spending. The law has similarly reduced costs for contraception, which used to be a major barrier women faced in accessing contraception. On average, women with private insurance who use oral contraceptives or intrauterine devices have been able to save about \$250 a year since the ACA was enacted over ten years ago.²⁰

The very coverage that the Braidwood case targeted—Truvada—is the first FDA-approved medication for HIV prevention and the only form of PrEP available for women. Without insurance, Truvada can cost between \$1,600 and \$2,000 per month, not including the cost of routine HIV testing and ancillary services that are required for continued prescriptions. One in five new HIV cases now affect women²¹ and, when taken as recommended, PrEP reduces the risk of getting HIV by 99 percent, according to the CDC.²² PrEP has also been used in combination with HIV medications to reduce the risk of mother-to-child HIV transmission during pregnancy, treat survivors of intimate partner violence and sexual assault, and protect people living with hemophilia and other immunocompromised people from HIV exposure.

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¹⁸ Access to Preventive Services Without Cost-sharing: Evidence from the Affordable Care Act, Department of Health and Human Services, Assistant Secretary for Planning and Evaluation (Jan. 11, 2022), available at https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf
¹⁹ Background; The Affordable Care Act's New Rules on Preventive Care, Centers for Medicare and Medicaid Services (July 14, 2010), available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/preventive-care-background#_ftnref6.
²⁰ Nora Becker, Daniel Polsky, Women Saw Large Decrease In Out-Of-Pocket Spending For Contraceptives After ACA Mandate Removed Cost Sharing, Health Affairs (July 2015), available at https://www.cdc.gov/hiv/pdf/group/gender/women/cdc-hiv-women.pdf.
²¹ Centers for Disease Control and Prevention, Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, PrEP Effectiveness (June 6, 2022), https://www.cdc.gov/hiv/pdf/group/gender/women/cdc-hiv-women.pdf.
²² Centers for Disease Control and Prevention, Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, PrEP Effectiveness (June 6, 2022), https://www.cdc.gov/hiv/pdf/group-gender/women/cdc-hiv-women.pdf.
²³ Centers for Disease Control and Prevention, Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, PreP Effectiveness (June 6, 2022), https://ww

PrEP Effectiveness, (June 6, 2022), https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html.

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When the ACA preventive services coverage requirements first took effect, it was predicted that there would be both public health and economic benefits; not only would there be reduced transmission and earlier treatment of diseases, but some of the recommended preventive services would also result in savings due to lower health care costs overall and fewer workers and students missing work and school due to illness.²³ Shortly after the coverage requirement took effect, the Department of Health and Human Services estimated that it led to 54 million more Americans receiving preventive care without any out-of-pocket spending.²⁴ The Department also recently issued a comprehensive review of research examining the impact of the preventive service coverage requirement.²⁵ This review found that:

- Nearly 150 million people are estimated to have benefited from the law through increased screenings and improved health outcomes.
- Regarding cancer screenings, research suggests that increased access and lower costs have helped cancer survivors obtain the care they need. The greatest improvements have been for colorectal and cervical cancer screenings. Increased screening has resulted in an overall decrease in colorectal cancer incidence, and data show that newly insured immigrants, in particular, are being screened at higher rates than they were before the law took effect.
- The combination of the preventive service coverage requirement and the ACA's requirement that any dependent coverage be available up to age 26 has led to significantly more women receiving vaccinations for human papillomavirus (HPV), which prevents cervical cancer.
- More adults are receiving their annual recommended flu shots.
- The increase in access to contraception has been profound. Cost has historically been a major barrier to accessing contraception and PrEP, and better access is associated with reduced rates of poverty. By one estimate, in the first year after the preventive service coverage requirement took effect, women collectively saved approximately \$1.4 billion on out-of-pocket expenses for contraception.

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²³ Interim final regulations, supra note 7, at 41733.

²⁴ Fifty-Four Million Additional Americans Are Receiving Preventive Services Without Cost-Sharing Under The Affordable Care Act, Department of Health and Human Services, Assistant Secretary for Planning and Evaluation (Feb. 14, 2012), available at https://aspe.hhs.gov/reports/fifty-four-million-additional-americans-are-receiving-preventive-services-without-cost-sharing-under-0.

²⁵ Access to Preventive Services Without Cost-sharing: Evidence from the Affordable Care Act, supra note 19.

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