No. 24-316

In the Supreme Court of the United States

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

Petitioners,

v.

BRAIDWOOD MANAGEMENT, INC., ET AL.

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF ILLINOIS, ARIZONA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, HAWAII, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, WASHINGTON, AND WISCONSIN AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the court of appeals erred in holding that the structure of the U.S. Preventive Services Task Force (Task Force), which sits within the Public Health Service of the Department of Health and Human Services (HHS), violates the Appointments Clause, U.S. Const. Art. II, § 2. Cl. 2, and in declining to sever the statutory provision that it found to unduly insulate the Task Force from the HHS Secretary's supervision.

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INTERESTS OF AMICI CURIAE

Amici States of Illinois, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin (collectively, "amici States") submit this brief in support of the petition for a writ of certiorari filed by petitioners Xavier Becerra, in his official capacity as Secretary of Health and Human Services; Janet Yellen, in her official capacity as Secretary of the Treasury; Julie A. Su, in her official capacity as Acting Secretary of Labor; and the United States of America.[1]

Amici States have a substantial interest in safeguarding the health and welfare of their residents. The preventive services provision of the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. §§ 300gg-13(a)(1)-(4), advances this interest by expanding state residents' access to important and often lifesaving care. Specifically, the provision requires private insurers to cover certain preventive services and treatments without imposing cost sharing on patients. *Ibid.*

The Fifth Circuit's conclusion that the structure of the U.S. Preventive Services Task Force violates the Appointments Clause interferes with the States' vital interest in ensuring their residents are healthy and safe. Congress instructed the Task Force to issue recommendations for preventive medical services

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[1] All counsel of record received timely notice of amici States' intent to file this amicus brief under Rule 37.2.

that, under the preventive services provision, health insurance issuers and group health plans must cover without imposing additional out-of-pocket expenses on patients. 42 U.S.C. § 300gg-13(a)(1). But the Fifth Circuit concluded that the structure of the Task Force violates the Appointments Clause because its members are principal officers of the United States who must be (but are not) nominated by the President and confirmed by the Senate. Pet. App. 26a. On that basis, it affirmed an injunction prohibiting the federal government from enforcing the preventive services provision against respondents. *Id.* at 47a.

The Fifth Circuit's decision adversely impacts the amici States by calling into question their residents' access to lifesaving medical care. It has created substantial uncertainty and confusion regarding the enforceability of the preventive services provision within the amici States, raising questions about what services insurers are required to cover and ultimately putting the States' residents' health coverage at risk. This issue is of particular concern to the amici States because it is not one that they can address fully on their own, given federal preemption principles and practical constraints. The amici States thus urge the Court to grant the petition for certiorari, reverse, and hold that the Task Force's structure complies with the Appointments Clause and that the preventive services provision can be enforced.

SUMMARY OF ARGUMENT

The Fifth Circuit's opinion calls into question the enforceability of a provision of federal law that has significantly improved the health of the amici States' residents for over a decade. Since 2010, millions of Americans—and particularly members of vulnerable

populations—have relied on no-cost coverage to access critical preventive care that they would otherwise forego because of its substantial costs. As a result, healthcare providers have been able to detect, treat, and prevent severe illnesses throughout the amici States.

The decision below puts these achievements at risk. If the preventive services provision is unenforceable, private insurers would once more limit the preventive services covered by their plans, impairing the amici States' residents' access to care and harming health outcomes across the Nation. The amici States would not be able to fill the gap left behind, both because federal law limits the States' authority over certain insurance plans and because the States have traditionally relied on the federal government to determine the services that are most important for insurance plans to cover. The lower court's decision to narrow the scope of the injunction does not obviate the need for this Court's review. The decision remains binding within the Fifth Circuit, and other litigants can and will seek more sweeping relief based on its reasoning. The resulting uncertainty as to the provision's enforceability in the interim harms the amici States and their residents. The Court should grant certiorari and reverse.

ARGUMENT

The Court Should Review The Decision Below.

The Court should grant certiorari to make clear that the Task Force's structure is constitutional and that the preventive services provision can be enforced. The amici States agree with the United States that

respondents' Appointments Clause challenge lacks merit because the Task Force members are inferior officers who are subordinate to the Secretary. Pet. 14-22. The amici States also agree that, in the alternative, any constitutional defect should be cured by severing the provision that allegedly elevates Task Force members to the status of principal officers. Pet. 22-27. The amici States write separately to detail the negative impact of the Fifth Circuit's ruling on the States' public health objectives.

The preventive services provision has significantly improved public health outcomes in the amici States by expanding access to important and often life-saving care. The decision below puts these advancements at risk because the States will not be able to fill the significant gap in coverage that would result if a court were to enjoin the United States from enforcing the Task Force's recommendations. First, federal law preempts the States from regulating the insurance plans that cover many of their residents. Second, state-level mandates are less effective without corresponding federal guidance on implementation and enforcement. The preventive services provision thus is an integral counterpart to the amici States' public health efforts; without it, the States' existing preventive services programs and broader public health systems will suffer.

A. The Preventive Services Provision Has Significantly Improved Public Health Outcomes For The Amici States' Residents.

1. When the ACA was enacted, the medical community widely agreed that several leading causes

of death in the United States were largely avoidable.[2] Although the American healthcare system offers robust preventive care, such as cancer screenings and vaccinations, many Americans did not avail themselves of these critical services because the costs were significant and often prohibitive.[3] This was true even for people with insurance because many insurers either did not cover preventive services or they imposed significant out-of-pocket costs, like deductibles, copayments, and coinsurance, for those services.[4] These expenses deterred individuals of all backgrounds from accessing preventive care, but they

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[2] See, *e.g.*, Jared B. Fox & Frederic E. Shaw, *Clinical Preventive Services Coverage and the Affordable Care Act*, 105(1) Am. J. Pub. Health 7, 7-8 (2015) (concluding based on 2010 data that 9 out of 10 leading causes of death were preventable); Mark Mather & Paola Scommegna, *Up to Half of U.S. Premature Deaths are Preventable; Behavioral Factors Key*, Population Reference Bureau (Sept. 14, 2015), https://tinyurl.com/mpmhtbmv (48% of deaths before age 80 were preventable in 2010); *Background: The Affordable Care Act's New Rules on Preventive Care*, Ctrs. for Medicare & Medicaid Servs. (July 14, 2010), https://tinyurl.com/mwhawnjr (many deaths due to chronic illnesses, which cause 70% of deaths in America, were preventable).

[3] Fox & Shaw, *supra* note 2, at 7; *Background: The Affordable Care Act's New Rules on Preventive Care*, *supra* note 4; Hope C. Norris et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, 79(2) Med. Care Rsch. and Rev. 175, 175 (2022); Laura Skopec & Jessica Banthin, *Free Preventive Services Improve Access to Care*, Urban Inst., 2 (July 2022), https://tinyurl.com/5ejun8ez; U.S. Preventive Servs. Task Force, *A & B Recommendations*, https://tinyurl.com/3hjfanj3.

[4] Sabrina Corlette, *A World Without the ACA's Preventive Services Protections: The Impact of the* Braidwood *Decision*, Georgetown Univ., Health Pol'y Inst. (Apr. 18, 2023), https://tinyurl.com/2p9xr6j2.

particularly impacted marginalized and vulnerable communities, such as people of color, individuals living in poverty, and single parents.[5] By one estimate, more than 100,000 individuals lost their lives each year to conditions that could have been remediated by preventive care.[6]

Congress passed the preventive services provision and established the U.S. Preventive Services Task Force to ensure that no other Americans would lose their lives for inability to access preventive services.[7] Within 4 years of the ACA's passage, approximately 76 million Americans gained expanded coverage to one or more preventive services.[8] This number has grown steadily: As of 2020, an estimated 151.6 million people are enrolled in private insurance plans that cover preventive services at no cost to patients.[9] And as Congress anticipated, when individuals do not

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[5] Danielle Kilchenstein et al., *Cost Barriers to Health Services in U.S. Adults Before and After the Implementation of the Affordable Care Act*, 14(2) Cureus 1, 12-14 (2022).

[6] *Background: The Affordable Care Act's New Rules on Preventive Care*, *supra* note 2; see also Michael V. Maciosek et al., *Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost*, 29(9) Health Affs. 1656, 1659 (2010) (explaining that greater use of preventive services could prevent the loss of more than two million life-years annually).

[7] Norris, *supra* note 3, at 175-76.

[8] Amy Burke & Adelle Simmons, Off. of the Assistant Sec'y for Plan. & Evaluation, *Increased Coverage of Preventive Services With Zero Cost Sharing Under the Affordable Care Act* 1 (June 27, 2014), https://tinyurl.com/4h5yynnr.

[9] *Access to Preventive Services Without Cost-Sharing: Evidence from the Affordable Care Act*, Off. of the Assistant Sec'y for Plan. & Evaluation, 3 (Jan. 11, 2022), https://tinyurl.com/5a8bducj.

face significant financial barriers to preventive services, they use them.[10] Numerous studies confirm that, after the preventive services provision was enacted, the use of preventive care—such as routine examinations, blood pressure checks, and cholesterol screenings—increased across the board.[11]

These services improve public health outcomes by enabling medical professionals to identify and treat illnesses earlier, and, in some cases, prevent them.[12] For instance, colorectal cancer—the second leading cause of cancer fatalities in America—is considered largely preventable with screening, which allows doctors to identify and then remove cancerous pregrowths.[13] At the time the ACA was enacted, however, a colorectal cancer screening could cost patients $1,600 out of pocket, which was often

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[10] Norris, *supra* note 3, at 192.

[11] Xuesong Han et al., *Has Recommended Preventive Service Use Increased After Elimination of Cost-Sharing as Part of the Affordable Care Act in the United States?*, 78 Preventive Med. 85, 90-91 (2015); Josephine S. Lau et al., *Improvement in Preventive Care of Young Adults After the Affordable Care Act*, 168(12) JAMA Ped. 1101, 1105 (2014) (finding a significant increase in routine examinations, blood pressure and cholesterol screenings, and dental visits by young adults following no-cost coverage).

[12] *Preventive Services Covered by Private Health Plans Under the Affordable Care Act*, Kaiser Fam. Found. (May 15, 2023), https://tinyurl.com/3tka45ff.

[13] *Access to Preventive Services Without Cost-Sharing: Evidence from the Affordable Care Act, supra* note 9, at 7-8; Michelle R. Xu et al., *Impact of the Affordable Care Act on Colorectal Cancer Outcomes: A Systematic Review*, 58(4) Am. J. Prev. Med. 1, 2 (2020) (screening for colorectal cancer can decrease incidence and mortality by 30 to 60%).

financially prohibitive, and the number of colorectal screenings was declining.[14] But when this financial barrier was removed following the Task Force's recommendation, colorectal cancer screening rates increased for many populations.[15] As predicted, this increase in screening has been associated with decreased incidence of colorectal cancer, as well as resulting deaths.[16]

2. The preventive services provision has had a particularly notable impact on populations traditionally underserved by the healthcare system. Studies show that those with socioeconomic disadvantages have benefited the most from this provision, as the coverage has increased the likelihood they will receive preventive care and thereby reduced disparities in access to healthcare.[17] For instance, community health centers, which serve individuals with limited financial means, received increasing visits for a variety of screenings and

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[14] Djenaba A. Joseph et al., *Prevalence of Colorectal Cancer Screening Among Adults—Behavioral Risk Factor Surveillance System, United States, 2010*, Ctrs. for Disease Control & Prevention ("CDC") (June 15, 2012), https://tinyurl.com/nv5kt994.

[15] Xu et al., *supra* note 13, at 6.

[16] *Access to Preventive Services Without Cost-Sharing: Evidence from the Affordable Care Act*, *supra* note 9, at 8. The number of lives saved is likely to increase, as the Task Force recently updated its recommendation to require insurers to also cover certain follow-up tests for colorectal cancer. *FAQs About Affordable Care Implementation Part 51*, Dep't of Labor 12 (Jan. 10, 2022), https://tinyurl.com/282nxzk2.

[17] Norris, *supra* note 3, at 192, 194; Gregory S. Cooper et al., *Cancer Preventive Services, Socioeconomic Status, and the Affordable Care Act*, 123(9) Cancer 1585, 1588 (Jan. 9, 2017).

treatments after the ACA, including the preventive services provision, became effective.[18] Women, too, have benefited from the preventive services coverage requirements. Before the ACA, many insurers charged women higher rates and excluded numerous women's health services from coverage.[19] After the ACA, the Task Force recommended no-cost coverage for services specific to women's health such as mammograms, gestational diabetes tests, and cervical cancer screenings.[20] And no-cost coverage has also reduced racial and ethnic disparities in accessing health care by expanding access to a variety of preventive services.[21] For example, Hispanic and Black women have the highest rates of cervical cancer in the general population, and they increased their use of cervical cancer screenings following the enactment of the preventive services provision.[22]

3. In addition to improving health outcomes for specific individuals, the preventive services provision has promoted the public health more broadly by reducing the spread of highly infectious diseases. As one example, PrEP medication reduces the risk of

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[18] Nathalie Huguet et al., *Cervical and Colorectal Cancer Screening Prevalence Before and After Affordable Care Act Medicaid Expansion*, 124 Prev. Med. J. 91, 96 (2019).

[19] Munira Z. Gunja et al., *How the Affordable Care Act Has Helped Women Gain Insurance and Improved Their Ability to Get Health Care*, The Commonwealth Fund (Aug. 10, 2017), https://tinyurl.com/cfazjvw9.

[20] U.S. Preventive Servs. Task Force, *supra* note 3.

[21] *Access to Preventive Services Without Cost-Sharing: Evidence from the Affordable Care Act*, *supra* note 9, at 7.

[22] Huguet, *supra* note 18.

contracting HIV from sex by 99% and from intravenous drug use by 74%.[23] It is thus an invaluable tool in preventing the spread of this highly contagious, and lifelong, infection.[24] But the high cost of PrEP medication deters usage.[25] In 2018, when insurers were not required to cover PrEP medication, 87% of surveyed District of Columbia residents who inject drugs and are at high risk for HIV stated that they were not taking the medication but would be very or somewhat likely to do so if it were free.[26]

The Task Force has since recommended the use of PrEP medication, and private insurers have been required to cover the medication without cost sharing since 2021.[27] That year, 30% of the 1.2 million individuals who could benefit from PrEP were prescribed the medication—as compared to 13% of

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[23] *How Effective is PrEP?*, CDC (June 6, 2022), https://tinyurl.com/2s3k6w9z. CDC guidelines require those who receive PrEP medication to undergo comprehensive and frequent testing for sexually transmitted infections, so the receipt of PrEP medication also reduces the spread of other infections. *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update, A Clinical Practice Guideline*, CDC, 43 (2021), https://tinyurl.com/bddaxcd8.

[24] *How Effective is PrEP?*, *supra* note 23.

[25] Karishma Srikanth et al., *Associated Costs Are a Barrier to HIV Preexposure Prophylaxis Access in the United States*, 112(6) Am. J. Pub. Health 834, 835 (2022) (30-day supply costs $2,000).

[26] *Annual Epidemiology and Surveillance Report: Data Through December 2019*, D.C. Dep't of Health, 31 (2020), https://tinyurl.com/bdhtyz2u.

[27] Katie Keith, *USPSTF Recommends Access Without Cost Sharing to HIV Prevention*, Health Affs. (June 13, 2019), https://tinyurl.com/2t5tm254.

such individuals in 2017.[28] Without no-cost coverage, however, the country will backtrack in the progress it has made in combatting the spread of HIV.[29]

In short, the preventive services provision improves healthcare outcomes, reduces healthcare disparities, and saves lives.

B. The Amici States Depend On The Preventive Services Provision To Protect Their Residents' Access to Vital Health Care.

The Fifth Circuit's opinion places these advancements at risk. The court held that the members of the Task Force were "principal officers" of the United States who had not been validly appointed under the Appointments Clause. Pet. App. 26a. The court therefore concluded that respondents were entitled to an injunction barring the government from enforcing preventive services coverage requirements based on the Task Force's recommendations against them. *Id.* at 43a.[30] Although the injunction is limited

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[28] Press Release, CDC, *HIV Declines Among Young People and Drives Overall Decrease in New HIV Infections* (May 23, 2023), https://tinyurl.com/yh76ap9r.

[29] Meredithe McNamara et al., Braidwood *Misreads the Science: the PrEP Mandate Promotes Public Health for the Entire Community*, Yale Univ. (Feb. 13, 2023), https://tinyurl.com/ynzce8da (discussing a Harvard and Yale study estimating that if PrEP medication coverage is reduced by just 10%, there will be 2,083 additional HIV infections in the following year).

[30] The Fifth Circuit also revived respondents' challenges to the enforceability of preventive care recommendations issued by the Advisory Committee on Immunization Practices and the Health Resources and Services Administration, remanding these claims

to respondents, other litigants may rely on the Fifth Circuit's decision to persuade courts to reach the same conclusion and more broadly enjoin the Task Force's recommendations.

If the Task Force's recommendations cannot be enforced, the amici States will face significant obstacles in ensuring their residents' access to preventive services. That is because federal law prevents States from regulating the most common form of employer-sponsored health insurance. And even where States can mandate specific coverage, they rely on federal guidance as a practical matter. The elimination of the preventive services provision or uncertainty around its legality would thus strain the amici States' existing preventive services programs and their public health systems more broadly.

1. The amici States' authority to act on their own to ensure access to no-cost preventive care for their residents is constrained by the Employee Retirement Income Security Act of 1974 (ERISA), which limits the ways in which States can regulate employer-sponsored health plans. 29 U.S.C. §§ 1003(a), 1144(a), 1144(b)(2)(A). As a result, an injunction prohibiting the federal government from implementing the preventive services provision would leave significant gaps in coverage that the amici States would be unable to fill.

Employer-sponsored health plans are generally structured in one of two ways. The first is a "fully

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to the district court for further consideration. See Pet. App. 47a. An adverse ruling on those claims would further jeopardize public-health outcomes within the amici States.

insured" plan, in which the employer purchases an insurance contract to cover risks associated with its employee health plan.[31] The second is a "self-funded" plan, in which the employer uses its own funds to cover such costs directly.[32] Self-funded plans are increasingly common for a variety of reasons. For instance, many employers choose these plans because they prefer paying for actual bills presented by employees rather than pre-paying large premiums to insurance carriers.[33]

ERISA preempts the States from directly regulating self-funded employer health plans. 29 U.S.C. §§ 1003(a), 1144(a), 1144(b)(2)(A); see *FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) (States cannot directly regulate "self-funded employee benefit plans" under ERISA). Accordingly, if the preventive services provision cannot be enforced, the amici States would not be able to respond by enacting similar mandates to protect their residents enrolled in self-funded plans. And there are many such residents: In 2023, 65% of employees with employer-sponsored coverage were enrolled in self-funded plans.[34]

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[31] Paul Fronstin, *Trends in Self-Insured Health Plans Since the ACA*, Emp. Benefit Rsh. Inst. (Sept. 30, 2021), https://tinyurl.com/23cz42ph.

[32] *Ibid.*

[33] *What Is Self Funding?*, Health Care Adm'rs Assoc., https://tinyurl.com/2zfnsbkz.

[34] *2023 Employer Health Benefits Survey, Sec. 10: Plan Funding*, Kaiser Fam. Found. (Oct. 18, 2023), https://tinyurl.com/538n42zm.

In the absence of a federal preventive services mandate, then, it would be up to employers with self-funded plans to decide whether to continue to fully cover preventive services. As explained, before the ACA, many employer-sponsored plans did not fully cover preventive care despite the medical consensus regarding the benefits of such care. See *supra* p. 7; see also *Skyline Wesleyan Church v. Cal. Dep't of Managed Health Care*, 968 F.3d 738, 750 (9th Cir. 2020) (that insurers offered restricted coverage before California imposed coverage requirements was "strong evidence" that insurers would revert to original plans absent state regulation). Without a mandate, employers with self-funded plans are likely to revert to their prior practice, especially as to the more expensive preventive services. This will result in a patchwork of coverage within state borders, with many state residents left without access to preventive care. Experience teaches that these gaps in covered care will be felt most strongly by those least able to afford services,[35] including historically disadvantaged minorities and individuals, including children, living in poverty, as they took particular advantage of preventive care following the ACA's enactment, see *supra* pp. 9-10.[36]

2. To be sure, notwithstanding ERISA preemption, the amici States retain the authority to regulate many plans other than self-funded employee plans, including fully insured employee plans, plans purchased directly from the insurance market, and

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[35] Skopec & Banthin, *supra* note 3, at 3.

[36] *Corlette*, *supra* note 4.

state and local government plans.[37] The States have long exercised this authority to enact insurance mandates for the purpose of ensuring coverage for their residents.[38] But, as a practical matter, the decision below adversely impacts the States' ability to implement such mandates even where their authority to regulate is not preempted.

Generally, establishing insurance mandates at the state level is a multi-step, resource- and time-intensive process. Among other things, States must define qualifying coverage, set penalties for noncompliance, determine any exemptions, establish regulations for implementing the mandates, and provide guidance to stakeholders (such as employers and insurers) on the mandates' requirements.[39] Although costs vary from State to State, the process can be expensive and onerous.

When a federal mandate is in effect, the States can minimize these costs by adapting federal regulatory and statutory language, guidance, forms, instructions, and educational materials, rather than

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[37] Catherine Stamm et al., *A Primer on ERISA's Preemption of State Laws*, Mercer (Mar. 22, 2022), https://tinyurl.com/25f8658d; Justin Giovanelli et al., *The ACA's Preventive Services Benefit Is in Jeopardy: What Can States Do to Preserve Access?*, The Commonwealth Fund (Nov. 21, 2022), https://tinyurl.com/2t68c2um.

[38] Giovanelli et al., *supra* note 37.

[39] See Press Release, Cal. Dep't of Ins., *New Insurance Laws for 2022 Will Protect Californians' Health and Safety* (Jan. 4, 2022), https://tinyurl.com/mrzyrud3 (describing steps taken to implement California mandate); Jason A. Levitis, *State Individual Mandates*, Brookings Inst., 18 (Oct. 2018), https://tinyurl.com/37c6f8vm.

starting from scratch. As one example, federal guidance is particularly beneficial for States when determining which services to cover. Under the federal preventive services provision, the Task Force's medical experts provide and update science-backed recommendations for preventive care services. The States, in turn, can adopt these recommendations. Indeed, a number of States have chosen to do so.[40] Illinois, for example, requires covered insurers to provide no-cost coverage for all services recommended by the federal government pursuant to the ACA's preventive services provision.[41]

If the federal government cannot implement and enforce the preventive services provision, Illinois and the other amici States will have to conduct their own reviews of which services to cover (and for which populations) as well as continually update their determinations as medical knowledge and social needs evolve. Not only will this be time- and resource-intensive, but the amici States' experience implementing pre-ACA insurance mandates shows that relying on the States' individual processes leads to inconsistent coverage nationwide, produces confusion, and deters the use of preventive services.[42] Before there was a uniform national standard, for instance, individuals working for out-of-state

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[40] See, *e.g.,* Cal. Health & Saf. Code § 1367.002(a); D.C. Code § 31-3834.02(a)(2); 18 Del. Code § 3558(b); Md. Code Ann., Ins. § 15-1A-10; N.H. Stat. § 173B:26-2mm; N.Y. Ins. Law § 3216(g)(17)(E); Va. Code Ann. § 38.2-3438-3442.

[41] 50 Ill. Admin. Code § 2001.8(a)(1).

[42] Nicole M. Bellows, *State-Mandated Benefit Review Laws*, 41 Health Serv. Res. 1104, 1109 (June 2006).

employers had to determine whether they were entitled to insurance coverage according to the laws of the State where they resided or the State where their employer was headquartered.[43] And insurers operating in multiple States were required to consult state law in determining which preventive services to cover, a burden alleviated by the preventive services provision's national scope. To address these concerns, States will have to invest significant resources to enhance existing (or establish new) review processes and also to provide guidance to their residents and other stakeholders.

In short, although state preventive care mandates are an important tool for protecting the public health, they will be less effective without a corresponding federal mandate.

3. Finally, the fact that the Fifth Circuit determined that a party-specific rather than a universal injunction was warranted does not eliminate the problem for the amici States. As the United States explains, Pet. 30-31, unless corrected by this Court, the Fifth Circuit's opinion will remain binding precedent within that circuit, thus permitting a future litigant to bring an APA claim challenging any or all of the Task Force's decisions "and obtain a sweeping remedy that would render the Task Force preventive-services scheme inoperative nationwide." *Id.* at 31. The Fifth Circuit's opinion thus creates substantial uncertainty regarding the enforceability of the preventive services provision. This not only creates confusion for patients and providers

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[43] See Melissa Stuart, *Autism Insurance Reform: A Comparison of State Initiatives*, 8 Ind. Health L. Rev. 497, 524 (2011).

regarding what insurance plans will cover, but it also frustrates the amici States' ability to anticipate their residents' healthcare needs and prioritize their limited public health resources.

Absent clarity from this Court, for example, States will have to decide whether to proactively reallocate resources to state-operated medical facilities, which currently rely on the preventive services provision to bill insurance providers directly for preventive services that covered residents receive.[44] Similarly, amici States will have to evaluate whether and how to bolster existing programs geared towards providing no-cost preventive services for individuals not currently covered by the federal mandate, as these programs would be overwhelmed by the increased number of individuals needing assistance if the preventive services provision were unenforceable. Massachusetts, for instance, has established a PrEP Drug Assistance Program for residents whose access to the drug is not covered by the federal mandate.[45] This program served almost 300 clients in fiscal year 2022, but Massachusetts anticipates that its program capacity would be strained if the PrEP mandate were eliminated, as significantly more individuals would require the program's assistance. Other States and the District of Columbia have implemented similar

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[44] Nadia Chait & Sherry Glied, *Promoting Prevention Under the Affordable Care Act*, 39 Ann. Rev. Pub. Health 507, 514 (2018).

[45] *How Can Community Resource Initiative's PrEPDAP Help?*, Community Resource Initiative, https://tinyurl.com/2p9fn2dy.

financial assistance programs that could be exhausted if no-cost coverage of PrEP ended.[46]

Given the cloud cast by the opinion below over their residents' health coverage, the amici States must prepare now to address the serious repercussions that would result from elimination of this key component of the ACA. These concerns are not merely hypothetical; indeed, several States have already begun this time- and resource-intensive process.[47] But the States should not have to bear this burden while litigation remains pending in the lower courts, especially given the flawed nature of the Fifth Circuit's opinion. Instead, the Court should grant certiorari to clarify the constitutionality of the preventive services provision, safeguarding the amici States' ability to protect the health of their residents.

CONCLUSION

The petition for a writ of certiorari should be granted.

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[46] *Fact Sheet: Pre Exposure Prophylaxis Drug Assistance Program (PrEP DAP)*, D.C. Health, https://tinyurl.com/4rz62ubz; Erin Kim & Lyndsay Sanborn, *How Can States Stop HIV Transmission? Increase Access to Pre-Exposure Prophylaxis (PrEP)*, Nat'l Acad. for State Health Pol'y (Oct. 2018), https://tinyurl.com/2uf3t7at.

[47] For example, following the district court's decision in this case, Michigan undertook efforts to enact a partial preventive services mandate modeled on the federal provision in response to the district court's ruling in this case. See Letter from Governor Gretchen Whitmer to Mich. Dep't of Ins. Dir. Anita Fox (Apr. 3, 2023), https://tinyurl.com/mpjerj84; Press Release, Exec. Off. of the Governor, *Governor Whitmer Signs Legislation Protecting Health Care for Millions of Michiganders* (Oct. 19, 2023), https://tinyurl.com/bddrnuej.

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