Health Care in Motion

Timely, Substantive Updates on Policy Shifts · Actionable Advocacy to Protect Health Care

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Policy Flashpoints Heating up this Summer

Four fast-moving issues to watch and their impact on people with chronic conditions and disabilities

It has been a very eventful spring for health policy with major implications for health care access for individuals living with chronic conditions and disabilities or who would benefit from preventive care. Much of the policy tumult is coming from sweeping court decisions impacting a range of federal health laws and regulations. Meanwhile, Republicans in Congress are reprising a well-worn policy agenda that proposes major cuts to Medicaid and other safety net programs in the name of deficit reduction. Read on for an overview of these policy developments and how CHLPI and others are gearing up to respond, as well as for a bright spot on the horizon in the national fight against hepatitis C.

Medicaid Work Requirements

After a bit of a lull in the debate about Medicaid work requirements, the issue is back in the forefront. During the Trump Administration, the Centers for Medicare and Medicaid Services (CMS) encouraged state Medicaid programs to implement work requirements as a condition of Medicaid eligibility. As a result, thirteen states obtained approval to include work requirements in their Section 1115 waiver demonstration projects, a mechanism that allows CMS to waive traditional federal Medicaid rules to enable states to test out new ways to deliver and pay for care. However, following a slew of court decisions striking down work requirements and a change in Administration, few such programs were ever implemented, and work requirements seemed to lose momentum.

HIV Advocacy Opposing Work Requirements

The Federal AIDS Policy Partnership HIV Health Care Access Working Group (HHCAWG), which CHLPI currently co-chairs, has been one of many chronic illness advocacy groups strongly opposed to work requirements in Medicaid. For example, HHCAWG opposed Oklahoma's and Indiana's 2020 Section 1115 proposals to impose or extend work requirements.

Widescale adoption and implementation of work requirements in Medicaid would likely have disastrous implications for access to care, particularly for communities that already experience health care inequities. In Arkansas, over 18,000 individuals lost Medicaid coverage as a result of the state's brief implementation of work requirements. Many of those individuals lost coverage because they had difficulty navigating the complex system for reporting work

activities or showing that they qualified for an exemption. Research has suggested that work requirements are especially likely to harm women, people living with HIV, and adults with disabilities, and may be particularly hard to meet for the one in four Medicaid beneficiaries with limited internet access. There is also little evidence to demonstrate that work requirements advance the policy objective proponents claim, which is to push Medicaid beneficiaries to seek and gain employment. In fact, providing affordable health insurance through Medicaid helps people to work, particularly when coupled with well-administered, voluntary employment support programs.

Despite the evidence that work requirements threaten access to health care and do not promote employment among Medicaid beneficiaries, Republicans in Congress are reigniting the debate about Medicaid work requirements as part of discussions around lifting the debt ceiling. At the end of April, House Speaker Kevin McCarthy rallied Republicans to pass a debt ceiling package that included new work requirements for both Medicaid and the Supplemental Nutrition Assistance Program (SNAP). President Biden and Senate Democratic leadership have vowed to oppose work requirements.

Meanwhile, Georgia is moving forward with a work requirement in its Pathways to Coverage Section 1115 Medicaid waiver. Georgia—one of ten states that have not expanded Medicaid under the ACA—tied the work requirement to a modest expansion of coverage for uninsured Georgians with income below 100% of federal poverty level. The waiver was approved in the waning days of the Trump Administration, but the Biden Administration rescinded the approval on grounds that Georgia's program did not advance Medicaid's objective, which is to provide health coverage for low-income people. However, last year a federal court struck down the Biden Administration's decision, finding that CMS's rescission of the work requirement was arbitrary and capricious and that CMS had failed to take into account all potential benefits of implementing the requirement, including that rescinding the waiver approval would mean less Medicaid coverage in Georgia. CMS did not appeal this decision and the Pathways to Coverage program is slated to go into effect in Georgia on July 1, 2023. All eyes are on Georgia to see how implementation of the work requirement goes, and other states with Republican governors are eyeing this policy again.

Georgia's situation highlights the tension inherent in proposals that pair limited expansions of coverage with onerous requirements. On the one hand, many Georgians may be able to access Medicaid for the first time. However, the way the program is structured and the requirements to report work activities may leave out many members of communities most in need of expanded health care access.

Braidwood vs. Becerra

On March 30, 2023, Judge Reed O'Connor issued his much-anticipated decision on the remedy in *Braidwood Management. Inc. v. Becerra*. Judge O'Connor had ruled last year that a key component of the ACA's preventive services mandate was unconstitutional—specifically, the requirement that most private health plans cover without cost sharing services with a U.S. Preventive Services Task Force (USPSTF) grade of A or B. He also ruled that the requirement to provide pre-exposure prophylaxis for HIV (PrEP) violated the religious rights under the Religious Freedom and Restoration Act of one plaintiff, Braidwood Management, Inc. The court delayed ruling on the remedy for the violations until after additional briefing from both parties.

In his remedy decision, Judge O'Connor vacated and barred all federal agency action to enforce the mandate for private insurance plans to cover USPSTF-recommended services, including PrEP, without cost sharing when the recommendation issued after 2010, the year that Congress passed the ACA. The Biden Administration appealed the decision to the Fifth Circuit and asked for a stay of the decision during the appeal. On May 15, 2023, the Fifth Circuit stayed Judge O'Connor's decision until the Fifth Circuit decides the appeal, which means that the preventive services mandate remains fully enforceable at least until the Fifth Circuit rules.

CHLPI Advocacy to Defend Preventive Services

- CHLPI has provided information and analysis about the recent decision and its impact on access to various preventive services, including PrEP, through an FAQ and other media.
- CHLPI recently testified before the Massachusetts Legislature in support of state legislation to implement an ACA-like preventive services mandate at the state level.
- CHLPI is working with the Chronic Illness and Disability Partnership and others to identify cross-disease advocacy strategies to preserve access to preventive services and to highlight the ways in which *Braidwood Management* impedes efforts to promote health equity.

The stakes are high on appeal as the plaintiffs have filed a cross-appeal seeking an even broader judicial order that would potentially affect the ACA's mandate to cover other preventive services. These include women's and children's preventive services recommended by the Health Resources and Services Administration (HRSA) and vaccines recommended by the Advisory Committee on Immunization Practices (ACIP). Advocates are gearing up to support the Department of Justice in the appeal and to identify state and federal regulatory actions that could safeguard continued access for at least some populations to these important preventive services without cost sharing.

For various reasons, including the popularity of the ACA's preventive services protections, it is unlikely that most plans and employers will change plan designs mid-year, meaning most beneficiaries are unlikely to experience major changes in coverage immediately. Three key federal agencies that regulate health insurance (the Department of Labor, the Treasury, and the Department of Health and Human Services) also released an FAQ guidance document on the decision's applicability and encouraged insurers and employers not to make any mid-year plan changes. Nevertheless, the decision puts future plan designs with zero cost sharing, especially for more expensive preventive services, at risk. Advocacy will also likely include public pressure campaigns urging insurers and employers to maintain zero cost sharing for USPSTF-recommended preventive services even without a federal mandate to do so.

Mifepristone Cases

The battle over reproductive health rights continues, with the most recent fight centering around the Food and Drug Administration's (FDA) approval of mifepristone, one of two drugs commonly prescribed together for medication abortion. The FDA approved mifepristone over two decades ago, and during those two decades it has been safely and effectively used in the United States. However, last fall anti-abortion groups and individuals challenged the FDA's approval in federal court. On April 7, 2023, Texas federal district court Judge Matthew Kacsmaryk issued a decision overturning the FDA's approval of mifepristone and issuing a preliminary injunction that blocks the FDA's approval

of the drug. Just hours later, a federal district court in Washington issued a contradictory ruling in a case brought by Democratic state Attorneys General; that ruling prohibits the FDA from reducing the availability of mifepristone in the plaintiff states.

The Biden Administration asked the Fifth Circuit Court of Appeals for an emergency stay of Judge Kacsmaryk's ruling. The Fifth Circuit ruled that mifepristone could remain on the market, but with severe limitations on access. The Biden Administration and a manufacturer of mifepristone quickly asked the U.S. Supreme Court for a full stay of the Texas decision pending appeal, and the Supreme Court granted this request on April 21, 2023. This means that this decision will not affect the legal availability of mifepristone in any state until the case makes its way through appeal.

There is a lot at stake in the Texas case for reproductive justice and health care access advocates generally. Mifepristone is not solely used in medication abortion—it is also used to manage miscarriage and to treat a rare disease called Cushing's syndrome, and is being investigated as possible treatment for a host of other conditions, including multiple types of cancer. Moreover, if affirmed on appeal, the Texas court decision could threaten the legitimacy of the FDA itself by ushering in a new era where the FDA's authority to review and approve new drugs based on research results and scientific expertise is greatly diminished. It may also inject uncertainty into the drug research and approval process jeopardizing access to future life-saving treatments, as patient advocacy groups have argued. And, the case represents a further politicization of the courts, in which a judge may substitute their opinion for the scientific and clinical evidence review of the FDA. Both the federal district court and the Fifth Circuit ignored mifepristone's long history of safe and effective use as well as the significant record of evidence that the FDA used to approve and expand mifepristone's use.

National Hepatitis C Elimination Program

On a more positive note, the President's Budget for FY2024 includes a proposal for an ambitious new federal program that would greatly expand access to hepatitis C treatment in the United States. The budget proposes to allocate more than $11 billion in mandatory funding over five years for a National Hepatitis C Elimination Program. The high upfront cost of the proposal reflects the urgent need to eliminate hepatitis C as a public health threat: more than 2.4 million people living in the United States have chronic hepatitis C. And although the cure for hepatitis C has a more than 95% success rate, more than 15,000 U.S. residents die of hepatitis C every year.

CHLPI Advocacy to Eliminate Hepatitis C

CHLPI is committed to supporting efforts to combat hepatitis C and is engaged in a multi-pronged national advocacy and litigation campaign to end discriminatory restrictions to curative hepatitis C treatment, and to champion laws and policies that support the elimination of viral hepatitis.

The proposed Elimination Program identifies three main priorities: accelerating availability of point-of-care testing to remove barriers to treatment, broadening access to curative medications, and improving health care infrastructure to reach all affected individuals. The program would include a subscription model pricing mechanism for direct acting antivirals (DAAs), which are highly effective drugs that doctors have used for approximately 10 years to cure hepatitis C. Under the subscription model pricing mechanism, the federal government would negotiate

directly with manufacturers for access to drugs for people on Medicaid, justice-involved populations, people without insurance, and American Indian and Alaska Native individuals who are treated through the Indian Health Service. Louisiana and Washington have implemented similar subscription models for DAA access with some success. Additional funding would be allocated to clinical care services, provider network expansion, linkage and support services, and public education campaigns to identify the estimated millions of individuals who are living with hepatitis C but unaware of their status.

Former National Institutes of Health (NIH) Director and now White House Special Advisor Francis Collins is leading the effort to develop the Elimination Program alongside Senior Advisor Rachael Fleurence. However, for these efforts to reach fruition, Congress must appropriate funds through the congressional budget process. While a new mandatory spending program is unlikely to muster the bipartisan support needed to pass a divided Congress, the inclusion in the President's budget signals political energy to push for more visionary and systemic approaches to eradicating hepatitis C.

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