Health Care in Motion

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

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Where are we at on Health Policy?

8 Health Care Access Priorities to Follow in 2022

The year 2022 has already shown to be one of uncertainty, opportunities, and challenges. For people living with chronic illness and disabilities conditions, significant federal legislative and administrative priorities to protect and expand access to affordable and comprehensive care hang in the balance. As we near the end of the first 100 days of 2022, Health Care in Motion takes a moment to consider where we are at and what is ahead.

1. Build Back Better

Despite ambitious promises to deliver a bill to President Biden by the end of 2021, Build Back Better – the massive social spending bill <u>supported by the White House</u> and <u>passed by the House</u> in November – has hit significant stumbling blocks in the Senate. Though Senator Manchin (D-WV) had signaled a desire to work with the White House and his more progressive Democratic colleagues, collaboration on the bill ended acrimoniously in December with Manchin taking to Fox News to declare his <u>unequivocal opposition</u>. Since Congress reconvened, there has been relatively little action on negotiations, and Democrats moved to champion a voting rights package first. There was some hope that provisions of Build Back Better could be split up and passed separately, but those efforts have largely <u>fallen to the wayside</u>. (Though <u>recent comments</u> from Manchin suggest there might be room for movement.) Even President Biden's recently-released budget <u>failed to explicitly mention</u> key provisions of Build Back Better, though it did include an unspecified line item dedicated to "legislation that reduces costs, expands productive capacity, and reforms the tax system," leaving a door open for future agreements.

Build Back Better Health Care Priorities

- Close the Medicaid coverage gap in non-Medicaid expansion states (see CHLPI advocacy effort supporting this)
- Expand the ACA subsidies included in the American Rescue Plan Act, currently set to expire after 2022
- Expand Medicare benefits to include dental, vision, and hearing aids
- Allow the Secretary of Health and Human Services to negotiate Medicare drug costs
- Reduce cost sharing in Medicare Part D
- Extend post-partum care in Medicaid to 12 months
- Invest in home and community-based services





2. The 2023 budget process

The President's Budget was submitted to Congress on March 28, laying out President Biden's vision for revenue spending for the upcoming fiscal year. Although the budget did not include many of the priorities previously set out in the Build Back Better legislative campaign, the budget did include a series of key health care priorities for Congress' consideration. Among other priorities, the budget emphasizes spending on: (1) bio-preparedness; (2) addressing health disparities; (3) improving access to behavioral health services; and (4) investing in services for children and their families. The budget proposes a number of new funding streams, including \$9.9 billion to increase the ability for Centers for Disease Control and Prevention (CDC) to build health systems capacity; \$9.8 billion of mandatory funding to establish a national pre-exposure prophylaxis (PrEP) program that would guarantee access to the HIV prevention medication for all uninsured and under-insured individuals; and \$2.1 billion of mandatory funding to create a Vaccines for Adults program, providing no-cost vaccines for uninsured adults. Additionally, the budget proposes key policy changes to various insurance programs, which would improve access to care. Under the budget, Medicare beneficiaries and those enrolled in private insurance would have access to three behavioral health visits without cost sharing; the Medicare program would be required to increase access to behavioral health services by offering such services on par with medical and surgical offerings; and Medicaid programs would be required to offer PrEP without cost sharing or prior authorization. Existing programs would also get enhanced funding support. The Indian Health Services (IHS) would receive an additional \$2.5 billion of funding, and IHS funding would be made mandatory rather than discretionary, ensuring adequate funding for the program moving forward. The Title X family planning program would receive \$400 million, a 40% increase in funding over last year's budget.

The release of the President's Budget kicks off the annual budgeting process. Largely, the President's Budget serves as a recommendation for what Congress should prioritize. Congress is then responsible for passing a budget resolution, laying out planned revenue and spending, which will then guide budget legislation. However, in recent years, Congress has failed to pass a budget resolution. If that happens again, then the most recently passed budget resolution will remain in effect. From there, Congress is responsible for passing budget legislation, including appropriations bills and any reconciliation legislation that could impact mandatory spending. What remains to be seen is how quickly Congress will act, and whether the President's priorities will be realized in the final legislation.

3. Non-discrimination enforcement

Even without sweeping federal legislation, there is still much that can be done to strengthen and expand the Affordable Care Act (ACA) through administrative action. For instance, the Administration released the much-awaited Notice of Benefit and Payment Parameters (NBPP) rule for the 2023 plan year on December 28, 2021 (see Health Care in Motion issue from December 2021 for a run-down of key issues). The NBPP sets the rules and requirements for ACA regulated private insurance plans, and the proposed rule bolstered may of the ACA consumer protections that had languished or been rolled back under the Trump Administration. The proposed rule adds important protections for the LGBTQ community and people living with HIV and other chronic conditions, including clearer non-discrimination standards to identify and prohibit adverse tiering and other discriminatory plan designs, affordable standardized plan options that will be mandatory for plans being sold in the federally facilitated Marketplaces, and stronger provider network adequacy standards (including time and distance and waiting time access standards, as well as increased Essential





Community Provider requirements). Unfortunately, and despite strong advocacy from CHLPI and others, the proposed rule did not include any provisions prohibiting the use of co-pay accumulator policies (where a plan does not count co-pay assistance from a manufacturer toward a beneficiary's deductible or out-of-

pocket maximum). Advocates will continue to urge HHS to prohibit these policies, particularly for drugs that have no generic equivalent. Finally, the proposed rule asks for comments on how HHS can work with Qualified Health Plans to better address health disparities and promote health equity. Click here for comments submitted by the Federal AIDS Policy Partnership — HIV Health Care Access Working Group. Last week, a finalized NBPP was sent to the Office of Management and Budget (OMB) for review before publication in the Federal Register.

Section 1557 Regulation Rewrite?

Section 1557, one of the Affordable Care Act's most significant non-discrimination provisions, is also set for a regulatory update. Last week, HHS submitted a proposed rule to OMB for review. A revised rule could expand protections, particularly for the LGBTQ community and individuals living with HIV and chronic conditions. Stay tuned for more details!

4. Medicaid 1115 waivers

Medicaid 1115 waivers will continue to be in the forefront as states contemplate innovative ways to deliver and pay for services. Though the parade of dangerous policies that were proposed and approved by the Trump Administration has largely ended, there continue to be concerns about the outer limits of 1115 waiver authority, especially when it comes to waiving important benefits requirements and other patient protections on which people living with chronic illness and disabilities depend. All eyes are currently on the proposed 1115 waiver from Oregon. Last year, advocates pushed hard against a proposal to close the Medicaid formulary, limiting coverage to one drug per category/class and jeopardizing access to lifesaving medications for vulnerable communities. Oregon removed this element of its proposal before sending the application to the Centers for Medicare and Medicaid Services (CMS) for review. While there are certainly some laudable elements of the waiver – including a 24-month continuous coverage provision and expanded services to address social determinants of health – the proposal still contains a proposal to limit coverage of certain drugs that have been approved by the Food and Drug Administration through an accelerated pathway. This move could keep lifesaving drugs out of reach of Medicaid beneficiaries. CMS is accepting comments on Oregon's proposal until April 13th.

5. Implementation of national strategies to address the syndemics of HIV, hepatitis, STIs, and overdose

Last year, the Administration finalized several new or updated national strategies to address and end the overlapping and intersecting syndemics of HIV, hepatitis, sexually transmitted infections (STIs), and overdose in the U.S. These include the National HIV/AIDS Strategy, the Viral Hepatitis National Strategic Plan, the Sexually Transmitted Infections National Strategic Plan, and the Overdose Prevention Strategy. These plans and strategies provide an ambitious federal commitment to bolstering prevention and treatment across these syndemics, placing health equity and reducing widening health disparities at the center of each approach. Whether these plans translate to systemic reforms depends on how they are implemented and funded. (See the HIV Health Care Access Working Group co-chairs' letter to CMS about the National HIV/AIDS Strategy.) Advocates, including CHLPI, will be working to hold federal and state





policymakers accountable to ensure that the goals of each plan or strategy are realized. In an effort to support states in meeting the goals of the Viral Hepatitis National Strategic Plan, CHLPI has partnered with the O'Neill Institute and the National Viral Hepatitis Roundtable to launch Hep ElimiNATION, an initiative that will assess and evaluate the policy landscape and programmatic strategies impacting viral hepatitis elimination in the 50 states, Washington, DC, and Puerto Rico. This project will also offer guidance for states' ongoing efforts to develop viral hepatitis elimination strategies.

6. PrEP

Pre-exposure prophylaxis (PrEP) represents both the promise of scientific advances in ending the HIV epidemic and the failure of public health and health care policy to capitalize on those advancements. Despite the promises of this HIV prevention intervention, in 2018 only about 18% of the 1.2 million individuals who could benefit from PrEP were actually taking it. In 2022, the HIV community once again finds itself at a crossroads, with promising new medications recently approved or in the research pipeline hitting up against continued access challenges and growing disparities based on race and ethnicity. In December, the Food and Drug Administration (FDA) approved the first long-acting injectable medication for PrEP – long-acting cabotegravir, marketed under the brand name Apretude. The approval adds an important tool to the HIV prevention toolbox, particularly for individuals who struggle with adherence to daily oral regimens. However, the price tag – a list price of \$3,700 per dose (for an annual cost of \$22,200) – may put access out of reach for many individuals. Advocates are simultaneously pushing back on the list price and continuing to ensure that public and private payers provide affordable access to Apretude for those who could benefit.

In the coming weeks and months, it will be critical to ensure that public health and community-based programs are prepared to facilitate access to PrEP (particularly for people from communities that have been historically underserved), that prescribing and access decisions are based on sound, evidence-based policy, and that public and private payers adopt non-discriminatory access policies. It is imperative that HHS leads robust monitoring and enforcement efforts against health insurers that do not comply with the Affordable Care Act's preventive services mandate (including providing no-cost coverage of PrEP-related ancillary services such as lab testing). The President's Budget has also included a ten-year \$9.8 billion commitment for a national PrEP program for uninsured and underinsured people. (Read more about the national PrEP program proposals developed by Johns Hopkins University and colleagues and PrEP4All.) Advocates are also watching for notice and comment periods from the U.S. Preventive Services Task Force (USPSTF) on a potential update to the Grade A recommendation for PrEP. In November 2021, USPSTF requested comments on a proposed research plan to review the current USPSTF grade A for PrEP to incorporate new evidence and products and on January 13, 2022, the USPSTF finalized its PrEP research plan with only minor changes from the proposed version.

7. Looking to the courts

Health care continues to be a hot topic in the courthouse. Last year, as the Biden administration reevaluated several harmful Section 1115 waivers that had already been granted by the Trump administration, but had not yet come into effect, the Supreme Court opted not to hear arguments in *Cochran v. Gresham*, a consolidated case that challenged CMS' approval of Medicaid work requirements; instead, the case was held in abeyance pending further order by the court. *McCutchen v. Becerra*, another case challenging approval of





a Section 1115 waiver (this one with a closed formulary), was also stayed in federal district court pending further decision-making by the Biden administration. For now, both cases remain on hold, but litigation regarding 1115 waivers is far from over.

This year, in *Georgia v. Brooks-LaSure*, a federal district court in Georgia will weigh in on CMS' authority to withdraw approval of Section 1115 waivers. On December 23, 2021, CMS formally informed Georgia that it was withdrawing approval for the work and premium requirements contained in Georgia's section 1115 demonstration. CMS left other aspects of Georgia's demonstration in place—most crucially, a planned expansion of the Medicaid income eligibility threshold. In response, Georgia filed suit in federal court, arguing that the proposed Medicaid expansion was contingent on keeping the work and premium requirements in place, and that CMS' rescission of one provision, but not the other, amounts to a "bait and switch." According to Georgia, Section 1115 bestows upon CMS the power to waive Medicaid requirements, but there are no takebacks: once a waiver has been approved, the statute "provides CMS with no authority whatsoever to rescind, withdraw, or reconsider an approved demonstration."

Looking ahead, some cases that were previously stayed in federal court may move forward again in 2022. *Pennsylvania v. Trump*, originally filed in 2017, concerns a Trump-era rule that created a broad exemption to the Affordable Care Act's birth control coverage mandate for employers (and in some cases insurers) who claimed religious or moral objections. After a federal district court in Pennsylvania issued a nationwide preliminary injunction to prevent the rule from coming into effect, the Trump administration appealed, and the Supreme Court ultimately reversed, <u>lifting the nationwide injunction in 2020</u>. (You can read CHLPI's amicus brief opposing the rule here.) On remand to federal district court, the case was stayed pending new rulemaking by the Biden administration. Although the federal government missed its projected deadline to issue a new rule by February 2022, recent progress on other ACA rulemaking indicates that a new rule is likely forthcoming, which could reopen the case.

Meanwhile, in *Kelley v. Becerra*, a federal district court in Texas is considering a challenge to the preventive services mandate more broadly. The plaintiffs in *Kelley* object to the ACA's requirement that they must offer lifesaving preventive services without cost-sharing, and argue that the preventive services mandate violates the Appointments Clause, the Vesting Clause, the nondelegation doctrine, and the Religious Freedom Restoration Act. Although plaintiffs raise a specific religious objection to being required to cover PreP, their challenge is to the entire preventive services mandate, and a negative court ruling could result in a widespread loss of access to all types of preventive care. Both sides have moved for summary-judgment, and briefing is scheduled to be complete by May 6, 2022.

Finally, keep an eye out for a future issue of Health Care in Motion, which will explore a number of cases involving Section 1557, the nondiscrimination provision of the Affordable Care Act, with a focus on access to gender affirming care.

8. COVID outlook

As COVID continues to surge, advocates, providers, and consumers should monitor and inform state and federal policies aimed at keeping people safe and healthy. At the federal level, many COVID testing and treatment initiatives face substantial funding questions as the federal government stops accepting claims for reimbursement due to insufficient funds. At some point, the federal government is also expected to end the





Public Health Emergency (PHE), which has been <u>continuously renewed</u> since early 2020 and is currently set to expire on April 16th. The PHE has allowed federal and state governments to more nimbly respond to the pandemic. While the eventual end of the PHE may signal that the pandemic is under greater control, it will also mean the end to several health care access protections that were put in place during the pandemic to ensure low-income individuals had continuous access to care and treatment, particularly in Medicaid. During the pandemic, states received enhanced federal funding for their Medicaid programs as long as they kept individuals enrolled in Medicaid throughout the duration of the pandemic. When the PHE ends, the enhanced federal funding for Medicaid will also end and states will begin their regular renewal processes. This is likely to cause a significant number of people to lose coverage, either because they are no longer eligible for the program or because they fail to submit the necessary paperwork to keep their coverage. States have been aware of this transition issue, and some have been proactive about putting in place plans to ensure that individuals do not fall through the cracks. Nonetheless, this will be a massive change in the state Medicaid landscape, and individuals with chronic conditions are at risk of dangerous disruptions to care and treatment if adequate protections are not in place. CHLPI will dive into what the PHE means for people living with chronic conditions in an upcoming installment of Health Care in Motion.

In short, we have already seen major developments in health care policy in 2022 and expect more opportunities and challenges to come. Advocates should watch this space for more updates and ways to make your voices heard!

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