



Health Policy Briefing

August 30, 2021

House of Representatives Agrees to FY 22 Budget Resolution

The House of Representatives reached an agreement on the Senate-approved \$3.5 trillion fiscal year (FY) 2022 budget resolution, passing the spending plan along a party-line vote of 220-212 on Tuesday. The budget document contains reconciliation instructions and top-line spending figures for a broader package of measures such as Medicare expansion, immigration reform, climate change, and universal pre-K that could be advanced through the Senate without GOP support.

House Speaker Nancy Pelosi (D-Calif.) had pledged to not pass the Senate-cleared bipartisan infrastructure framework (H.R. 3684) until an agreement was reached on the budget reconciliation package, but she faced pushback from a moderate faction of her party that threatened to withhold support of the budget resolution without a commitment to hold a standalone vote on the infrastructure bill. Democratic leadership agreed to schedule a vote on the infrastructure package no later than September 27, regardless of the status of the budget reconciliation bill, and have also committed to consulting with moderate Senate Democrats in the drafting of the reconciliation bill given current concerns about the total size of the social spending package. Current surface transportation programs expire on October 1. Progressives in the House, however, continue to insist that a vote on infrastructure be held until after passage of the reconciliation bill to ensure that the Senate adopts their priorities, warning that they will vote against infrastructure if reconciliation is not passed first.

Congressional committees have already started drafting their portions of the spending package. Chairman Richard Neal (D-Mass.) announced that the House Ways and Means Committee will begin marking up its portion of the legislation the week of September 6. Provisions under the jurisdiction of Ways and Means include the expansion of Medicare benefits to include hearing, dental, and vision care, and the extension of enhanced Affordable Care Act (ACA) premium assistance, which is currently set to expire in 2022. The Energy and Commerce Committee is expected to hold its markup, which will include the expansion of Medicaid coverage in states that have opted not to expand their programs already, on September 13. Committees of jurisdiction are instructed to report their portions of the tax and spending legislation by September 15. Each chamber's Budget Committee will then compile the proposals into a single reconciliation package.

Inside

- Lawmakers Push HHS to Disburse Unspent COVID Relief Funds.....2
- Democrats Urge Leadership to Make Enhanced ACA Tax Credits Permanent.....2
- CBO Releases New Drug Pricing Modeling.....2
- FDA Approves First COVID-19 Vaccine.....2
- Agreement Reached on PDUFA VII Commitment Letter.....2
- Upcoming Congressional Hearings and Markups.....3
- Recently Introduced Health Legislation.....3

Lawmakers Push HHS to Disburse Unspent COVID Relief Funds

A bipartisan group of 41 senators has sent a [letter](#) to U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra urging the administration to disburse the unspent money remaining in the Provider Relief Fund (PRF) and other COVID-19 relief programs. The Government Accountability Office (GAO) recently reported that 25% of the approximately \$178 billion appropriated by Congress has not yet been distributed. The letter was led by Sens. Jeanne Shaheen (D-N.H.) and Susan Collins (R-Maine). They ask Secretary Becerra for an immediate update on the Department's plans to distribute the unobligated funds.

Democrats Urge Leadership to Make Enhanced ACA Tax Credits Permanent

A group of more than 30 members of the House of Representatives led by Rep. Lauren Underwood (D-Ill.) sent a [letter](#) to congressional leadership in support of a permanent expansion of the advance premium tax credits included in the *American Rescue Plan Act of 2021*. The lawmakers argue that "Americans across the country are already seeing their health care costs decrease substantially," and cite the recent announcement that during the special enrollment period (SEP) that ended on August 15 more than 2.5 million Americans signed up for new health insurance coverage through the health insurance marketplace. They urge leadership to include a permanent advance premium tax credit expansion in the forthcoming reconciliation package.

CBO Releases New Drug Pricing Modeling

The Congressional Budget Office (CBO) has released a [working paper](#) simulating the impact of legislative proposals that may substantially affect new drug development. CBO [previously estimated](#) that Democrats' signature drug-pricing legislation (H.R. 3) would have led to approximately eight fewer drugs introduced to the U.S. market over the 2020–2029 period (a 3% reduction) and 30 fewer drugs over the following decade (a 10% reduction). CBO's updated model estimates the impact of a policy that reduces the top quintile of expected returns on drugs by 15 to 25%. CBO estimates that such a policy would reduce the number of drugs entering the market by 0.5% in the first decade of the policy being in effect, and by 8% in the third decade. The impact of the policy would not be felt immediately because, given the long "runway" for new drugs to get to market, investment and development decisions for products launching in the near future have already been made within the paradigm of current law. According to industry experts, the CBO model underestimates the full impact of H.R. 3 on future drug development.

FDA Approves First COVID-19 Vaccine

The Food and Drug Administration (FDA) has approved the first COVID-19 vaccine – from Pfizer-BioNTech – for the prevention of COVID-19 disease in individuals 16 years of age and older. Pfizer's vaccine will continue to be made available for individuals aged 12-15 under an emergency use authorization (EUA). Full approval of the vaccine followed the manufacturer's submission of a biologics license application (BLA) building on the data and information evaluated in support of the company's EUA, which was first issued on December 11, 2020. The EUA was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial of thousands of individuals. To support the agency's approval decision, the FDA reviewed updated data and included a longer duration of follow-up in a larger clinical trial population.

Agreement Reached on PDUFA VII Commitment Letter

The Food and Drug Administration has reached an agreement with the pharmaceutical industry on the next round of prescription drug user fees. The parties released the [commitment letter](#) last Monday outlining the goals and procedures for the seventh reauthorization of the Prescription Drug User Fee Act (PDUFA VII) spanning 2023 through 2027. The agreement letter directs the agency, including the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), to improve staff hiring and retention, upgrade information technology, and to further incorporate real-world evidence (RWE) into regulatory decision making. Congress must pass legislation to renew the user fees, which fund 70% of CDER's annual budget, before the current authorization expires in September 2022.

Upcoming Congressional Hearings and Markups

House Small Business Committee hearing “What Comes Next? PPP Forgiveness,” 1:00 p.m.; September 1

House Homeland Security Subcommittee on Cybersecurity, Infrastructure Protection, & Innovation hearing “Stakeholder Perspectives on the Cyber Incident Reporting for Critical Infrastructure Act of 2021,” 12:00 p.m.; September 1

Recently Introduced Health Legislation

H.R.5067 — To amend title XVIII of the Social Security Act to clarify congressional intent and preserve patient access to home infusion therapy under the Medicare program, and for other purposes. Sponsor: Rep. Sewell, Terri A. [D-AL-7]; Committees: House - Energy and Commerce; Ways and Means

H.R.5061 — To direct the Secretary of Defense to carry out a pilot program to survey access to mental health care under the military health system, and for other purposes. Sponsor: Resident Commissioner Gonzalez-Colon, Jennifer [R-PR-At Large]; Committees: House - Armed Services

H.R.5054 — To amend title XVIII of the Social Security Act to improve the accuracy of geographic adjustment factors under the Medicare program and to permanently extend certain adjustments to such factors for certain localities, and for other purposes. Sponsor: Rep. Axne, Cynthia [D-IA-3]; Committees: House - Energy and Commerce; Ways and Means

H.R.5073 — To improve the Veterans Crisis Line of the Department of Veterans Affairs, and for other purposes; Sponsor: Rep. Delgado, Antonio [D-NY-19]; Committees: House - Veterans' Affairs

H.Res.603 — Expressing support for the designation of the week of August 25 through August 31, 2021, as “Black Breastfeeding Week” to bring national attention to the United States maternal child health crisis in the Black community and the important role that breastfeeding plays in improving maternal and infant health outcomes; Sponsor: Rep. Adams, Alma S. [D-NC-12]; Committees: House - Energy and Commerce

H.R.5086 — To amend the Comprehensive Addiction and Recovery Act of 2016 to authorize the Attorney General, in coordination with the Administrator of the Drug Enforcement Administration, the Secretary of Health and Human Services, and the Director of the Office of National Drug Control Policy, to award grants to covered entities to establish or maintain disposal sites for unwanted prescription medications, and for other purposes; Sponsor: Rep. Bonamici, Suzanne [D-OR-1]; Committees: House - Energy and Commerce

H.R.5091 — To establish certain requirements with respect to the appointment of the Attending Physician, and for other purposes; Sponsor: Rep. Gohmert, Louie [R-TX-1]; Committees: House - House Administration

H.R.5092 — To prohibit the federal government from requiring any citizen to be vaccinated, including federal agencies from requiring its employees to take any vaccination, without the citizen being fully advised in writing of all known potential risks from the vaccine and consultation with a physician followed by the voluntary informed consent of the citizen, and for other purposes; Sponsor: Rep. Gohmert, Louie [R-TX-1]; Committees: House - Energy and Commerce; Judiciary; Oversight and Reform

H.R.5094 — To amend title XX of the Social Security Act to provide for nursing home worker training grants; Sponsor: Rep. Horsford, Steven [D-NV-4]; Committees: House - Ways and Means

H.R.5099 — To amend title XVIII of the Social Security Act to move Medicare cost-sharing benefits from Medicaid to Medicare, and for other purposes; Sponsor: Rep. Schneider, Bradley Scott [D-IL-10]; Committees: House - Energy and Commerce; Ways and Means