



Health Policy Briefing

July 18, 2022

Build Back Better Pared Down to Drug Pricing, ACA Subsidies

After more than a year of negotiations, Sen. Joe Manchin (D-W.Va.) announced that he will only support provisions to lower the cost of prescription drugs and extend enhanced Affordable Care Act subsidies in the latest iteration of the President’s Build Back Better economic agenda. Democrats need the support of their entire caucus to pass the package via the budget reconciliation process. Manchin had previously raised concerns about the Democratic proposal to expand some taxes on businesses to extend the solvency of the Medicare program. He had stated that the language should be further scrutinized to ensure that it would not contribute to inflation or negatively impact taxpayers, but then pivoted to outright opposition to all tax increases in the package later in the week. The West Virginia Democrat also stated that he would not support new spending on climate measures or tax increases in the reconciliation bill. President Joe Biden has endorsed Democrats moving ahead on the drug pricing and ACA provisions, vowing to take executive action on the issue of climate change. Schumer has said he wants to pass the reconciliation bill by early August. Democrats are currently working with the Senate Parliamentarian to ensure the drug pricing measure complies with the rules of budget reconciliation. September 30 is the hard deadline for Democrats to use the fast-track budget process via the current resolution.

Burr Exits UFA Negotiations and Introduces Clean Bill

Senate Health, Education, Labor, and Pensions (HELP) Committee Ranking Member Richard Burr (R-N.C.) has pulled out of negotiations on the reauthorization of the Food and Drug Administration’s medical product user fees. Burr introduced a clean version of the reauthorization legislation last week. The ***Food and Drug Administration Simple Reauthorization Act (S. 4535)*** does not include provisions to overhaul the accelerated approval pathway or regulation of cosmetics, dietary supplements, and laboratory-developed tests – measures that are a part of

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the version of the bill ([S. 4348](#)) advanced by the Senate HELP Committee in June. He stated that his legislation “preserves the user fee agreements as they’ve already been negotiated—without harmful additions.” House Energy and Commerce Committee leadership Frank Pallone (D-N.J.) and Cathy McMorris Rodgers (R-Wash.) issued a statement urging the Senate to quickly take up the House-passed proposal ([H.R. 7667](#)). Congress must reauthorize the user fee programs for the next five fiscal years before the current agreements expire on September 30. Industry-paid user fees comprise a large part of the FDA’s budget. Therefore, if the timeline for passage slips, the FDA may need to send out pink slips notifying employees of impending furloughs or layoffs to comply with Federal employee union contracts requiring 60 days’ notice.

House Passes Veteran Burn Pit Legislation

The House of Representatives passed the ***Sergeant First Class Heath Robinson Honoring Our Promise to Address Comprehensive Toxics (PACT) Act*** ([S.3373](#)) last week by a 342-88 vote. The legislation would support veterans who have been exposed to toxic substances during military deployments. The bill would increase access to medical care and disability benefits for veterans by establishing presumptions of service connection related to toxic exposure, and by adding 23 burn pit and toxic exposure-related conditions to the VA’s list of service presumptions. It would also mandate more federal research on toxic burn pits. The Senate must clear the legislation before it is sent to President Joe Biden for his signature.

Appropriations Update

Senate Appropriations subcommittee chairs are working to draft their fiscal year (FY) 2023 spending bills for release at the end of this month, according to a panel spokesman. On the other side of the Capitol, House Democratic leadership is aiming to pass nine of the 12 annual appropriations bills by the August recess, with Defense, Homeland Security, and Legislative Branch being held back. A continuing resolution (CR) will likely be necessary to keep the government funded beyond the end of the fiscal year on September 30.

Focus Remains on Abortion, Reproductive Health

Abortion remains a focus of lawmakers on Capitol Hill following the recent Supreme Court decision to overturn ***Roe v. Wade***. The House of Representatives passed two bills last week aimed at protecting access to abortion. The ***Women’s Health Protection Act*** ([H.R. 8296](#)) would codify the right to an abortion. The ***Ensuring Access to Abortion Act*** ([H.R. 8297](#)) is focused on interstate abortion services and would protect individuals and abortion providers from prosecution. The votes were largely along party lines. The House plans to vote this week on legislation to create a statutory right to contraception ([H.R. 8373](#)). Sen. Catherine Cortez Masto (D-Nev.) attempted to pass legislation ([S.4504](#)) similar to H.R. 8297 last week, but Sen. James Lankford (R-Okla.) blocked the bill. Sen. Tim Kaine (D-Va.) stated that he is working with Sen. Susan Collins (R-Maine) and Lisa Murkowski (R-Alaska) on legislation to codify “a minimum federal guarantee of reproductive freedom” that would reflect the status quo prior to the Supreme Court ruling.

A group of more than 80 House Democrats sent a [letter](#) to the White House urging the Biden administration to issue a national emergency and public health emergency declaration on abortion access and to invoke the Public Readiness and Emergency Preparedness Act. “A public health emergency declaration can provide significant new authority and flexibility for a federal emergency response. Relevant activities may include but are not limited to Public Health Services Corps team deployments, Medicaid State Plan Amendment flexibilities to support safe-haven states, and the ability to accelerate access to new medications authorized for abortion,” the letter states.

The Biden administration released updated guidance last week to assure health care providers that they are protected by the Emergency Medical Treatment and Active Labor Act (EMTALA) if they terminate a pregnancy as a part of treatment in emergency circumstances. Since the Supreme Court overturned ***Roe v. Wade*** last month, there has been confusion around when providers can perform abortions without risking prosecution in states that have enacted bans on the procedure. “Today, in no uncertain terms, we are reinforcing that we expect providers to continue offering these services, and that

federal law preempts state abortion bans when needed for emergency care,” said Health and Human Services Secretary Xavier Becerra. “Under the law, no matter where you live, women have the right to emergency care — including abortion care.” HHS issued the rule saying that EMTALA requires that physicians’ judgment prevail to protect the health of women in labor and with conditions such as ectopic pregnancies or dangerously high blood pressure. To ensure hospitals and physicians comply, HHS said it will fine them and block payments from Medicare and Medicaid for non-compliance. Those in violation face fines ranging from about \$60,000 to \$120,000. In response, Texas has sued to block the new Biden administration rule.

The Federal Trade Commission (FTC) has committed to enforcing improper and illegal consumer location and health data privacy practices. Many lawmakers have raised concerns about the selling of location data by data brokers following the Supreme Court’s overturning of *Roe v. Wade*. “We will vigorously enforce the law if we uncover illegal conduct that exploits Americans’ location, health, or other sensitive data,” Acting Associate Director of the FTC’s Division of Privacy and Identity Protection Kristen Cohen wrote in a blog post last week. “The FTC’s past enforcement actions provide a roadmap for firms seeking to comply with the law.”

Marijuana Decriminalization Bill Coming This Week

According to recent reports, Senate Democrats plan to introduce legislation to decriminalize marijuana this week. The package has been negotiated by Majority Leader Chuck Schumer (D-N.Y.), Cory Booker (D-N.J.), and Ron Wyden (D-Ore.). The ***Cannabis Administration and Opportunity Act*** would remove marijuana from the list of drugs covered by the Controlled Substances Act, create grant programs to aid communities and individuals most impacted by drug offenses, and establish funding programs to provide loans to small cannabis businesses owned by disadvantaged individuals. It also requires that federal non-violent cannabis-related convictions and arrests be expunged within one year of enactment. The House of Representatives passed similar legislation earlier this year, but the bill faces long odds in the Senate, where most Republicans and some Democrats have expressed opposition to the proposal.

GAO Report on CDC Contact Tracing

The Government Accountability Office (GAO) has released a new [report](#) calling on the Centers for Disease Control and Prevention (CDC) to update the tools it uses for air traveler contact tracing. The report characterizes the agency’s current approach as old, slow, and prone to problems. “The data management system — developed in the mid-2000s — was not designed for rapid assessment or aggregation of public health data across individual cases” and does not allow the CDC to “efficiently analyze and disseminate data to inform public health policies and respond to disease threats,” the report said. The GAO recommends that the CDC redesign its system or create one that would allow broader, more effective surveillance.

988 Suicide Lifeline Goes Live

The United States transitioned the previous 10-digit National Suicide Prevention Lifeline to 988 on Saturday. The number provides 24/7 crisis care and also links to the Veterans Crisis Line. The ***National Suicide Hotline Designation Act***, signed into law in 2020, authorized 988 as a new three-digit number for suicide and mental health crisis. All telephone service and text providers in the United States and the five major U.S. territories were required to activate 988 no later than July 16. The 988 Suicide & Crisis Lifeline is a network of more than 200 state and local call centers supported by the U.S. Department of Health and Human Services through the Substance Abuse and Mental Health Services Administration. The 10-digit Lifeline number 1-800-273-TALK (8255) will continue to be operational after July 16 and will route calls to 988 indefinitely.

Biden, Trump Down in New NYT Poll

Sixty-four percent of Democratic voters prefer a candidate other than President Joe Biden in 2024, according to a New York Times/Siena College poll released last week, and only 13% of voters agreed that the nation was on the right track – a low that has not been seen in more than a decade. On the Republican side, nearly half of GOP primary voters prefer a candidate other than Donald Trump for president in 2024. Florida Governor Ron DeSantis is the most popular alternative.

Upcoming Congressional Hearings and Markups

Senate Homeland Security and Governmental Affairs hearing “Addressing Weapons of Mass Destruction and Health Security Threats to the Homeland;” 10:00 a.m.; July 19

House Oversight and Reform Select Subcommittee on the Coronavirus Crisis hearing “Understanding and Addressing Long COVID and Its Health and Economic Consequences;” 10:00 a.m.; July 19

House Veterans’ Affairs Committee markup of pending legislation including H.R. 6647 related to reimbursement for emergency treatment furnished through the Veterans Community Care program; 10:00 a.m.; July 19

House Energy and Commerce Subcommittee on Oversight and Investigations hearing “Roe Reversal: The Impacts of Taking Away the Constitutional Right to an Abortion;” 10:30 a.m.; July 19

Senate Commerce, Science, and Transportation Committee to consider President Biden’s nomination of Dr. Arati Prabhakar to be Director of the White House Office of Science and Technology Policy (OSTP); 10:00 a.m.; July 20

Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies hearing “Food Safety and the Food and Drug Administration;” the witness list can be found [here](#); 10:10 a.m.; July 20

House Veterans’ Affairs Subcommittee on Economic Opportunity hearing “Modernizing Veteran Education in the Shadow of COVID-19;” 1:00 p.m.; July 20

Senate Committee on Veterans’ Affairs hearing to examine the status of VA’s electronic health record modernization program; 3:00 p.m.; July 20

Recently Introduced Health Legislation

H.R.8323 — To amend the Social Security Act and the Internal Revenue Code of 1986 to include net investment income tax imposed in the Federal Hospital Insurance Trust Fund and to modify the net investment income tax; Sponsor: Rep. Doggett, Lloyd [D-TX-35]; Committees: House - Ways and Means

H.R.8324 — To amend title XXVII of the Public Health Service Act to establish requirements for the disclosure of certain information relating to health care sharing ministries, and for other purposes; Sponsor: Rep. Huffman, Jared [D-CA-2]; Committees: House - Energy and Commerce

S.Res.703 — A resolution designating June 2022 as “National Post-Traumatic Stress Awareness Month” and June 27, 2022, as “National Post-Traumatic Stress Awareness Day”; Sponsor: Sen. Sullivan, Dan [R-AK]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.4520 — A bill to establish the Food Safety Administration to protect the public health by ensuring the safety of food, preventing foodborne illness, maintaining safety reviews and reassessments of food additives, enforcing pesticide residue tolerances, improving the surveillance of foodborne pathogens, and for other purposes; Sponsor: Sen. Durbin, Richard J. [D-IL]; Committees: Senate - Health, Education, Labor, and Pensions

S.4521 — A bill to require the President to develop a strategy to ensure the health, safety, and general welfare of the civilian population of the United States in case of catastrophic incidents disabling 1 or more critical infrastructure sectors or significantly disrupting the critical functions of modern society, and for other purposes; Sponsor: Sen. Cornyn, John [R-TX]; Committees: Senate - Homeland Security and Governmental Affairs

H.Res.1226 — Expressing support for the designation of the week of July 19 through July 25, 2022, as “Black Maternal Mental Health Awareness Week”, and supporting the goals and ideals of raising awareness and understanding of maternal mental health conditions as they affect Black individuals; Sponsor: Rep. Blunt Rochester, Lisa [D-DE-At Large]; Committees: House - Energy and Commerce

H.R.8344 — To amend title XVIII of the Social Security Act to provide for additional requirements with respect to electrodiagnostic services under the Medicare program; Sponsor: Rep. Sessions, Pete [R-TX-17]; Committees: House - Energy and Commerce; Ways and Means

H.R.8345 — To prohibit an employer from terminating the coverage of an employee under a group health plan while the employer is engaged in a lock-out, and for other purposes; Sponsor: Rep. Axne, Cynthia [D-IA-3]; Committees: House - Education and Labor

H.R.8352 — To protect clean air and public health by expanding fence-line and ambient air monitoring and access to air quality information for communities affected by air pollution, to require hazardous air pollutant monitoring at the fence-line of facilities whose emissions are linked to local health threats, to ensure the Environmental Protection Agency promulgates rules that require hazardous air pollutant data measurement and electronic submission at fence-lines and stacks of industrial source categories, to expand and strengthen the national ambient air quality monitoring network, to deploy air sensors in communities affected by air pollution, and for other purposes; Sponsor: Rep. Blunt Rochester, Lisa [D-DE-At Large]; Committees: House - Energy and Commerce

H.R.8354 — To prohibit Federal financial participation under Medicaid for non-emergency transportation provided to access services for which Federal financial participation is prohibited; Sponsor: Rep. Carter, Earl L. “Buddy” [R-GA-1]; Committees: House - Energy and Commerce

H.R.8358 — To establish the Food Safety Administration to protect the public health by ensuring the safety of food, preventing foodborne illness, maintaining safety reviews and reassessments of food additives, enforcing pesticide residue tolerances, improving the surveillance of foodborne pathogens, and for other purposes; Sponsor: Rep. DeLauro, Rosa L. [D-CT-3]; Committees: House - Energy and Commerce

H.R.8361 — To help prevent suicide by giving people more control over their own lethal means purchase decisions, through the creation of a voluntary purchase delay database; Sponsor: Rep. Jayapal, Pramila [D-WA-7]; Committees: House - Judiciary

S.4535 — A bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes; Sponsor: Sen. Burr, Richard [R-NC]; Committees: Senate - Health, Education, Labor, and Pensions

S.4541 — Standing with Moms Act - A bill to require the Secretary of Health and Human Services to furnish tailored information to expecting mothers, and for other purposes; Sponsor: Sen. Rubio, Marco [R-FL]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.8373 — To protect a person's ability to access contraceptives and to engage in contraception, and to protect a health care provider's ability to provide contraceptives, contraception, and information related to contraception; Sponsor: Rep. Manning, Kathy E. [D-NC-6]; Committees: House - Energy and Commerce

H.R.8384 — To require the Secretary of Health and Human Services to furnish tailored information to expecting mothers, and for other purposes; Sponsor: Rep. Mace, Nancy [R-SC-1]; Committees: House - Energy and Commerce

H.R.8386 — To direct the Secretary of Veterans Affairs to establish internship programs relating to behavioral health, and for other purposes; Sponsor: Rep. Neguse, Joe [D-CO-2]; Committees: House - Veterans' Affairs

H.R.8390 — To require the Department of Defense to share best practices with, and offers training to, State and local first responders regarding how to most effectively aid victims who experience trauma-related injuries; Sponsor: Rep. Torres, Ritchie [D-NY-15]; Committees: House - Armed Services

H.R.8391 — To amend the Public Health Service Act to direct the Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Abuse, to award grants to eligible crisis centers to provide follow-up services to individuals receiving suicide prevention and crisis intervention services, and for other purposes; Sponsor: Rep. Trone, David J. [D-MD-6]; Committees: House - Energy and Commerce