



Health Policy Briefing

August 9, 2021

Infrastructure Update

The Senate worked over the weekend to consider the \$550 billion bipartisan infrastructure package, voting 68-29 to end debate on the bill. The process was delayed over disagreements about allowing additional votes on amendments, with Republicans forcing the chamber to use all 60 hours of debate before a final vote on passage of the bill. Without an agreement about votes on additional amendments to the bill, opponents could use up to an additional 30 hours of debate – setting up a final vote on passage of the bill for Tuesday morning. The Congressional Budget Office (CBO) estimates that the bill will add \$256 billion to the deficit over the next decade, while raising \$50 billion in revenue during that time. The Senate was scheduled to begin its recess on August 9, but Majority Leader Chuck Schumer (D-N.Y.) has pledged to keep the chamber in session until they wrap up both the bipartisan infrastructure bill as well as the fiscal year (FY) 2022 budget resolution. Consideration of the budget resolution, which is expected to be released Monday, requires 50 hours of debate and allows for the possibility of an unlimited number of amendments being offered.

Senate Appropriators Begin Work on FY22 Spending Bills

The Senate Appropriations Committee advanced its fiscal year (FY) 2022 Agriculture-Food and Drug Administration (FDA), Energy and Water, and Military Construction-VA spending bills last week. Each measure was approved by a 25-5 vote. The FDA would receive \$3.4 billion, a \$200 million increase. The Department of Veterans Affairs would receive \$112.9 billion, including \$97.5 billion for VA medical programs, a \$7.5 billion increase. Mental health programs at the VA would receive \$13.2 billion, a \$2.9 billion increase. The committee adopted an

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amendment from Sen. Jeff Merkley (D-Ore.) that would allow physicians in the VA to respond to questions from veterans about medical cannabis.

The House of Representatives passed nine of the 12 annual appropriations bills before adjourning for August recess. Lawmakers have until the end of the fiscal year on September 30 to pass individual appropriations bills or an omnibus funding measure or to reach an agreement on a continuing resolution (CR) to avoid a federal government shutdown. Both Senate Appropriations Chairman Patrick Leahy (D-Vt.) and Minority Leader Mitch McConnell (R-Ky.) agree that Democrats and Republicans must first negotiate top-line spending figures for each of the 12 spending bills before legislation is considered on the Senate floor. Republicans are pushing to increase defense and nondefense discretionary spending by an even amount, while the White House's budget proposed a 16.5% increase for nondefense spending and a 1.7% increase for defense.

HELP Advances Suicide Prevention, Maternal Health Bills

The Senate Health, Education, Labor, and Pensions (HELP) Committee advanced four bipartisan pieces of legislation last week aimed at improving suicide prevention, protecting pregnant workers, and supporting individuals with disabilities. The ***Pregnant Workers Fairness Act*** (S. 1486), which would strengthen protections for pregnant workers, was advanced by a vote of 19-2. Identical legislation (H.R. 1065) was advanced with bipartisan support by the House of Representatives in May. The ***Suicide Training and Awareness Nationally Delivered for Universal Prevention (STANDUP) Act of 2021*** (S. 1543) would incentivize states to implement suicide awareness and prevention training in schools. The ***Suicide Prevention Lifeline Improvement Act*** (S. 2425) aims to improve the suicide prevention hotline to provide higher quality support for callers. Each was approved by voice vote. The ***21st Century Assistive Technology (AT) Act*** (S. 2401) was also advanced by voice vote. The bill would reauthorize the ***Assistive Technology Act of 1998***.

Finance Leadership Launches Bipartisan Mental Health Effort

The Senate Finance Committee has launched a bipartisan effort to address barriers to mental health care in the U.S. Chairman Ron Wyden (D-Ore.) and Ranking Member Mike Crapo (R-Idaho) [invite](#) all panel members to contribute to the development of a bipartisan legislative package that they hope to introduce and markup this year. They specifically seek input on improving the behavioral health workforce, care integration, coordination, and access, mental health parity, and ways to expand telehealth services.

Democrats Push for Medicaid Expansion in Reconciliation Package

A group of 30 Democrats have sent a [letter](#) to congressional leadership urging the inclusion of the federally-administered Medicaid-like program from the ***Medicaid Saves Lives Act*** (S. 2315/H.R. 4595) in the upcoming budget reconciliation package. This bill would create a program almost identical to Medicaid that is administered by the federal government, allowing individuals with low incomes living in states that have not expanded Medicaid to access health care coverage. "We do not believe that access to health coverage should be dependent on where you live and people should not be penalized for living in states that continue to deny them Medicaid," the lawmakers state.

Lawmakers Express Opposition to Purdue Bankruptcy Plan

Sen. Elizabeth Warren (D-Mass.), Sen. Richard Blumenthal (D-Conn.), Rep. Carolyn Maloney (D-N.Y.), and Rep. Mark DeSaulnier (D-Wis.) have sent a [letter](#) to the Department of Justice (DOJ) urging it to immediately appeal Purdue Pharma's bankruptcy plan. The lawmakers argue that the plan, which would prevent individuals and states from pursuing further claims against the Sackler family, is an abuse of the bankruptcy system. "There is still time for the DOJ to play a key role in this case by seeking an immediate direct appeal to the Second Circuit Court of Appeals on the constitutionality of the Plan's nonconsensual third-party releases," the letter states, "Such an immediate direct appeal is appropriate as there is no controlling precedent on the constitutionality of nonconsensual third-party releases either in the Second Circuit or from the Supreme Court of the United States and this case involves a matter of public importance."

Warren, Blumenthal Push Back Against Juul Safety Claims

Senators Elizabeth Warren (D-Mass.) and Richard Blumenthal (D-Conn.) are asking regulators to take action against e-cigarette manufacturer Juul and its claims about its product's safety. The lawmakers sent letters to the [Food and Drug Administration](#) (FDA) and the [Federal Trade Commission](#) (FTC) as the FDA works to review premarket applications for e-cigarettes and certain other tobacco products and is expected to soon reach a determination about whether such products can remain on the market. They call on the FTC to take action against the company's "apparent efforts to perpetuate baseless claims on its product's safety compared to combustible cigarettes in an effort to addict not only adult smokers, but also youth non-smokers."

Lindsey Graham Tests Positive for COVID-19

Sen. Lindsey Graham (R-S.C.) announced that he has tested positive for COVID-19, after being fully vaccinated. He is experiencing mild symptoms. Graham had attended a recent event hosted by Sen. Joe Manchin (D-W.Va.) on his houseboat during which other members of the Senate were also in attendance. So far, no other members have tested positive.

MDUFA Negotiations Ongoing

Current negotiations between the Food and Drug Administration (FDA) and the medical device industry on a new user fee agreement appear to be at an impasse over how much user fees should be raised and about how the more than \$200 million carryover balance from past device user fee agreements should be spent. Historically, the two parties have set an informal deadline of mid-August to send a draft of the agreement to Congress for approval. The U.S. Department of Health and Human Services (HHS) is required to submit an agreement to Congress by January 15, 2022. The current user fee agreement is in effect through fiscal year (FY) 2022.

Treasury Begins Extraordinary Measures After Reinstatement of Debt Limit

The Treasury Department has begun taking special measures to avoid U.S. default on its obligations after the debt limit was reinstated on August 1 following a two year suspension. The Treasury department is pausing new investments in several federal employee retirement and benefit funds but noted that government retirees and employees will be unaffected. Treasury Secretary Janet Yellen has warned that such extraordinary measures could be exhausted soon after Congress returns from its August recess, while the Congressional Budget Office (CBO) estimates that lawmakers will likely have until October or November to raise or suspend the debt limit. In the meantime, the Treasury Department will need to continue curtailing borrowing to preserve cash. Action on the nation's borrowing authority is currently expected to move with a continuing resolution (CR) to fund the federal government beyond the end of the fiscal year on September 30.

Recently Introduced Health Legislation

H.R.4902 — *To amend the Internal Revenue Code of 1986 to treat diapers as qualified medical expenses; and to prohibit States and local governments to impose a tax on the retail sale of diapers. Sponsor: Rep. Watson Coleman, Bonnie [D-NJ-12]; Committees: House - Ways and Means; Judiciary*

H.R.4897 — *To amend the Public Health Service Act to require States receiving a block grant for prevention and treatment of substance abuse to allocate not less than 10 percent for recovery support services, and for other purposes. Sponsor: Rep. Spanberger, Abigail Davis [D-VA-7]; Committees: House - Energy and Commerce*

H.R.4890 — *To amend title XVIII of the Social Security Act to establish a program to allow qualified group practices to furnish certain items and services at qualified skilled nursing facilities to individuals entitled to benefits under part A and enrolled under part B of the Medicare program to reduce unnecessary hospitalizations, and for other purposes. Sponsor: Rep. Kuster, Ann M. [D-NH-2]; Committees: House - Ways and Means; Energy and Commerce*

H.R.4888 — *To encourage States to allow local governments to implement laws to reduce gun violence, and for other purposes. Sponsor: Rep. Kelly, Robin L. [D-IL-2]; Committees: House - Judiciary*

H.R.4884 — *To restrict employers from requiring an employee or an applicant for employment with such employer to undertake a medical procedure, including a vaccine, and for other purposes. Sponsor: Rep. Higgins, Clay [R-LA-3]; Committees: House - Education and Labor*

H.R.4880 — *To direct the Secretary of Veterans Affairs to establish a national clinical pathway for prostate cancer, and for other purposes. Sponsor: Rep. Dunn, Neal P. [R-FL-2]; Committees: House - Veterans' Affairs*

H.R.4870 — *To amend title XVIII of the Social Security Act to permit nurse practitioners and physician assistants to satisfy the documentation requirement under the Medicare program for coverage of certain shoes for individuals with diabetes. Sponsor: Rep. Blumenauer, Earl [D-OR-3]; Committees: House - Energy and Commerce; Ways and Means*

S.2576 — *A bill to amend title XVIII of the Social Security Act to establish a program to allow qualified group practices to furnish certain items and services at qualified skilled nursing facilities to individuals entitled to benefits under part A and enrolled under part B of the Medicare program to reduce unnecessary hospitalizations, and for other purposes. Sponsor: Sen. Thune, John [R-SD]; Committees: Senate - Finance*

S.2575 — *A bill to help individuals receiving disability insurance benefits under title II of the Social Security Act obtain rehabilitative services and return to the workforce, and for other purposes. Sponsor: Sen. Cotton, Tom [R-AR]; Committees: Senate - Finance*

S.Res.332 — *A resolution honoring the Centers for Disease Control and Prevention on the 75th anniversary of its establishment and expressing deep gratitude on behalf of the people of the United States to the scientists, disease detectives, career civil servants, and support staff at the Centers for Disease Control and Prevention for their dedication to protecting the health, safety, and security of the United States and to strengthening public health in the United States and abroad. Sponsor: Sen. Ossoff, Jon [D-GA]*

S.2586 — *A bill to amend the Public Health Service Act to enhance the national strategy for combating and eliminating tuberculosis, and for other purposes; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Health, Education, Labor, and Pensions*

S.2588 — *A bill to study the extent to which individuals are more at risk of maternal mortality or severe maternal morbidity as a result of being a victim of intimate partner violence, and for other purposes; Sponsor: Sen. Shaheen, Jeanne [D-NH]; Committees: Senate - Health, Education, Labor, and Pensions*

S.2589 — *A bill to amend the 21st Century Cures Act to provide for designation of institutions of higher education that provide research, data, and leadership on advanced and continuous manufacturing as National Centers of Excellence in Continuous Pharmaceutical Manufacturing, and for other purposes; Sponsor: Sen. Blackburn, Marsha [R-TN]; Committees: Senate - Health, Education, Labor, and Pensions*

S.2590 — *A bill to designate an Anomalous Health Incidents Interagency Coordinator to coordinate the interagency investigation of, and response to, anomalous health incidents, and for other purposes; Sponsor: Sen. Shaheen, Jeanne [D-NH]; Committees: Senate - Intelligence (Select)*

H.R.4911 — *To amend title XVIII of the Social Security Act to eliminate a provision under the Medicare Advantage program that inadvertently penalizes Medicare Advantage plans for providing high quality care to Medicare beneficiaries; Sponsor: Rep. Kind, Ron [D-WI-3]; Committees: House - Ways and Means; Energy and Commerce*

H.R.4916 — *To study the extent to which individuals are more at risk of maternal mortality or severe maternal morbidity as a result of being a victim of intimate partner violence, and for other purposes; Sponsor: Rep. Moore, Gwen [D-WI-4]; Committees: House - Energy and Commerce*

H.R.4918 — *To amend title XVIII of the Social Security Act to include store-and-forward technologies as telecommunications systems through which telehealth services may be furnished for payment under the Medicare program; Sponsor: Rep. Rosendale Sr., Matthew M. [R-MT-At Large]; Committees: House - Energy and Commerce; Ways and Means*

S.Res.336 — *A resolution designating September 15, 2021, as “International Myotonic Dystrophy Awareness Day” and supporting the goals and ideals of International Myotonic Dystrophy Awareness Day; Sponsor: Sen. Kaine, Timothy [D-VA]; Committees: Senate – Judiciary*

S.2595 — *A bill to address prescription drug shortages and improve the quality of prescription drugs, and for other purposes; Sponsor: Sen. Cardin, Ben [D-MD]; Committees: Senate - Health, Education, Labor, and Pensions*

S.2599 — *An original bill making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for the fiscal year ending September 30, 2022, and for other purposes; Sponsor: Sen. Baldwin, Tammy [D-WI]; Committees: Senate – Appropriations*

S.2604 — *An original bill making appropriations for military construction, the Department of Veterans Affairs, and related agencies for the fiscal year ending September 30, 2022, and for other purposes; Sponsor: Sen. Heinrich, Martin [D-NM]; Committees: Senate – Appropriations*

S.2609 — *A bill to amend title XVIII of the Social Security Act to ensure equitable payment for, and preserve Medicare beneficiary access to, diagnostic radiopharmaceuticals under the Medicare hospital outpatient prospective payment system; Sponsor: Sen. Blackburn, Marsha [R-TN]; Committees: Senate – Finance*

S.2612 — *A bill to amend title XVIII of the Social Security Act to add physical therapists to the list of providers allowed to utilize locum tenens arrangements under Medicare; Sponsor: Sen. Lujan, Ben [D-NM]; Committees: Senate - Finance*