



Health Policy Briefing

September 20, 2021

House to Consider CR, NDAA, and Debt Limit This Week

The Rules Committee in the House of Representatives will meet today to take up a stop gap funding bill and the National Defense Authorization Act (NDAA), setting up a House vote on the bills this week. The funding measure to avoid a government shutdown on October 1 is expected to run through December 3. It will include emergency relief in response to recent natural disasters and funding to support the processing of Afghan refugees. Majority Leader Steny Hoyer (D-Md.) stated that along with the continuing resolution (CR), the House would also take action on the debt limit this week. It remains unclear whether the CR will include a measure to raise or suspend the debt limit, with Democrats insisting that they will not address the debt limit via reconciliation and nearly all Senate Republicans in opposition to a clean debt limit increase or suspension. The House also plans to vote on both the bipartisan infrastructure framework and the **Build Back Better** reconciliation package during its current work period, which ends on October 1. Democrats still plan to move the two pieces of legislation in tandem, though House Budget Committee Chair John Yarmuth (D-Ky.) has suggested that House Speaker Nancy Pelosi (D-Calif.) could hold the infrastructure bill for a period of time prior to sending it to the President for his signature as the Senate begins its work on the reconciliation package.

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Reconciliation Content, Scope Under Debate as House Committees Complete Markups

Committees of jurisdiction in the House of Representatives have wrapped up work on the \$3.5 trillion ***Build Back Better*** reconciliation package, but significant differences remain to be negotiated both within the House Democratic caucus and between the House and Senate on the content and scope of the bill.

During the Energy and Commerce Committee's three-day markup, the panel agreed to the proposal to add vision, dental, and hearing benefits to the Medicare program. Rep. Kurt Schrader (D-Ore.) was the only Democrat to vote against the provision. Under the new benefit, vision coverage would begin in 2022, hearing coverage would begin in 2023, and dental coverage would begin starting in 2028. Energy and Commerce also cleared a proposal to expand Medicaid in states that have not yet done so prior to the creation of a federally-run Medicaid program in 2025. The measure would extend Affordable Care Act (ACA) insurance subsidies to Americans making less than 138% of the poverty level and would be coupled with a \$10 billion annual reinsurance program.

Democrats' signature drug pricing proposal, however, failed to advance in a tied committee vote. Reps. Kurt Schrader (D-Ore.), Scott Peters (D-Calif.), and Kathleen Rice (D-N.Y.) joined Republicans in voting against a measure that would have capped price increases for certain medications and created an international reference pricing mechanism. The proposal would have also placed a cap on out-of-pocket costs for Medicare beneficiaries. Rep. Peters is opposed to the bill's 95% penalty on manufacturers that do not agree to the government's price and has stated that he is working with congressional leadership on his own drug pricing proposal for inclusion in the reconciliation package. Democrats had planned to use the savings stemming from the drug pricing provisions to help pay for the reconciliation package overall.

Identical drug pricing language was advanced separately by the Ways and Means Committee last week. The only Democrat to oppose the Ways and Means reconciliation package was Rep. Stephanie Murphy (D-Fla.) who had announced her opposition in advance of the committee's consideration. The panel also approved legislation to make permanent the ACA's enhanced premium tax credits and to allow individuals receiving unemployment benefits to access premium-free insurance plans through 2025. In addition to the health care provisions, Ways and Means considered tax provisions that would raise more than \$2 trillion in revenue to pay for the social spending provisions. The tax portion of the Democrats' plan, which was advanced by a vote of 24-19, would raise the top corporate tax rate from 21% to 26.5% and increase the top rate on capital gains from 20% to 25%. Ways and Means adopted a proposal that would double the current rate of excise taxes on cigarettes and other tobacco products, while also imposing taxes on e-cigarettes. The Committee estimates that these provisions would generate \$96 billion in revenue.

President Joe Biden hosted Sens. Joe Manchin (D-W.Va.) and Kyrsten Sinema (D-Ariz.) for separate meetings at the White House last week to discuss the reconciliation bill. Both members have stated that they wish to pare back the total size of the package, with Manchin recently asserting that he would support a package totaling between \$1 and \$1.5 trillion. Democrats will have to be unified in their support for the reconciliation bill in the evenly divided Senate, and House Speaker Nancy Pelosi (D-Calif.) can only afford to lose three votes from her caucus when the bill comes to the House floor.

Lawmakers Encourage USPTO to Reform IPR Process

A bipartisan, bicameral group of lawmakers have sent a [letter](#) to the U.S. Patent and Trademark Office (USPTO) urging the agency to reassert its role in reviewing drug manufacturer's anticompetitive practices, specifically by ending the policies that have caused an increase in discretionary denials of patent challenges. The lawmakers assert that the inter partes review (IPR) process has been weakened by administrative changes that are not based in statute, and that USPTO's increasingly frequent denials for IPR for reasons not based on merits has made it more difficult to curb anti-competitive practices by prescription drug companies. "Without a sufficiently strong IPR system to serve as a check against questionable patents, brand manufacturers will continue to wield patent thickets that are nearly impossible to challenge and engage in product hopping, further burdening the American people with needlessly high drug prices," the letter states.

Lawmakers Urge CMS to Address Physician Fee Cuts

A group of more than 70 bipartisan members of the House of Representatives have sent a [letter](#) to the administration urging Director of the Center for Medicare Meena Seshamani to not finalize the clinical labor policy in the 2022 physician fee schedule (PFS) final rule. The letter, led by Reps. Bobby Rush (D-Ill.) and Gus Bilirakis (R-Fla.), warns that the cuts in the proposed rule disproportionately impact certain providers and may lead to practices closing down or consolidating with larger health systems. “Year-over-year ‘budget-neutral’ cuts, being implemented during a pandemic, are causing significant disruption to the health care system and are being implemented without regard to patient outcomes, actual PFS provider resource needs, or any other rationale policy,” the lawmakers argue. They urge Seshamani to work with Congress on fundamental reform to the PFS this year to better address the scheduled cut to the conversion factor resulting from budget neutrality requirements.

Lawmakers Push for PCHETA Inclusion in Reconciliation Bill

Sen. Tammy Baldwin (D-Wis.) and Rep. Yvette Clarke (D-N.Y.) are [urging](#) congressional leadership to include investments in the hospice and palliative care workforce in the reconciliation package currently under consideration. The lawmakers argue this funding is necessary “to keep pace with patient need and to help improve the well-being of Americans with serious illnesses.” They suggest that the bipartisan ***Palliative Care and Hospice Education and Training Act*** (PCHETA) be used as a model for these efforts. The request was [echoed](#) by more than 40 patient, health professional, and health system organizations including the American Academy of Hospice and Palliative Medicine, Oncology Nursing Society, Alzheimer’s Association, American Cancer Society Cancer Action Network, and Catholic Health Association of the United States.

DeGette, Upton Prepare Cures 2.0 for Introduction This Month

Reps. Diana DeGette (D-Colo.) and Fred Upton (R-Mich.) expect to introduce their Cures 2.0 legislation later this month, with the goal to pass the bill before the end of the year. The bill will include provisions to increase telehealth flexibility, speed the development of cutting-edge treatments, improve clinical trial diversity, increase pandemic preparedness, and authorize the Advanced Research Projects Agency for Health (ARPA-H). The ***Build Back Better*** reconciliation package currently under negotiation includes \$3 billion to start the President’s proposed biomedical research agency.

FDA Opens New Office of Digital Transformation

The Food and Drug Administration (FDA) has announced the creation of a new Office of Digital Transformation (ODT). The agency will be reorganizing its information technology (IT), data management, and cybersecurity functions under the new office, which will report directly to the FDA commissioner. The change is intended to aid in the reduction of duplicative processes, implementation of technological efficiencies, and promotion of shared services within agency offices and centers. It stems from the FDA’s Technology Modernization Plan first launched in September 2019 and the Data Modernization Action Plan released earlier this year. Vid Desai, who has worked as the FDA’s Chief Technology Officer since August 2019, will serve as ODT’s Chief Information Officer.

FDA Panel Recommends Boosters for At-Risk, 65+

The Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee voted in favor of recommending the Pfizer COVID-19 vaccine booster shot for individuals aged 65 or older and those who are at high risk of severe COVID. The panel voted against providing the booster to the population at-large by a vote of 16-2. Advisory committee members argued that Pfizer had not provided adequate data on the safety of an extra dose and questioned the potential efficacy of a mass-booster shot campaign. While the FDA is not obligated to follow the recommendations of the panel, it typically does so. A final decision from the agency is expected this week. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices will hold a two-day meeting this week to discuss COVID-19 booster shots for older Americans, nursing home residents, and front-line health care workers. Separate decisions from both the FDA and CDC will be required to move forward with providing booster shots for the three available COVID-19 vaccines. The U.S. has already approved an extra dose of the Pfizer and Moderna vaccines for populations with weakened immune systems. The White House had previously targeted September 20 to begin rolling out additional boosters.

New York Congressman Tests Positive for COVID-19

Rep. Joseph Morelle (D-N.Y.) announced that he has tested positive for COVID-19. He is the latest fully-vaccinated lawmaker to experience a breakthrough coronavirus case. Morelle stated that his vaccination against the virus has prevented him from experiencing a severe infection and urged others to get the COVID-19 vaccine to protect both themselves and their communities from the impacts of the disease.

Upcoming Congressional Hearings and Markups

House Rules Committee meeting on [H.R. 3755](#), Women's Health Protection Act; [H.R. _____](#) — An act making continuing appropriations for the fiscal year ending September 30, 2022, and for providing emergency assistance; [H.R. 4350](#), National Defense Authorization Act for Fiscal Year 2022; 12:00 p.m., September 20

House Committee on Veterans' Affairs hearing "Veteran Suicide Prevention: Innovative Research and Expanded Public Health Efforts;" 10:00 a.m., September 22

Senate Finance Committee hearing on the nomination of Christi A. Grimm, of Colorado, to be Inspector General, Department of Health and Human Services, and Neil Harvey MacBride, of Virginia, to be General Counsel for the Department of the Treasury; 10:00 a.m., September 22

House Energy and Commerce Subcommittee on Oversight and Investigations hearing "Putting Kids First: Addressing COVID-19's Impacts on Children;" 10:30 a.m., September 22

House Oversight and Reform Select Subcommittee on the Coronavirus Crisis hearing "Recognizing and Building on the Success of Pandemic Relief Programs;" 2:00 p.m., September 22

Senate Special Committee on Aging hearing to examine fraud, scams, and COVID-19, focusing on how older Americans have been targeted during the pandemic; 9:30 a.m., September 23

Recently Introduced Health Legislation

H.R.5241 — To amend title XX of the Social Security Act to provide grants to States to support linkages to legal services and medical legal partnerships. Sponsor: Rep. Spanberger, Abigail Davis [D-VA-7]; Committees: House - Ways and Means

H.R.5240 — To require geographical diversity in the provision of health profession opportunity grants under section 2008 of the Social Security Act, and to require the support services provided through the use of the grants to include a transportation assistance plan. Sponsor: Rep. Sewell, Terri A. [D-AL-7]; Committees: House - Ways and Means

H.R.5239 — To amend the Public Health Service Act to limit the liability of health care professionals who volunteer to provide health care services in response to a disaster. Sponsor: Rep. Ruiz, Raul [D-CA-36]; Committees: House - Energy and Commerce; Judiciary

H.R.5238 — To amend the Family and Medical Leave Act of 1993 and title 5, United States Code, to permit leave to care for an adult child, grandchild, or grandparent who has a serious health condition, and for other purposes. Sponsor: Rep. Ruiz, Raul [D-CA-36]; Committees: House - Education and Labor; Oversight and Reform; House Administration

H.R.5237 — To amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes. Sponsor: Rep. Peters, Scott H. [D-CA-52]; Committees: House - Energy and Commerce; Ways and Means; Judiciary

H.R.5235 — To amend the Public Health Service Act to authorize the Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, to award grants to eligible entities to establish or maintain a student mental health and safety helpline, and for other purposes. Sponsor: Rep. Newman, Marie [D-IL-3]; Committees: House - Energy and Commerce

H.R.5226 — To amend title 18, United States Code, to enhance criminal penalties for health related stalking, and for other purposes. Sponsor: Rep. Jackson Lee, Sheila [D-TX-18]; Committees: House - Judiciary

H.R.5224 — To amend the Public Health Service Act to authorize grants to eligible entities to develop strategic response plans with respect to the opioid crisis, and to require health care practitioners prescribing an opioid for certain patients to also prescribe an opioid overdose reversal drug, and for other purposes. Sponsor: Rep. Hill, J. French [R-AR-2]; Committees: House - Energy and Commerce

H.R.5218 — To amend the Public Health Service Act to increase uptake of the Collaborative Care Model. Sponsor: Rep. Fletcher, Lizzie [D-TX-7]; Committees: House - Energy and Commerce

H.R.5216 — To promote State requirements for local educational agencies and public elementary and secondary schools relating to the prevention and treatment of concussions suffered by students. Sponsor: Rep. DeSaulnier, Mark [D-CA-11]; Committees: House - Education and Labor

H.R.5214 — To amend the Internal Revenue Code of 1986 to permit expenditures from health savings accounts, flexible spending arrangements, and health reimbursement arrangements for dietary supplements. Sponsor: Rep. Curtis, John R. [R-UT-3]; Committees: House - Ways and Means

H.R.5212 — To amend title 38, United States Code, to require an annual report on veteran access to gender specific services under community care contracts, and for other purposes. Sponsor: Rep. Correa, J. Luis [D-CA-46]; Committees: House - Veterans' Affairs

H.R.5204 — To require certain passengers, employees, contractors, and subcontractors of Amtrak and air carriers to provide proof of vaccination against COVID-19 or a negative test for COVID-19 for certain transportation or employment, and for other purposes. Sponsor: Rep. Beyer, Donald S., Jr. [D-VA-8]; Committees: House - Transportation and Infrastructure

H.Res.633 — Expressing support for the designation of September 2021 as “National Prostate Cancer Awareness Month”. Sponsor: Rep. Payne, Donald M., Jr. [D-NJ-10]; Committees: House - Energy and Commerce; Ways and Means

S.Res.355 — A resolution supporting the recognition and goals of Overdose Awareness Day in the United States; Sponsor: Sen. Markey, Edward [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.2720 — A bill to direct the Secretary of Veterans Affairs to establish a national clinical pathway for prostate cancer, and for other purposes; Sponsor: Sen. Moran, Jerry [R-KS]; Committees: Senate - Veterans’ Affairs

S.Res.364 — A resolution supporting the designation of September 17, 2021, as “National Physician Suicide Awareness Day” to raise awareness of, and promote a national discussion about, physician suicide and to reduce the stigma of mental health issues; Sponsor: Sen. Stabenow, Debbie [D-MI]; Committees: Senate - Health, Education, Labor, and Pensions

S.2730 — A bill to direct the Secretary of Education to establish a pilot grant program to develop, implement, and evaluate comprehensive mental health services programs in elementary schools and secondary schools, and for other purposes; Sponsor: Sen. Padilla, Alex [D-CA]; Committees: Senate - Health, Education, Labor, and Pensions

S.2734 — A bill to require Senate confirmation of the Director of the Centers for Disease Control and Prevention; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate - Health, Education, Labor, and Pensions

S.2740 — A bill to establish a strategic active pharmaceutical ingredient reserve to maintain a domestic supply of active pharmaceutical ingredients and key starting materials needed for the manufacturing of essential generic medicines, and to build a pipeline for domestic active pharmaceutical ingredient production; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Health, Education, Labor, and Pensions

S.2741 — A bill to amend the Public Health Service Act to promote healthy eating and physical activity among children; Sponsor: Sen. Booker, Cory [D-NJ]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.5247 — To amend the Public Health Service Act to promote healthy eating and physical activity among children; Sponsor: Rep. Cohen, Steve [D-TN-9]; Committees: House - Energy and Commerce

H.R.5248 — To amend the Public Health Service Act to authorize the Provider Bridge Program, and for other purposes; Sponsor: Rep. Crow, Jason [D-CO-6]; Committees: House - Energy and Commerce

H.R.5260 — To amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients’ out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes; Sponsor: Rep. Peters, Scott H. [D-CA-52]; Committees: House - Energy and Commerce; Ways and Means; Judiciary