



Health Policy Briefing

October 11, 2021

Senate Passes Short-Term Increase to Debt Limit

Congress has temporarily averted a default on U.S. debt obligations, reaching an agreement to increase the debt limit by \$480 billion, which is estimated to allow the nation to meet its obligations through December 3, the same day the current continuing resolution (CR) funding the federal government is set to expire. Senate Majority Leader Chuck Schumer (D-N.Y.) and Minority Leader Mitch McConnell (R-Ky.) struck a deal that provided the 60 votes necessary to advance the bill. Republicans had previously refused to vote for a clean debt limit increase or suspension, insisting that Democrats address the debt limit through reconciliation, which would have necessitated a time-consuming process – time Democrats have argued they lacked before breaching the debt limit – and required Democrats to increase the cap to a specific number, rather than using a simple suspension through a certain date. McConnell has stated that Republicans will not provide assistance on the debt limit again. The House of Representatives is expected to pass the bill on Tuesday and send it to the President's desk for his signature.

Democrats Weigh Changes to Reconciliation Bill

While Democrats continue to iron out a path to passage of the **Build Back Better Act** reconciliation package, White House representatives have stated that there is no time frame for the bill. Negotiations involving progressive and moderate Democrats and President Joe Biden himself are ongoing, with lawmakers exploring the possibility of including more short-term spending in the domestic policy package. This would reduce the overall size of the legislation without having to choose specific cuts to the bill, leaving the opportunity to extend the programs to the future. Progressives appear to be in favor of maintaining as many programs as possible in the bill for a shorter time, while others in the party have argued in favor of funding a smaller number of programs for the long-term – to reduce the number of political votes that would be required when programs must be extended and to avoid the risk of letting programs lapse.

Sen. Joe Manchin (D-W. Va.) continues to insist that the total size of the package not exceed \$1.5 trillion, a

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figure many progressives have characterized as unacceptably low. The House version of the bill is estimated to cost at least \$3.5 trillion. While Manchin is standing by his concerns regarding the expansion of health and social welfare programs, he supports the inclusion of drug pricing reform and additional funding for home health care. Senate Budget Committee Chairman Bernie Sanders (I-Vt.) has criticized Manchin's calls for means testing new or expanded safety net programs, including the addition of dental, vision, and hearing care benefits to the Medicare program. President Biden has reportedly told progressives that he is open to setting income limits for some social programs in the bill, but it remains unclear just how much the lawmakers will be willing to scale back the size and scope of their priorities. Manchin has also stated that he will not support the package without the inclusion of the Hyde Amendment, which restricts federal funding for most abortions; the President has said he will sign a bill with or without the amendment. Sanders is requesting that Sens. Manchin and Kyrsten Sinema (D-Ariz.), who has also expressed opposition to the total size of the package, detail exactly what provisions they want to remove.

Progressives are standing by their demand that the stalled bipartisan infrastructure framework (BIF) and reconciliation bill be passed in tandem. Democrats are now targeting October 31 by which to pass the physical infrastructure legislation, in alignment with the 30-day extension of the Surface Transportation Authorization recently passed by Congress.

ARPA-H Out of Reconciliation Bill

The Advanced Research Projects Agency for Health (ARPA-H) will no longer be included in the Democratic reconciliation package currently under negotiation in Congress. The social spending and tax bill as drafted by the House of Representatives included \$3 billion for President Joe Biden's proposed research initiative to be housed within the National Institutes of Health (NIH). Senate Democrats confirmed last week that this funding is unlikely to be included in the final domestic policy legislation because it would not pass the chamber's rules for budget reconciliation. Reps. Diana DeGette (D-Colo.) and Fred Upton (R-Mich.) have confirmed that they will include ARPA-H authorizing language in their Cures 2.0 bill, an update to their biomedical innovation law the **21st Century Cures Act** (Public Law No. 114-255), and that they will release Cures 2.0 in the coming weeks. ARPA-H was proposed as a part of the President's fiscal year (FY) 2022 budget proposal, and the House's FY22 Labor, Health and Human Services, Education, and Related Agencies spending bill included appropriations funding, contingent on authorization of the new research agency. The outlook for the annual appropriations process, however, remains unclear as Congress is currently operating under a continuing resolution (CR) funding the federal government through December 3.

Ways and Means Leadership Criticizes Surprise Billing Regulation

House Ways and Means Committee Chair Richard Neal (D-Mass.) and Ranking Member Kevin Brady (R-Texas) have sent a [letter](#) to the Biden administration criticizing the latest regulation to implement the **No Surprises Act**, which aims to avoid patient receipt of surprise medical bills and provide an independent dispute resolution (IDR) process for disputes between plans and providers over payment. The lawmakers argue that the recent rule outlining how the (IDR) process will work to resolve billing disputes between providers and insurers does not "reflect the law that Congress passed." Neal and Brady state that the rule "biases the IDR entity toward one factor (a median rate) as opposed to evaluating all factors equally as Congress intended." They ask the administration to provide additional justification for how the proposed implementation of the IDR process is in line with the **No Surprises Act** statute. House Energy and Commerce Chair Frank Pallone (D-N.J.) and Senate Health, Education, Labor, and Pensions (HELP) Committee Chair Patty Murray (D-Wash.) applauded the rule for establishing "a fair payment resolution process between providers and insurers while finally taking patients out of the middle."

MA Prior Authorization Bill Continues to Gain Support

A majority of members in the House of Representatives have signed on as cosponsors of the *Improving Seniors' Timely Access to Care Act* (H.R. 3173). The bill would make changes to prior authorization in the Medicare Advantage (MA) program by establishing an electronic prior authorization process, minimizing the use of prior authorization for services that are routinely approved, requiring plans to report on the extent of their use of prior authorization and the rate of delays and denials, ensuring prior authorization requests are reviewed by qualified medical personnel, and ensuring that plans adhere to evidence-based medicine guidelines. H.R. 3173 currently has 227 cosponsors, with 129 Democrats and 98 Republicans in support of the bill introduced by Rep. Suzan DelBene (D-Wash.).

Democrats Urge Review of Contraception Coverage

House Energy and Commerce Committee Chair Frank Pallone (D-N.J.) and House Ways and Means Committee Chair Richard Neal (D-Mass.) have sent a [letter](#) to the Biden administration urging them to ensure the Affordable Care Act's (ACA) requirements to provide health insurance coverage for contraceptives approved by the Food and Drug Administration (FDA) continue to be enforced. The lawmakers express concerns about reports of recent denials of coverage and extensive medical management requirements "in contravention of the requirements under the law that ensure individuals can obtain coverage without cost-sharing for the full range of FDA-approved contraceptives." They ask the secretaries of Health and Human Services, Labor, and the Treasury to evaluate whether additional enforcement actions or the issuance of additional guidance is necessary.

NIH Director Collins to Retire

National Institutes of Health (NIH) Director Francis Collins has announced plans to resign after a nearly three-decade career at the agency. Collins, a physician-geneticist, was nominated to lead the NIH by President Obama in 2009 and was confirmed unanimously by the Senate. He is the longest-serving NIH director and the first presidentially appointed NIH director to serve in more than one administration. Collins previously directed the National Human Genome Research Institute and led the Human Genome Project. He plans to retire by the end of the year, and the President is expected to nominate a replacement before Collins leaves the agency.

FDA Commissioner Nomination Expected in Coming Weeks

President Joe Biden is closing in on a nominee to head the Food and Drug Administration (FDA) and is expected to announce his decision prior to November 15. Current names reportedly under consideration include Laurie Glimcher, president and CEO of the Dana-Farber Cancer Institute; Joshua Sharfstein, a former FDA deputy commissioner; and Michelle McMurry-Heath, head of the Biotechnology Innovation Organization. The White House faces a legal deadline to pick a nominee. Janet Woodcock, who is currently serving as acting FDA commissioner, can only remain in charge of the agency until mid-November unless she or another individual has been officially nominated for the position.

Senate Confirms DHS General Counsel

The Senate confirmed Jonathan Meyer as general counsel of the Department of Homeland Security (DHS) last week. Meyer's nomination was advanced by a 51-47 vote. As DHS' chief legal official, Meyer will play a role in shaping the department's immigration, cybersecurity, and counterterrorism policies. He previously worked as DHS deputy general counsel and senior counselor during the Obama administration.

DoD Sets Deadline for Civilian Vaccination

Department of Defense civilian employees will be required to be fully vaccinated against COVID-19 by November 22, 2021, according to an announcement from the department last week. Those with previous COVID-19 infections or previous serology will not be considered fully vaccinated for the purposes of this mandate. Additional guidance, including procedures for processing vaccination exemption requests, will be published by the Under Secretary of Defense for Personnel and Readiness in the future.

Upcoming Congressional Hearings and Markups

House Veterans' Affairs Subcommittee on Health legislative hearing; 2:00 p.m.; October 13

House Energy and Commerce Subcommittee on Consumer Protection and Commerce legislative hearing "Investing in American Jobs: Legislation to Strengthen Manufacturing and Competitiveness;" 12:00 p.m.; October 14

Recently Introduced Health Legislation

H.R.5474 — To make exclusive the authority of the Federal Government to regulate the labeling of products made in the United States and introduced in interstate or foreign commerce, and for other purposes. Sponsor: Rep. Trahan, Lori [D-MA-3]; Committees: House - Energy and Commerce

H.R.5471 — To amend the Occupational Safety and Health Act of 1970 to prohibit the Secretary of Labor from issuing a temporary standard with respect to COVID-19 vaccination or testing, and for other purposes. Sponsor: Rep. Tenney, Claudia [R-NY-22]; Committees: House - Education and Labor

H.R.5469 — To amend the 21st Century Cures Act to support State and local agencies with responsibility for children services in their response to the opioid abuse crisis, and for other purposes. Sponsor: Rep. Strickland, Marilyn [D-WA-10]; Committees: House - Energy and Commerce

H.R.5467 — To amend the Federal Food, Drug, and Cosmetic Act to clarify that artificial intelligence and machine learning technologies can qualify as a practitioner eligible to prescribe drugs if authorized by the State involved and approved, cleared, or authorized by the Food and Drug Administration, and for other purposes. Sponsor: Rep. Schweikert, David [R-AZ-6]; Committees: House - Energy and Commerce

H.R.5465 — To amend title 18, United States Code, to require federally licensed firearms importers, manufacturers, and dealers to meet certain requirements with respect to securing their firearms inventory, business records, and business premises. Sponsor: Rep. Schneider, Bradley Scott [D-IL-10]; Committees: House - Judiciary

H.R.5464 — To prohibit the imposition of a fine, fee, or taxation on any person for violation of a COVID-19 vaccine mandate issued by the Occupational Safety and Health Administration or any other executive agency, and for other purposes. Sponsor: Rep. Roy, Chip [R-TX-21]; Committees: House - Energy and Commerce; Education and Labor; Oversight and Reform; Ways and Means

H.R.5463 — To increase reporting requirements and transparency requirements in the 340B Drug Pricing Program, and for other purposes. Sponsor: Rep. Rosendale Sr., Matthew M. [R-MT-At Large]; Committees: House - Energy and Commerce; Ways and Means

H.R.5462 — To amend the Internal Revenue Code of 1986 to repeal the excise tax on indoor tanning services. Sponsor: Rep. Reed, Tom [R-NY-23]; Committees: House - Ways and Means

H.R.5461 — To rescind 1.3 percent of total defense spending and authorize the same amount for international COVID vaccine production and distribution. Sponsor: Rep. Pocan, Mark [D-WI-2]; Committees: House - Foreign Affairs; Appropriations

H.R.5452 — To amend title XVIII of the Social Security Act to include physical therapists as practitioners able to furnish telehealth services under the Medicare program. Sponsor: Rep. Hinson, Ashley [R-IA-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.5450 — To prohibit the use of Federal funds to implement or enforce a COVID-19 vaccine mandate, and for other purposes. Sponsor: Rep. Harshbarger, Diana [R-TN-1]; Committees: House - Energy and Commerce; Education and Labor; Oversight and Reform; Ways and Means

H.R.5442 — To direct the Secretary of Health and Human Services to submit to Congress a report on actions taken by the Secretary to ensure compliance with disclosure requirements relating to foreign influence. Sponsor: Rep. Curtis, John R. [R-UT-3]; Committees: House - Energy and Commerce

H.R.5440 — To amend the Homeland Security Act of 2002 to establish the Cyber Incident Review Office in the Cybersecurity and Infrastructure Security Agency of the Department of Homeland Security, and for other purposes. Sponsor: Rep. Clarke, Yvette D. [D-NY-9]; Committees: House - Homeland Security

H.R.5436 — To prohibit the sale of a firearm unless the firearm or packaging carries a label that provides the number of the National Suicide Prevention Lifeline. Sponsor: Rep. Brownley, Julia [D-CA-26]; Committees: House - Energy and Commerce

H.R.5435 — To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a Neuroscience Center of Excellence and a Neuroscience Translation Working Group, and for other purposes. Sponsor: Rep. Blumenauer, Earl [D-OR-3]; Committees: House - Energy and Commerce

H.R.5432 — To amend the Families First Coronavirus Response Act to require group health plans and health insurance issuers to cover T cell immune response testing without the imposition of cost sharing. Sponsor: Rep. Miller-Meeks, Mariannette [R-IA-2]; Committees: House - Energy and Commerce; Ways and Means; Education and Labor

H.R.5430 — To amend title XVIII of the Social Security Act to provide coverage for wigs as durable medical equipment under the Medicare program, and for other purposes. Sponsor: Rep. McGovern, James P. [D-MA-2]; Committees: House - Energy and Commerce; Ways and Means

H.Res.698 — Supporting the designation of October 2, 2021, as World Ostomy Day and National Ostomy Awareness Day. Sponsor: Rep. Payne, Donald M., Jr. [D-NJ-10]; Committees: House - Oversight and Reform

S.2925 — A bill to provide for a strategic plan for the domestic manufacture of necessary medical supplies or supplies needed to facilitate emergency or medical response, and for other purposes; Sponsor: Sen. Rosen, Jacklyn [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.5478 — To direct the Secretary of Health and Human Services to require disclosure of participation in foreign talent programs as a condition of receipt of Federal extramural biomedical research; Sponsor: Rep. Bilirakis, Gus M. [R-FL-12]; Committees: House - Energy and Commerce

H.R.5479 — To establish the Supply Chain Resiliency and Crisis Response Office in the Department of Commerce, and for other purposes; Sponsor: Rep. Bourdeaux, Carolyn [D-GA-7]; Committees: House - Energy and Commerce

H.R.5480 — To clarify the applicability of the Religious Freedom Restoration Act of 1993 to rules issued under the Occupational Safety and Health Act of 1970 and to amend such Act to prohibit emergency temporary standards with respect to vaccines, and for other purposes; Sponsor: Rep. Estes, Ron [R-KS-4]; Committees: House - Education and Labor

H.R.5487 — To improve research and data collection on stillbirths, and for other purposes; Sponsor: Rep. Herrera Beutler, Jaime [R-WA-3]; Committees: House - Energy and Commerce

H.R.5488 — To amend the Public Health Service Act to clarify that the Secretary of Health and Human Services shall lead all Federal public health and medical response to emergencies and disasters declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, and for other purposes; Sponsor: Rep. Hudson, Richard [R-NC-8]; Committees: House - Energy and Commerce; Transportation and Infrastructure; Homeland Security

H.R.5491 — To authorize the Director of the Cybersecurity and Infrastructure Security Agency to designate certain elements of critical infrastructure as systemically important, and for other purposes; Sponsor: Rep. Katko, John [R-NY-24]; Committees: House - Homeland Security

H.R.5492 — To establish an Office of Manufacturing Security and Resilience in the Department of Commerce, and for other purposes; Sponsor: Rep. Kinzinger, Adam [R-IL-16]; Committees: House - Energy and Commerce

H.R.5495 — To establish the Supply Chain Resiliency and Crisis Response Office in the Department of Commerce, and for other purposes; Sponsor: Rep. Malinowski, Tom [D-NJ-7]; Committees: House - Energy and Commerce

H.R.5503 — To amend title XVIII of the Social Security Act to preserve access to rehabilitation innovation centers under the Medicare program; Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Ways and Means; Energy and Commerce

H.R.5505 — To establish a National Resilience Center of Excellence in the Department of Commerce, and for other purposes; Sponsor: Rep. Wild, Susan [D-PA-7]; Committees: House - Energy and Commerce

S.2941 — A bill 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: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Health, Education, Labor, and Pensions

S.2952 — A bill to amend the Federal Food, Drug, and Cosmetic Act to allow manufacturers and sponsors of a drug to use alternative testing methods to animal testing to investigate the safety and effectiveness of a drug, and for other purposes; Sponsor: Sen. Paul, Rand [R-KY]; Committees: Senate - Health, Education, Labor, and Pensions

S.2971 — A bill to require the Secretary of Labor to revise the Standard Occupational Classification System to accurately count the number of emergency medical services practitioners in the United States; Sponsor: Sen. Casey, Bob [D-PA]; Committees: Senate - Health, Education, Labor, and Pensions

S.2973 — A bill to establish an Inspector General of the National Institutes of Health; Sponsor: Sen. Blackburn, Marsha [R-TN]; Committees: Senate - Health, Education, Labor, and Pensions

S.2974 — A bill to amend the Public Health Service Act to provide for a Reducing Youth Use of E-Cigarettes Initiative; Sponsor: Sen. Blumenthal, Richard [D-CT]; Committees: Senate - Health, Education, Labor, and Pensions

S.2982 — A bill to authorize the Secretary of Health and Human Services to award grants to establish or expand programs to implement evidence-aligned practices in health care settings for the purpose of reducing the suicide rates of covered individuals, and for other purposes; Sponsor: Sen. Schatz, Brian [D-HI]; Committees: Senate - Health, Education, Labor, and Pensions

S.2983 — A bill to provide for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions