



Health Policy Briefing

October 4, 2021

Congress Passes CR; Impasse Remains on Debt Limit, Infrastructure, and Reconciliation

The federal government will remain open following passage of a continuing resolution (CR) on September 30, the final day of the fiscal year (FY). The stopgap spending bill (H.R. 5305) funds the federal government at current levels through December 3. The measure also provides emergency funding for disaster relief and Afghan refugee resettlement and extends current restrictions on fentanyl analogues through January 28, 2022. The government’s authority to prosecute illegal possession of such substances was currently set to expire on October 22. The funding package passed both chambers with bipartisan support.

The government funding measure does not address the debt ceiling, which must be raised or suspended in the coming weeks to avoid a U.S. default. Treasury Secretary Janet Yellen warned lawmakers in a [letter](#) last week that her department will exhaust its extraordinary measures if Congress has not acted on the debt limit by October 18, warning that a failure to act will result in a financial crisis and recession. Democrats had hoped to address both government funding and the debt ceiling in a single vehicle, but Republicans have vowed to vote against a clean debt limit suspension or increase while Democrats have ruled out using the latest reconciliation package.

Passage of the bipartisan infrastructure framework has stalled because of Democratic disagreements over the latest reconciliation package. The House of Representatives had planned to vote on the \$550 billion infrastructure bill last week, but the vote has been postponed indefinitely because it lacked the necessary support for passage. Progressive Democrats have pledged to oppose the infrastructure legislation until agreement has been reached on the details and passage of the Build Back Better reconciliation measure. Sens. Joe Manchin (D-W. Va.) and Kyrsten Sinema (D-Ariz.) oppose the total size of the reconciliation bill as it currently stands at \$3.5 trillion. Following discussions between

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President Joe Biden and the two moderate senators on Friday, the upper limit of the social spending plan is now expected to land between \$1.5 trillion and \$2.3 trillion. It remains unclear whether there is enough support for the inclusion of certain health care related measures, such as the current versions of Medicare and Medicaid expansion and drug pricing provisions.

Latest Surprise Billing Regulation Released

The Biden administration released regulations last week outlining how the *No Surprises Act's* independent dispute resolution (IDR) process will work to resolve billing disputes between providers and insurers. The law, which applies to items and services provided under plans or coverage beginning on January 1, 2022 or later, aims to avoid patient receipt of surprise medical bills and provide a resolution process for disputes between plans and providers over payment. In the case of a billing dispute, patients can only be billed for the amount for which they would be responsible if the care had been delivered by a provider at a facility in their insurance network. This latest interim final rule details how dispute resolution process will work at the federal level for disputes that are not governed by state law or regulation.

As part of the federal IDR process, under the statute, arbitrators must consider rates paid for the same service in an area, the training and experience of the health care provider, the market share held by providers and payers, the complexity of a patient's case, certain facility factors, and whether providers and payers have made good faith efforts to contract with each other. They are prohibited from considering usual and customary rates or payment rates by public programs (i.e., Medicare and Medicaid). The rules released last week create an IDR framework where the qualifying payment amount (QPA) – based on a health plan's median contract rate for similar services in a geographic area – will be relied on as the primary benchmark upon which billing disputes are settled (when eligible for the federal IDR process). The Independent Dispute Resolution (IDR) entities that will conduct payment determinations will be certified on a rolling basis; applications are due by November 1. The rule also details requirements for providing cost estimates to uninsured individuals and for the external review process for individuals to dispute denied payment for some types of claims. The agency released two fact sheets on the rule, one on [requirements](#) related to surprise billing, and [another](#) on “what you need to know” about the administration's actions to prevent surprise billing. The administration also released a [fee guidance](#) for the IDR process, specifying the allowable fees that certified IDR entities will be able to charge in 2022, as well as the administrative fee that parties to a dispute must pay to undergo the dispute process.

The administration is expected to continue to release regulations as necessary to implement the No Surprises Act. While 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,” others such as Rep. Brad Wenstrup (R-Ohio) argued that the rule is not in keeping with congressional intent. “This HHS Second Rule on surprise billing is a disaster for patient access. Congress was very clear that we did not intend to create a de facto benchmark for negotiations when creating the arbitration process...If unchanged, this rule will disincentivize insurance companies from keeping providers in their networks, limiting care for Americans, and threatening the health and safety of our nation,” Wenstrup stated.

A bipartisan group of 97 representatives previously sent a [letter](#) to the agencies stating, “To match Congressional intent, your implementation of the law should ensure an IDR process that captures the unique circumstances of each billing dispute and does not cause any single piece of information to be the default one considered.”

Egorin Confirmed as HHS Assistant Secretary

The Senate confirmed Melanie Anne Egorin to serve as assistant secretary of Health and Human Services last week. Egorin has previously worked as deputy staff health director for the House Ways and Means Committee. Her nomination was approved by voice vote.

House Judiciary Advances Health, Marijuana Legislation

The House Judiciary Committee advanced four bills last week aimed at curbing anticompetitive practices that result in higher pharmaceutical prices. The ***Stop Stalling Access to Affordable Medications Act*** (H.R. 2883) would prohibit the use of citizen petitions by branded-drug companies to keep lower-cost generic competitors off the market. The ***Preserve Access to Affordable Generics and Biosimilars Act*** (H.R. 2891) would prohibit manufacturers from compensating other drug companies to delay the entry of a generic or biosimilar product to the market. The ***Affordable Prescriptions for Patients Through Promoting Competition Act*** (H.R. 2873) would enable the Federal Trade Commission (FTC) to crack down on product hopping. The ***Affordable Prescriptions for Patients Through Improvements to Patient Litigation Act*** (H.R. 2884) would limit the number of patents a biologic drug manufacturer can assert in litigation against a biosimilar competitor. The panel also advanced the ***Marijuana Opportunity, Reinvestment, and Expungement (MORE) Act*** (H.R. 3617), which aims to reform federal cannabis regulations by removing marijuana from the list of federally controlled substances and providing for the expungement of Federal marijuana convictions and arrests.

Lawmakers Release Agenda on Mental Health, Addiction

The Bipartisan Addiction and Mental Health Task Force released its [2021 legislative agenda](#) last week. The agenda contains measures that aim to increase access to recovery resources, end the stigma around addiction and mental health, support the public health infrastructure, and create safeguards against the flow of illicit drugs. The lawmakers are asking leadership of the House of Representatives to dedicate at least a week to the consideration of up to 60 addiction and mental health-related measures. The Task Force, announced earlier this year, merged the 116th Congress' Bipartisan Opioid Task Force and Freshmen Working Group on Addiction.

Burr Releases Latest Brief on Pandemic Response

Ranking Member of the Senate Health, Education, Labor, Pensions (HELP) Committee Richard Burr (R-N.C.) has released the latest in a series of reports on the federal government's continued pandemic response. The policy brief, "[Strengthening FDA's Regulatory Readiness: Implementing Lessons Learned from the COVID-19 Pandemic](#)," focuses on the Food and Drug Administration's (FDA) role throughout the pandemic and the challenges that arose during the agency's pandemic response. The report contains the following key recommendations:

- FDA should build on the steps it took to expedite the development and review of tests, therapeutics, and vaccines by encouraging the use of technologies, leveraging cross-agency scientific resources, and providing a clear and predictable pathway for test developers.
- FDA should prioritize the sustainability of medical product supply chains to prevent future disruptions by simplifying regulatory processes, incentivizing new ways to manufacture medical products, and modernizing the agency's use of remote tools to conduct inspections.
- FDA should leverage the regulatory authorities and flexibilities that were used throughout the pandemic to inform long-term improvements at the agency, strengthening overall FDA readiness and operations and enhancing real-time communication with American innovators.

Doc Caucus Urge CDC to Recognize Natural Immunity

Members of the GOP Doctors Caucus have sent a [letter](#) to the U.S. Centers for Disease Control and Prevention (CDC) urging the agency to acknowledge natural immunity from COVID-19. "Natural immunity, to date, has been dismissed without adequate scientific acknowledgment and the CDC continues to ignore scientific evidence when making policies to achieve herd immunity," the letter asserts. The lawmakers asked the CDC to work with other federal agencies to ensure all future policies and federally funded research consider natural immunity. The letter to CDC Director Rochelle Walensky was led by Sen. Roger Marshall, MD (R-Kan.) and signed by Sens. Bill Cassidy, MD (R-La.) and Rand Paul, MD (R-Ky.) and Reps. Andy Harris, MD (R-Md.), Mariannette Miller-Meeke, MD (R-Iowa), Larry Bucshon, MD (R-Ind.), Scott DesJarlais, MD (R-Tenn.), Gregory Murphy, MD (R-N.C.), Neal Dunn, MD (R-Fla.), Diana Harshbarger, PharmD (R-Tenn.), Buddy Carter, R.Ph. (R-Ga.), Jeff Van Drew, DMD (R-N.J.), Ronny Jackson, MD (R-Texas), Mark Green, MD (R-Tenn.), and Brian Babin, DDS (R-Texas).

Three VRBPAC Meetings Announced to Discuss Vaccine Boosters

The Food and Drug Administration (FDA) has announced three forthcoming meetings of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss Janssen and Moderna COVID-19 vaccine boosters, as well as Pfizer data on its COVID-19 vaccine for children aged 5-11. The meetings on vaccine booster doses will be held on October 14 (Moderna) and October 15 (Janssen). The meeting on Pfizer's latest data will be held on October 26. In related news, President Joe Biden received his booster of the Pfizer-BioNTech COVID-19 vaccine last week. During the event, the President stated that boosters "are important, but that the most important thing we need to do is get more people vaccinated." Senate Minority Leader Mitch McConnell (R-Ky.) also received his booster dose last week.

Justice Kavanaugh Tests Positive for COVID-19

Supreme Court Justice Brett Kavanaugh announced that he has tested positive for COVID-19. He has been fully vaccinated since January and is not experiencing symptoms. The Supreme Court will open their nine-month term with arguments in five cases this week; Kavanaugh plans to participate virtually from home.

Summary of ARPA-H Listening Sessions Released

The National Institutes of Health (NIH) and the White House have released a [report](#) summarizing the listening sessions held to date on the President's proposed Advanced Research Projects Agency for Health (ARPA-H). Of the fifteen listening sessions, ten sessions, led by NIH, focused on specific research areas. These sessions were open to the public. The remaining five sessions, led by the Office of Science and Technology Policy (OSTP), were invite-only and attended by various stakeholder organizations representing patient advocacy groups, biomedical professional groups, venture capital firms, private industry, and other non-biomedical STEM professional organizations. The report summarizes the major themes that arose across the fifteen listening sessions ranging from specific project or program proposals, potential collaboration avenues, and operational considerations. An additional listening [session](#) is planned for October 20 for participants to respond to the summary and offer additional recommendations.

New GAO Report on MIPS Provider Experience, Performance

The Government Accountability Office (GAO) has released a new [report](#) on the experience and performance of providers under the Merit-Based Incentive Payment System (MIPS). The report found that from 2017-2019, over 90% of providers earned a small increase (less than 2%) to their Medicare payments. Providers questioned whether MIPS helps to meaningfully improve quality of care or patient outcomes. Some providers interviewed also raised concerns that the program's design incentivizing reporting over quality improvement.

Upcoming Congressional Hearings and Markups

Senate Commerce, Science, and Transportation Committee hearing "Enhancing Data Security;" 10:00 a.m.; October 6

House Energy and Commerce Subcommittee on Communications and Technology legislative hearing "Strengthening Our Communications Networks to Meet the Needs of Consumers;" 12:00 p.m., 2123 Rayburn Bldg.; October 6

House Veterans' Affairs Subcommittee on Technology Modernization hearing on the *VA Electronic Health Record Transparency Act of 2021* and IT Reform and Data Collection Bills; 10:00 a.m.; October 7

Senate Commerce, Science, and Transportation Subcommittee on Communication, Media, and Broadband hearing to examine the state of telehealth, focusing on removing barriers to access and improving patient outcomes; 10:00 a.m.; October 7

Recently Introduced Health Legislation

H.R.5360 — To nullify certain executive orders regarding COVID-19 vaccine mandates and to prohibit the Secretary of Labor from issuing a rule mandating vaccination against COVID-19, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Oversight and Reform; Education and Labor; Energy and Commerce; Ways and Means

H.R.5365 — To amend title XVIII of the Social Security Act to expand Medicare Rural Health Clinic Services and Federally Qualified Health Center Services to include physical therapy services; Sponsor: Rep. Kind, Ron [D-WI-3]; Committees: House - Energy and Commerce; Ways and Means

H.R.5370 — To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to conduct a demonstration program to assess the effects of a hospital providing to qualified individuals medically tailored home-delivered meals, and for other purposes; Sponsor: Rep. McGovern, James P. [D-MA-2]; Committees: House - Ways and Means; Rules

H.R.5372 — To prohibit the Department of Health and Human Services from using any Federal funds to create or maintain an office to address climate and health equity, or for any climate change program, project, or activity; Sponsor: Rep. Perry, Scott [R-PA-10]; Committees: House - Energy and Commerce

S.2852 — A bill to amend title 38, United States Code, to authorize the Secretary of Veterans Affairs to enter into contracts and agreements for the payment of care in non-Department of Veterans Affairs medical foster homes for certain veterans who are unable to live independently, and for other purposes; Sponsor: Sen. Sinema, Kyrsten [D-AZ]; Committees: Senate - Veterans' Affairs

H.Res.684 — Recognizing the importance of ending the stigmatization of substance use disorder; Sponsor: Rep. Joyce, David P. [R-OH-14]; Committees: House - Energy and Commerce

H.Res.685 — Expressing support for the recognition of September 26, 2021, as “World Contraception Day” and expressing the sense of the House of Representatives regarding global and domestic access to contraception; Sponsor: Rep. Velazquez, Nydia M. [D-NY-7]; Committees: House - Energy and Commerce; Foreign Affairs

H.R.5377 — To facilitate the development of treatments for cancers, and for other purposes; Sponsor: Rep. Butterfield, G. K. [D-NC-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.5386 — To amend the Health Care Quality Improvement Act Of 1986 to recognize that physicians need to be protected from abuses of the peer reviewed process, and for other purposes; Sponsor: Rep. Scott, David [D-GA-13]; Committees: House - Energy and Commerce

H.R.5388 — 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: Rep. Spanberger, Abigail Davis [D-VA-7]; Committees: House - Energy and Commerce

S.Res.389 — A resolution supporting the designation of September 2021 as “National Alcohol and Drug Addiction Recovery Month”; Sponsor: Sen. King, Angus [I-ME]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.393 — A resolution designating September 2021 as “National Spinal Cord Injury Awareness Month”; Sponsor: Sen. Rubio, Marco [R-FL]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Voice Vote.

S.2866 — A bill to prohibit the Secretary of Health and Human Services from restricting direct access by health care facilities to COVID-19 monoclonal antibody therapies; Sponsor: Sen. Rubio, Marco [R-FL]; Committees: Senate - Health, Education, Labor, and Pensions

S.2873 — A bill to require the Secretary of Health and Human Services to award grants to establish or expand programs and activities to increase access to high-quality culturally competent trauma support and mental health care, and for other purposes; Sponsor: Sen. Coons, Christopher [D-DE]; Committees: Senate - Health, Education, Labor, and Pensions

S.2874 — A bill to amend the Internal Revenue Code of 1986 to exclude from gross income payments under the Indian Health Service Loan Repayment Program and certain amounts received under the Indian Health Professions Scholarships Program; Sponsor: Sen. Cortez Masto, Catherine [D-NV]; Committees: Senate - Finance

S.2880 — A bill to amend the National Defense Authorization Act for Fiscal Year 2020 to modify certain deadlines relating to the Commission on Combating Synthetic Opioid Trafficking; Sponsor: Sen. Cotton, Tom [R-AR]; Committees: Senate - Foreign Relations

H.Res.687 — Supporting the designation of September 2021 as “National Ovarian Cancer Awareness Month”; Sponsor: Rep. DeLauro, Rosa L. [D-CT-3]; Committees: House - Oversight and Reform

H.R.5390 — To amend the American Rescue Plan Act of 2021 to extend the premium assistance for COBRA Continuation Coverage for individuals and their families; Sponsor: Rep. Mrvan, Frank J. [D-IN-1]; Committees: House - Ways and Means; Energy and Commerce

H.R.5391 — To amend the Occupational Safety and Health Act of 1970 to prohibit emergency temporary standards with respect to vaccines, and for other purposes; Sponsor: Rep. Mann, Tracey [R-KS-1]; Committees: House - Education and Labor

H.R.5394 — To require the Secretary of Health and Human Services to establish a new program which ensures meaningful access to claims data by clinician-led clinical data registries, and for other purposes; Sponsor: Rep. Bucshon, Larry [R-IN-8]; Committees: House - Energy and Commerce; Ways and Means

H.R.5395 — To strengthen Buy American requirements, and for other purposes; Sponsor: Rep. Delgado, Antonio [D-NY-19]; Committees: House - Oversight and Reform; Ways and Means

H.R.5403 — To direct the Secretary of Defense to provide medical providers of the Department of Defense mandatory training with respect to the potential health effects of perfluoroalkyl or polyfluoroalkyl substances; Sponsor: Rep. Slotkin, Elissa [D-MI-8]; Committees: House - Armed Services

H.R.5405 — To amend the National Security Act of 1947, to direct the Director of National Intelligence to submit a biennial report on the biodefense activities and duties of the intelligence community, and for other purposes; Sponsor: Rep. Swalwell, Eric [D-CA-15]; Committees: House - Intelligence (Permanent Select)

H.R.5406 — To require the development of a plan for the establishment of an interagency biodefense task force on the attribution of certain biological events, and for other purposes; Sponsor: Rep. Swalwell, Eric [D-CA-15]; Committees: House - Energy and Commerce; Armed Services; Homeland Security; Natural Resources; Foreign Affairs; Financial Services; Ways and Means; Veterans' Affairs; Judiciary; Intelligence (Permanent Select); Agriculture

H.R.5407 — To amend the Higher Education Act of 1965 to promote comprehensive campus mental health and suicide prevention plans, and for other purposes; Sponsor: Rep. Wild, Susan [D-PA-7]; Committees: House - Education and Labor

S.2890 — A bill to allow the participants in the National Health Service Corps to defer their obligated service in order to receive training in palliative care services; Sponsor: Sen. Rosen, Jacklyn [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

S.2891 — A bill to amend title 35, United States Code, to address matters relating to the Patent Trial and Appeal Board of the United States Patent and Trademark Office, and for other purposes; Sponsor: Sen. Leahy, Patrick [D-VT]; Committees: Senate – Judiciary

H.R.5416 — To amend the Federal Food, Drug and Cosmetic Act to establish additional authorities of the Food and Drug Administration regarding the conduct of pediatric investigations of molecularly targeted drugs to treat cancer, and for other purposes; Sponsor: Rep. Butterfield, G. K. [D-NC-1]; Committees: House - Energy and Commerce

H.R.5425 — To amend title XVIII of the Social Security Act to protect access to telehealth services under the Medicare program; Sponsor: Rep. O'Halleran, Tom [D-AZ-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.5426 — To amend title XVIII of the Social Security Act to provide for Medicare coverage of staff-assisted home dialysis for certain hemodialysis and peritoneal dialysis patients and to ensure all patients are educated on modality options and receive the resources, information, and support to succeed on the modality of their choice, and for other purposes; Sponsor: Rep. Rush, Bobby L. [D-IL-1]; Committees: House - Energy and Commerce; Ways and Means

S.Res.398 — A resolution designating September 2021 as “National Kinship Care Month”; Sponsor: Sen. Wyden, Ron [D-OR]; Committees: Senate – Judiciary

S.Res.400 — A resolution designating September 2021 as “National Childhood Cancer Awareness Month”; Sponsor: Sen. Manchin, Joseph [D-WV]; Committees: Senate – Judiciary

S.Res.403 — A resolution designating September 2021 as “National Healthy Aging Month” to raise awareness of and encourage healthy lifestyle behaviors and the prevention and management of chronic health conditions among older adults; Sponsor: Sen. Scott, Tim [R-SC]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.2910 — A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the 180-day exclusivity period, and for other purposes; Sponsor: Sen. Smith, Tina [D-MN]; Committees: Senate - Health, Education, Labor, and Pensions