

Hart Health Strategies Inc.



September 27, 2021

House Passes Stopgap Spending Bill, Debt Limit Suspension

The House of Representatives passed a stopgap spending bill to fund the federal government beyond the end of the fiscal year (FY) on September 30 along with a debt limit suspension to avoid the U.S. government defaulting on its debts. The bill was approved in a 220-211 party-line vote. It would provide government funding through December 3, 2021 and suspend the debt ceiling through December 16, 2022. Also included were several emergency provisions, such as \$28.6 billion in emergency relief for states responding to recent hurricanes and wildfires and \$6.3 billion to support the resettling of Afghan refugees. The bill would also extend current restrictions on fentanyl analogues through January 28, 2022. The government's authority to prosecute illegal possession of such substances is currently set to expire on October 22. The Senate will likely vote this week to proceed to consideration of this legislation. Senate Republicans, however, have pledged to block the measure because of their opposition to a clean debt limit suspension or increase. Former Treasury secretaries Henry Paulson, Robert Rubin, Timothy Geithner, and Larry Summers, who served under both democratic and republican presidents, sent a letter to House Speaker Nancy Pelosi (D-Calif.) last week urging lawmakers to raise the debt limit. "Failing to address the debt limit, and allowing an unprecedented default, could cause serious economic and national security harm," the letter argues. They also warn that postponing action to raise the debt limit until too close to the deadline "undermines confidence in our political system at home and abroad."

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House Expected to Vote on BIF, Build Back Better This Week

I ouse Speaker Nancy Pelosi (D-Calif.) has pledged that the chamber will pass the \$550 billion bipartisan infrastructure framework (BIF) this week. The bill could be brought before the House of Representatives for consideration as early as today. Progressive Democrats continue to insist that the Build Back Better reconciliation bill be moved in tandem with or prior to the infrastructure package, and Speaker Pelosi stated her intention to pass both bills this week.

The House Budget Committee advanced the reconciliation bill on Saturday, assembling the 13 individual committee measures into a single 2,465 page piece of legislation, a necessary step before the legislation can be brought for a floor vote. The panel voted 20-17 to send the bill to the Rules Committee, with Rep. Scott Peters (D-Calif.) joining Republicans in opposition to the measure. Peters has been vocal in his opposition to the inclusion of the Medicare drug price negotiation provision. The reconciliation process precluded any substantive changes from being made to the package by the Budget Committee. Pelosi has indicated that she expects the reconciliation bill, which currently stands at \$3.5 trillion, to be scaled back. House Budget Committee Chairman John Yarmuth (D-Ky.) has made similar remarks, stating that he expects the Senate to make changes to the bill that will necessitate another House vote at a later date.

Senate Majority Leader Chuck Schumer (D-N.Y.) announced that the White House and congressional Democrats have reached an agreement on a framework to pay for the economic and social spending measure but did not provide any further details on the plan. It is nevertheless clear that intraparty disagreements remain between the moderate and progressive wings of the Democratic Party. Sens. Joe Manchin (D-W.Va.) and Kyrsten Sinema (D-Ariz.) continue to raise concerns about the total size of the President's tax and spending plan, with Manchin recently stating that he also opposes the expansion of Medicare benefits without first addressing the program's long-term solvency. It also is unknown whether the bill's drug pricing provisions – which would produce \$600 billion in funds to pay for the package – have enough Democratic support for inclusion. The proposals were opposed by four House moderates during committee markup and have also been criticized by Sen. Sinema.

Sanders Proposes Voucher Cards to Expand Medicare Benefits

Sen. Bernie Sanders (I-Vt.) is proposing a voucher system for the provision of dental, hearing, and vision coverage to Medicare beneficiaries. Under his proposal, individuals making less than \$75,000 per year and families with incomes below \$150,000 would receive \$1,000 debit cards to be used for the purchase of dental visits, hearing aids, or eyeglasses. Sanders' proposal, which he is seeking to add on to the reconciliation package currently under negotiation, would allow seniors to access these services earlier than is currently provided for in the reconciliation bill. Under the House Build Back Better plan, vision coverage would begin in 2022, hearing coverage would begin in 2023, and dental coverage would begin starting in 2028.

FDA, CDC Sign-off on Booster Shot Recommendations

The Food and Drug Administration (FDA) has amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine to allow for use of a single booster dose, to be administered at least six months after completion of the primary series in:

- individuals 65 years of age and older;
- individuals 18 through 64 years of age at high risk of severe COVID-19; and
- individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

Director for the Centers for Disease Control and Prevention (CDC) Rochelle Walensky <u>broke</u> with the recommendations of her agency's advisory committee in her decision to endorse the Pfizer booster shot for people at risk of contracting COVID-19 because of on-the-job exposure. The CDC is recommending:

- people 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 50–64 years with underlying medical conditions should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 18–49 years with underlying medical conditions may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
- people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational
 or institutional setting may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their
 Pfizer-BioNTech primary series, based on their individual benefits and risks.

The CDC's Advisory Committee on Immunization Practices (ACIP) had previously endorsed the Pfizer-BioNTech booster shot for people 65 and older, nursing home residents, and those with underlying medical conditions at risk of developing severe disease. Last week, ACIP's interim recommendations rejected a booster campaign for health care workers and others who may be at increased risk of contracting their virus through their jobs or an institutional setting. In overruling the advisers, Walensky noted that the CDC's recommendations for booster use will align with the FDA's authorization. The booster shot rollout will likely rely on a system of self-attestation.

Bipartisan Committee Leadership Support Enforcement of Hospital Transparency Rule

House Energy and Commerce Committee Chairman Frank Pallone (D-N.J.) and Ranking Member Cathy McMorris Rodgers (R-Wash.) have sent a <u>letter</u> to U.S. Department of Health and Human Services (HHS) Secretary Xavier Beccera in support of a Trump-administration regulation that would impose penalties on hospitals that do not commit to certain measures of price transparency. The Hospital Price Transparency Final Rule requires hospitals to publicly report standard charges for all items and services. The lawmakers express concerns with reports of low hospital compliance with the final rule, which suggest that 65 of the largest 100 U.S. hospitals were noncompliant as of early February. Pallone and Rodgers state their support for a recent proposed rule that would provide for greater penalties for hospital noncompliance.

Oversight Democrats Release New Report on Medicare Drug Price Negotiation

Democrats on the House Oversight and Reform Committee have released a new <u>report</u> estimating that the current ban on Medicare drug price negotiation has cost taxpayers at least \$25 billion for just seven drugs over the last four years. This is the eighth staff report stemming from the panel's two-year investigation into pharmaceutical industry pricing. The lawmakers argue that Medicare Part D has driven financial growth for drug manufacturers faster than in the commercial market. The report asserts that permitting government negotiation with just three insulin manufacturers would have saved \$16.7 billion between 2011 and 2017.

OH Democrat Tests Positive for COVID-19

Rep. Tim Ryan (D-Ohio) announced that he has tested positive for COVID-19. He attributed the fact that he is only experiencing mild symptoms to the protection of the safe and effective vaccine. More than 80 members of Congress have contracted the virus since spread began in March 2020.

Grassley to Run for Reelection

I owa Republican Senator Chuck Grassley announced that he will seek an eighth term next year. Grassley, at 88 years old, is one of the oldest members of the Senate. Grassley has served in the Senate since 1981 and has recently chaired the Finance and Judiciary committees.

WH Increases Vaccine Donation Pledge

The White House announced during its global COVID-19 Summit last week that it plans to purchase 500 million additional doses of the vaccine to distribute to the world's poorest nations, bringing the United States' total commitment to 1.1 billion doses. The administration has set a goal of vaccinating 70% of the world's population by September 2022, though experts estimate that it could take at least that long to distribute the total amount of U.S. vaccine donations. Approximately 30% of people worldwide are fully vaccinated. Earlier in the week, a bipartisan group of House lawmakers led by Rep. Susan Wild (D-Pa.) sent a letter to the President arguing that "the speed at which critical donations are being provided, and appropriated funds are being transparently allocated, is neither matching the desperate urgency of this deadly pandemic nor fulfilling the previous commitments that have been made."

New COVID-19 Guidance for Federal Contractors

The White House has set a deadline of December 8 for federal contractors to be fully vaccinated. The <u>guidance</u>, released on Friday by the Office of Management and Budget (OMB), is expected to impact tens of millions of U.S. workers. The guidance was issued in response to an <u>executive order</u> signed by President Joe Biden on September 9 requiring federal contractors to mandate vaccinations.

Upcoming Congressional Hearings and Markups

House Education and Labor Subcommittee on Civil Rights and Human Services hearing "How to Save a Life: Successful Models for Protecting Communities from COVID-19;" 10:15 a.m.,; September 28

House Judiciary Committee markup of legislation including H.R. 3429, the "Stopping Harmful Offers on Platforms by Screening Against Fakes in E-commerce Act of 2021" or the "SHOP SAFE Act of 2021"; H.R. 2883, the "Stop Stalling Access to Affordable Medications"; H.R. 2891, the "Preserve Access to Affordable Generics and Biosimilars Act"; H.R. 2873, the "Affordable Prescriptions for Patients Through Promoting Competition Act of 2021"; H.R. 2884, the "Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act"; H.R. 3617, the "Marijuana Opportunity Reinvestment and Expungement Act of 2021" or the "MORE Act of 2021"; 10:00 a.m.; September 29

House Oversight and Reform Select Subcommittee on the Coronavirus Crisis hearing "Upgrading Public Health Infrastructure: The Need to Protect, Rebuild, and Strengthen State and Local Public Health Departments;" 2:00 p.m.; September 29

Senate Foreign Relations Committee hearing to consider nominations, including the nomination of Dr. Atul A. Gawande to be an assistant administrator of the U.S. Agency for International Development (USAID); 2:00 p.m.; September 29

House Veterans' Affairs Subcommittee on Technology Modernization hearing "Modernizing and Securing VA's IT Infrastructure;" 2:00 p.m.; September 30

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Recently Introduced Health Legislation

H.R.5287 — To award a Congressional Gold Medal to honor the contributions of all of those whose efforts led to the successful development of life saving vaccines to combat the novel coronavirus. Sponsor: Rep. Rush, Bobby L. [D-IL-1]; Committees: House - Financial Services; House Administration; Budget

H.R.5273 — To establish a Gun Safety Board, and for other purposes. Sponsor: Rep. DeSaulnier, Mark [D-CA-11]; Committees: House - Energy and Commerce

H.R.5270 — To prohibit the National Institutes of Health from conducting or supporting certain gain-of-function research, and for other purposes. Sponsor: Rep. Carter, Earl L. "Buddy" [R-GA-1]; Committees: House - Energy and Commerce

H.Res.656 — 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: Rep. Stevens, Haley M. [D-MI-11]; Committees: House - Energy and Commerce

H.Res.654 — Expressing support for the designation of September 17, 2021, as "National Concussion Awareness Day". Sponsor: Rep. Pascrell, Bill, Jr. [D-NJ-9]; Committees: House - Energy and Commerce

H.Res.653 — Supporting the goals to protect United States military personnel from malaria. Sponsor: Rep. Panetta, Jimmy [D-CA-20]; Committees: House - Foreign Affairs; Armed Services; Energy and Commerce

H.Res.649 — Supporting the goals and ideals of National HIV/AIDS and Aging Awareness Day; Sponsor: Rep. Lee, Barbara [D-CA-13]; Committees: House - Energy and Commerce

S.Res.367 — A resolution designating September 2021 as "National Ovarian Cancer Awareness Month"; Sponsor: Sen. Stabenow, Debbie [D-MI]; Committees: Senate – Judiciary

S.Res.369 — A resolution supporting the designation of September 17, 2021, as "National Concussion Awareness Day"; Sponsor: Sen. Hassan, Maggie [D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

S.2762 — A bill to amend title III of the Public Health Service Act to direct the Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, to award grants to eligible entities to carry out construction or modernization projects designed to strengthen and increase capacity within the specialized pediatric health care infrastructure, and for other purposes; Sponsor: Sen. Padilla, Alex [D-CA]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.659 — Expressing support for the designation of September 2021 as "National Kinship Care Month"; Sponsor: Rep. Bass, Karen [D-CA-37]; Committees: House - Ways and Means

H.Res.660 — Supporting the designation of the week of September 19 through September 25, 2021, as "Telehealth Awareness Week"; Sponsor: Rep. Curtis, John R. [R-UT-3]; Committees: House - Oversight and Reform

S.2769 — A bill to amend title XIX of the Social Security Act to cover physician services delivered by podiatric physicians to ensure access by Medicaid beneficiaries to appropriate quality foot and ankle care, to amend title XVIII of such Act to modify the requirements for diabetic shoes to be included under Medicare, and for other purposes; Sponsor: Sen. Stabenow, Debbie [D-MI]; Committees: Senate – Finance

S.2773 — A bill to amend the Leahy-Smith America Invents Act to address satellite offices of the United States Patent and Trademark Office, and for other purposes. Sponsor: Sen. Leahy, Patrick [D-VT]; Committees: Senate – Judiciary

- S.2774 A bill to amend title 35, United States Code, to address patent ownership, and for other purposes; Sponsor: Sen. Leahy, Patrick [D-VT]; Committees: Senate Judiciary
- S.2776 A bill to clarify that the Secretary of Health and Human Services has authority to implement a residential eviction moratorium under the quarantine authority vested by the Public Health Service Act, and for other purposes; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate Health, Education, Labor, and Pensions
- S.2777 A bill to amend title XVIII of the Social Security Act to authorize the Secretary of Health and Human Services to make adjustments to payment rates for skilled nursing facilities under the Medicare program to account for certain unique circumstances; Sponsor: Sen. Schatz, Brian [D-HI]; Committees: Senate Finance
- S.2779 A bill to amend the Public Health Service Act to provide for the establishment of a Task Force on Maternal Mental Health, and for other purposes; Sponsor: Sen. Hassan, Maggie [D-NH]; Committees: Senate Health, Education, Labor, and Pensions
- S.2780 A bill to amend title 10, United States Code, to prohibit certain adverse personnel actions taken against members of the Armed Forces based on declining the COVID-19 vaccine; Sponsor: Sen. Marshall, Roger [R-KS]; Committees: Senate Armed Services
- S.2787 A bill to amend title 38, United States Code, to clarify the role of doctors of podiatric medicine in the Department of Veterans Affairs, and for other purposes; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate Veterans' Affairs
- H.R.5305 Making continuing appropriations for the fiscal year ending September 30, 2022, and for providing emergency assistance, and for other purposes; Sponsor: Rep. DeLauro, Rosa L. [D-CT-3]; Committees: House Appropriations; Budget; Ways and Means.
- H.R.5307 To clarify that the Secretary of Health and Human Services has authority to implement a residential eviction moratorium under the quarantine authority vested by the Public Health Service Act, and for other purposes; Sponsor: Rep. Bush, Cori [D-MO-1]; Committees: House Energy and Commerce
- H.R.5312 To amend title XVIII of the Social Security Act to authorize the Secretary of Health and Human Services to make adjustments to payment rates for skilled nursing facilities under the Medicare program to account for certain unique circumstances; Sponsor: Rep. Kahele, Kaiali'i [D-HI-2]; Committees: House Ways and Means; Energy and Commerce
- H.R.5317 To direct the Secretary of Veterans Affairs to carry out a program to provide technical assistance to States and American Indian and Alaska Native tribes for the development of veteran suicide prevention activities, and for other purposes; Sponsor: Rep. Takano, Mark [D-CA-41]; Committees: House Veterans' Affairs
- S.Res.378 A resolution designating September 2021 as "National Prostate Cancer Awareness Month"; Sponsor: Sen. Menendez, Robert [D-NJ]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Voice Vote.
- S.2796 A bill to amend the Omnibus Crime Control and Safe Streets Act of 1968 to provide for the eligibility of rural community response pilot programs for funding under the Comprehensive Opioid Abuse Grant Program, and for other purposes; Sponsor: Sen. Ossoff, Jon [D-GA]; Committees: Senate Judiciary
- H.Res.674 Expressing support for the designation of September 22, 2021, as "National Hispanic Nurses Day"; Sponsor: Rep. Horsford, Steven [D-NV-4]; Committees: House Energy and Commerce

- H.R.5331 To amend title XVIII of the Social Security Act to improve access to innovative new medical devices furnished to individuals with end stage renal disease under part B of the Medicare program by establishing a new device add-on payment adjustment under such part; Sponsor: Rep. Davis, Danny K. [D-IL-7]; Committees: House Energy and Commerce; Ways and Means
- S.Res.383 A resolution designating the week beginning September 12, 2021, as "National Direct Support Professionals Recognition Week"; Sponsor: Sen. Cardin, Ben [D-MD]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.
- S.Res.385 A resolution supporting the designation of the week of September 19 through September 25, 2021, as "Telehealth Awareness Week"; Sponsor: Sen. Schatz, Brian [D-HI]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.
- S.2811 A bill to direct the Secretary of Defense to carry out a pilot program to pre-program suicide prevention resources into smart devices issued to members of the Armed Forces; Sponsor: Sen. Sinema, Kyrsten [D-AZ]; Committees: Senate Armed Services
- S.2814 A bill to provide for affordable access to insulin and epinephrine; Sponsor: Sen. Kennedy, John [R-LA]; Committees: Senate Health, Education, Labor, and Pensions
- S.2815 A bill to amend title XI of the Social Security Act to provide for the continued implementation on a permanent basis of the Part D Senior Savings model; Sponsor: Sen. Kennedy, John [R-LA]; Committees: Senate Finance
- S.2817 A bill to amend title 38, United States Code, to furnish readjustment counseling and related mental health services to family members of members of the Armed Forces or veterans who died by suicide, and for other purposes; Sponsor: Sen. Tillis, Thomas [R-NC]; Committees: Senate Veterans' Affairs
- S.2834 A bill to amend title XVIII of the Social Security Act to preserve access to rehabilitation innovation centers under the Medicare program; Sponsor: Sen. Durbin, Richard [D-IL]; Committees: Senate Finance
- S.2837 A bill to amend the Public Health Service Act to clarify rules relating to drug discounts for covered entities; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate Health, Education, Labor, and Pensions
- S.2840 A bill to permit civil actions against the United States for COVID-19 vaccination mandates; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Judiciary
- S.2841 A bill to require the Secretary of Health and Human Services to publicly disclose information regarding adverse effects of COVID-19 vaccines; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Health, Education, Labor, and Pensions
- S.2842 A bill to amend title 10, United States Code, to prohibit the Secretary of Defense from requiring that members of the Armed Forces receive a COVID-19 vaccine, and for other purposes; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Armed Services
- S.2843 A bill 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: Sen. Lee, Mike [R-UT]; Committees: Senate Health, Education, Labor, and Pensions
- S.2844 A bill to require the Secretary of Health and Human Services to publish all of its studies and findings related to COVID-19; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Health, Education, Labor, and Pensions

- S.2846 A bill to require Federal agencies to acknowledge, accept, and agree to truthfully present, natural immunity pertaining to COVID-19 pursuant to promulgating certain regulations; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Health, Education, Labor, and Pensions
- S.2847 A bill to prohibit the Federal Government from mandating vaccination against COVID-19 for interstate travel; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Commerce, Science, and Transportation
- S.2848 A bill to exempt individuals with a personal health concern from complying with a Federal COVID-19 vaccine mandate, and for other purposes; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Health, Education, Labor, and Pensions
- S.2849 A bill to stipulate that nothing in Federal law provides a Federal agency with the authority to mandate that an individual be inoculated by a COVID-19 vaccine; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Homeland Security and Governmental Affairs
- S.2850 A bill to exempt individuals from complying with a Federal COVID-19 vaccine mandate on the basis of a personal belief, and for other purposes; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Health, Education, Labor, and Pensions
- S.2851 A bill to require an audit of COVID-19 relief funding; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate Homeland Security and Governmental Affairs