



## Health Policy Briefing

December 20, 2021

### Manchin Says He Will Not Back Build Back Better

Consideration of President Joe Biden’s \$2 trillion tax and social spending package appears to be indefinitely delayed following stalled negotiations between the White House and Sen. Joe Manchin (D-W.Va.). During an interview on Fox News Sunday, Manchin stated “I cannot vote to continue with this piece of legislation. I just can’t. I’ve tried everything humanly possible. I can’t get there... This is a no on this legislation.” The White House later responded that Manchin’s remarks were “at odds with his discussions this week with the President” and that the administration will continue to press him to reverse his position. Democrats have spent months trying to achieve passage of the **Build Back Better Act** through the budget reconciliation process, which would allow them to bypass a Republican filibuster in the Senate, making Manchin’s vote essential in the evenly divided chamber.

### Debt Limit Raised through Early 2023

President Joe Biden has signed legislation (S.J.Res.33) to raise the U.S. debt limit by \$2.5 trillion, averting a U.S. default on its obligations and extending the federal government’s borrowing authority into early 2023. The measure increases the national debt ceiling to \$31.4 trillion. Lawmakers had previously secured an agreement requiring only a simple majority vote for passage of the bill, which was cleared by the Senate in a 50-49 vote and by the House of Representatives in a 221-209 vote. Rep. Adam Kinzinger (R-Ill.), who is not running for reelection, was the only Republican to vote in support of the bill. Congress has since adjourned for the year, with the Senate scheduled to reconvene for the second session of the 117th Congress on January 3 and the House of Representatives scheduled to return on January 10.

### Inside

- [ACT For ALS Act Sent to President for Signature.....](#)2
- [Wyden Urges Administration to Address Part B Premium Increases.....](#)2
- [Senate HELP Committee Questions FDA Nominee.....](#)2
- [Former Sen. Johnny Isakson Dies at 76.....](#)2
- [Former WH Testing Coordinator to Serve as HRSA Administrator.....](#)3
- [Dr. Collins Departs NIH.....](#)3
- [CMS to Consider DIR Fees.....](#)3
- [CMS Releases Final GMERegulation.....](#)3
- [HHS Announces \\$9 Billion in PRF Phase 4 Payments.....](#)4
- [Health Care Spending Increases by Almost 10%.....](#)4
- [OSHA Enforcement of Vaccine Mandate Delayed.....](#)4
- [Recently Introduced Health Legislation.....](#)5
- [Appendix - COVID Vaccine Mandates: State of Play](#)

## ACT For ALS Act Sent to President for Signature

The Senate passed legislation (H.R.3537) by voice vote last week directing the U.S. Department of Health and Human Services (HHS) to support research on and expanded access to investigational drugs for amyotrophic lateral sclerosis (ALS). The ***Accelerating Access to Critical Therapies (ACT) for ALS Act*** authorizes \$100 million annually to fund early access to ALS investigational therapies, accelerate ALS and neurodegenerative disease therapy development, and increase research on and development of interventions for rare neurodegenerative diseases. The bill was previously passed by the House of Representatives and will now be sent to President Joe Biden to be signed into law.

## Wyden Urges Administration to Address Part B Premium Increases

Senate Finance Committee Chair Ron Wyden (D-Ore.) is [urging](#) the Biden administration to cap the increase in Medicare Part B premiums stemming from the price of the new Alzheimer's treatment Aduhelm. "Medicare beneficiaries cannot afford to be saddled with a record increase in monthly premium costs," his letter to U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra states, "Especially when those premium costs are being driven up by uncertain expectations of sky-high Medicare costs for an outrageously expensive drug like Aduhelm that has presented limited clinical evidence of its effectiveness."

## Senate HELP Committee Questions FDA Nominee

Sens. Joe Manchin (D-W.Va.) and Bernie Sanders (I-Vt.) announced that they will join Sen. Richard Blumenthal (D-Conn.) in voting against the nomination of Robert Califf to serve as Commissioner of Food and Drugs. The lawmakers have been critical of Califf's ties to the pharmaceutical industry, with Manchin also underscoring Califf's prior failure to address the agency's role in the opioid crisis. Nevertheless, Califf's confirmation hearing before the Senate Health, Education, Labor, and Pensions (HELP) Committee last week proceeded relatively smoothly, with the nominee stating that he is on the record in support of making drugs more affordable and defending his record on opioids. Califf also pledged to undertake an extensive review of opioid regulations including product labeling. While a committee vote, which would proceed a Senate floor vote, has not yet been scheduled, Califf is expected to be confirmed as FDA Commissioner for a second time. He has the support of both HELP Committee Chair Patty Murray (D-Wash.) and Ranking Member Richard Burr (R-N.C.), who urged his Republican colleagues to support the nomination. Califf was previously confirmed by the Senate in an 89-4 vote. More than sixty of the senators who voted for his confirmation continue to serve in the Senate today.

## Former Sen. Johnny Isakson Dies at 76

Former Sen. Johnny Isakson (R-Ga.) passed away on Sunday at the age of 76. Isakson served in the House of Representatives between 1999 and 2004, and in the Senate from 2005 until his retirement in 2019. During his time in the Senate, he chaired the Ethics Committee, responsible for enforcing standards of behavior for senators and their staff, for five years. He also served on the Health, Education, Labor, and Pensions (HELP) Committee, championing the ***Over-the-Counter Monograph Safety, Innovation, and Reform Act***. As chair of the Veterans' Affairs Committee, Isakson was a longtime leader in veterans' suicide prevention policy and successfully introduced and passed the ***MISSION ZERO Act***. Last Congress, key veterans' health legislation was named in honor of him and former Rep. Phil Roe - the ***Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act***. Isakson also served on the Senate Finance Committee and co-chaired the Chronic Care Working Group, co-authoring the ***Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act***, a bipartisan bill to strengthen and improve health outcomes for Medicare beneficiaries living with chronic conditions.

## Former WH Testing Coordinator to Serve as HRSA Administrator

Carole Johnson will be assuming the role of Administrator of the Health Resources and Services Administration (HRSA) after her time spent as the Testing Coordinator for the White House COVID-19 Response Team. Prior to joining the Biden administration, Johnson worked as Commissioner of the New Jersey Department of Human Services and previously served as the White House Domestic Policy Council's public health lead in the Obama administration. Tom Inglesby will replace Johnson on the White House COVID-19 Response Team. Inglesby has been serving as senior advisor for COVID-Response in the Office of the Secretary of the U.S. Department of Health and Human Services (HHS).

## Dr. Collins Departs NIH

Dr. Francis Collins spent his last day at the helm of the National Institutes of Health (NIH) on December 19. 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, with a career spanning three decades at the agency. Collins previously directed the National Human Genome Research Institute and led the Human Genome Project. Dr. Collins's tenure will also be remembered for his frequent serenading of NIH staff and his membership in the [band](#) the Affordable Rock 'n' Roll Act.

## CMS to Consider DIR Fees

The Biden administration announced last week that it plans to issue new regulations to tackle direct and indirect remuneration (DIR) levied by pharmaceutical benefit managers (PBMs) on pharmacies. In a letter sent by Centers for Medicare and Medicaid Services (CMS) Administrator Chiquita Brooks-LaSure to lawmakers last week, Brooks-LaSure characterizes the recent spike in DIR fees as "troubling," and that CMS will use its administrative authority to issue proposed rulemaking to address price concessions and DIR. CMS estimates that the fees increased 91,500% between 2010 and 2019. The announcement was met with bipartisan support from lawmakers in Congress.

## CMS Releases Final GME Regulation

The Centers for Medicare and Medicaid Services (CMS) has released the fiscal year (FY) 2022 Hospital Inpatient Prospective Payment System (IPPS)/Long Term Care Hospital (LTCH) Prospective Payment System final rule. The regulation includes finalized graduate medical education (GME) policies, including policies to distribute 1,000 new Medicare-funded physician residency slots to qualifying hospitals, phasing in 200 slots per year over five years. In allocating these new residency slots, CMS will prioritize hospitals with training programs in areas demonstrating the greatest need for providers, as determined by Health Professional Shortage Areas (HPSAs). The first round of 200 residency slots will be announced by January 31, 2023, and will become effective July 1, 2023. The rule also solicits comment on certain other GME issues to inform potential future rulemaking. Comments are due 60 days after the regulation's publication in the Federal Register.

## HHS Announces \$9 Billion in PRF Phase 4 Payments

The U.S. Department of Health and Human Services (HHS) has announced the release of an additional \$9 billion in Provider Relief Fund (PRF) Phase 4 payments to support health care providers impacted by the COVID-19 pandemic. The average payment for small providers was \$58,000, for medium providers was \$289,000, and for large providers was \$1.7 million. More than [69,000 providers](#) in all 50 states, Washington, D.C., and eight territories will receive the Phase 4 payments, which started to be made last week. The payments are part of the \$25.5 billion the Administration is releasing to health care providers to recruit and retain staff, purchase masks and other supplies, modernize facilities, or other activities needed to respond to COVID-19. The Health Resources and Services Administration (HRSA) is currently reviewing the remaining Phase 4 applications and will make the remainder of Phase 4 payments in 2022. HRSA is prioritizing smaller providers by reimbursing a higher percentage of their losses and expenses and is distributing 25% of Phase 4 funding as bonus payments based on the amount and type of services provided to Medicare, Medicaid, or CHIP patients. HHS has also updated the Terms and Conditions for Phase 4 and American Rescue Plan (ARP) Rural payments. Recipients whose payment(s) exceed \$10,000 are required to notify HHS of a merger with or acquisition of any other health care provider. These providers who report a merger or acquisition may be more likely to be audited to ensure compliant use of funds.

## Health Care Spending Increases by Almost 10%

U.S. health care spending increased to \$4.1 trillion last year as the country worked to respond to the coronavirus pandemic. The latest data, released by the Centers for Medicare and Medicaid Services (CMS) last week, shows a 9.7% increase in national health spending in 2020, more than double the usual growth rate. The federal government's share of health spending increased by 36%. CMS attributes this growth to federal subsidies to prevent the closure of hospitals and medical practices; funding to develop and deploy COVID tests, vaccines, treatments, and countermeasures; and assistance to state Medicaid programs. The report also indicates that the number of uninsured people remained around 30 million, though there was a shift in coverage toward Medicaid and the Affordable Care Act (ACA) marketplaces. Out-of-pocket health care spending declined by 3.7%, largely due to postponed care in light of the pandemic.

## OSHA Enforcement of Vaccine Mandate Delayed

While the courts have put a preliminary injunction in place for half of the states with respect to the CMS rule related to certain providers and COVID vaccination and all of the states for the government contractor rule related to COVID vaccination, once the courts lifted the injunction for the OSHA emergency temporary standard (ETS) related to the employer COVID vaccination on Friday, OSHA updated its [website](#) on Saturday to state the following: "To account for any uncertainty created by the stay, OSHA is exercising enforcement discretion with respect to the compliance dates of the ETS. To provide employers with sufficient time to come into compliance, OSHA will not issue citations for noncompliance with any requirements of the ETS before January 10 and will not issue citations for noncompliance with the standard's testing requirements before February 9, so long as an employer is exercising reasonable, good faith efforts to come into compliance with the standard. OSHA will work closely with the regulated community to provide compliance assistance." Hart Health Strategies Inc. has prepared a new resource in its series of documents related to the COVID-19 pandemic to assist you in tracking the status of various COVID-19 vaccine mandates. The document is attached as an appendix to this newsletter and will be updated on a regular basis.

## Recently Introduced Health Legislation

S.Res.477 — A resolution expressing support for the designation of September 2021 as “Sickle Cell Disease Awareness Month” in order to educate communities across the United States about sickle cell disease and the need for research, early detection methods, effective treatments, and preventative care programs with respect to complications from sickle cell disease and conditions related to sickle cell disease; Sponsor: Sen. Scott, Tim [R-SC]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

H.Res.846 — Recognizing the maternal health crisis among indigenous women in the United States, which includes American Indian, Alaska Native, and Native Hawaiian women, recognizing the importance of reducing mortality and morbidity among indigenous women, and calling for urgent Federal funding changes to ensure comprehensive, high-quality, and culturally competent maternal health and family planning services are available; Sponsor: Rep. Craig, Angie [D-MN-2]; Committees: House - Natural Resources; Energy and Commerce

S.Res.479 — A resolution supporting the goals and ideals of American Diabetes Month; Sponsor: Sen. Shaheen, Jeanne [D-NH]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.3386 — A bill to prevent, treat, and cure tuberculosis globally; Sponsor: Sen. Menendez, Robert [D-NJ]; Committees: Senate - Foreign Relations

S.3389 — A bill to amend title XIX of the Social Security Act to establish a demonstration project to improve outpatient clinical care for individuals with sickle cell disease; Sponsor: Sen. Booker, Cory A. [D-NJ]; Committees: Senate – Finance

S.3390 — A bill to increase research, education, and treatment for cerebral cavernous malformations; Sponsor: Sen. Lujan, Ben Ray [D-NM]; Committees: Senate - Health, Education, Labor, and Pensions

S.3393 — A bill to amend the Internal Revenue Code of 1986 to permanently extend the Health Coverage Tax Credit; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate – Finance

S.3394 — A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to emergency use authorization transparency; Sponsor: Sen. Hassan, Margaret Wood [D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

S.3395 — A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to records and other information inspections; Sponsor: Sen. Baldwin, Tammy [D-WI]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.856 — Expressing support for the designation of “National Amplified Musculoskeletal Pain Syndrome Awareness Day”; Sponsor: Rep. Wild, Susan [D-PA-7]; Committees: House - Energy and Commerce

H.R.6257 — To prohibit the Federal Government from imposing a vaccine mandate on individuals traveling on public or private transportation for hire within the United States, and for other purposes; Sponsor: Rep. Webster, Daniel [R-FL-11]; Committees: House - Transportation and Infrastructure

H.R.6271 — To amend the Internal Revenue Code of 1986 to improve access to health care through expanded health savings accounts, and for other purposes; Sponsor: Rep. LaTurner, Jake [R-KS-2]; Committees: House - Ways and Means; Energy and Commerce; Judiciary

H.R.6273 — To direct the Secretary of Veterans Affairs to establish the Zero Suicide Initiative pilot program of the Department of Veterans Affairs; Sponsor: Rep. Lee, Susie [D-NV-3]; Committees: House - Veterans’ Affairs

H.R.6279 — To authorize a study on certain exemptions for treatment of opioid use disorder through opioid treatment programs during the COVID-19 public health emergency, and for other purposes; Sponsor: Rep. Norcross, Donald [D-NJ-1]; Committees: House - Energy and Commerce

H.R.6282 — To amend title III of the Public Health Service Act to eliminate immunity for manufacturers of COVID-19 vaccines, and for other purposes; Sponsor: Rep. Perry, Scott [R-PA-10]; Committees: House - Energy and Commerce

H.R.6286 — To amend the Federal Food, Drug, and Cosmetic Act to vest regulatory authority with respect to tobacco products containing nicotine not made or derived from tobacco, and for other purposes; Sponsor: Rep. Sherrill, Mikie [D-NJ-11]; Committees: House - Energy and Commerce

H.R.6290 — To provide for the establishment of a section of the website of the Department of Commerce that shall serve as the primary hub for information relating to Federal manufacturing programs, and for other purposes; Sponsor: Rep. Tonko, Paul [D-NY-20]; Committees: House - Energy and Commerce

S.3397 — A bill to direct the Secretary of Veterans Affairs to establish the Zero Suicide Initiative pilot program of the Department of Veterans Affairs; Sponsor: Sen. Rosen, Jacky [D-NV]; Committees: Senate - Veterans' Affairs

S.3399 — A bill to amend the Federal Food, Drug, and Cosmetic Act to provide a process to lock and suspend domain names used to facilitate the online sale of drugs illegally, and for other purposes; Sponsor: Sen. Rubio, Marco [R-FL]; Committees: Senate - Health, Education, Labor, and Pensions

S.3401 — A bill to require the Secretary of Health and Human Services to maintain a list of the country of origin of all drugs marketed in the United States, to ban the use of Federal funds for the purchase of drugs manufactured in the People's Republic of China, and for other purposes; Sponsor: Sen. Cotton, Tom [R-AR]; Committees: Senate - Health, Education, Labor, and Pensions

S.3413 — A bill to amend the Internal Revenue Code of 1986 to extend the credit for health insurance costs of eligible individuals; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Finance

S.3414 — A bill to require the Government Accountability Office to evaluate the policies and actions of the National Institutes of Health with respect to research involving the enhancement of potential pandemic pathogens and related activities; Sponsor: Sen. Marshall, Roger [R-KS]; Committees: Senate - Health, Education, Labor, and Pensions

S.3416 — A bill to expand the enforcement authority of the Food and Drug Administration with respect to counterfeit devices; Sponsor: Sen. Murphy, Christopher [D-CT]; Committees: Senate - Health, Education, Labor, and Pensions

S.3418 — A bill to provide emergency assistance to States, territories, Tribal nations, and local areas affected by substance use disorder, including the use of opioids and stimulants, and to make financial assistance available to States, territories, Tribal nations, local areas, public or private nonprofit entities, and certain health providers, to provide for the development, organization, coordination, and operation of more effective and cost efficient systems for the delivery of essential services to individuals with substance use disorder and their families; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.3422 — A bill to establish a grant program to support schools of medicine and schools of osteopathic medicine in underserved areas; Sponsor: Sen. Kaine, Tim [D-VA]; Committees: Senate - Health, Education, Labor, and Pensions

S.3427 — A bill to authorize the Secretary of Health and Human Services to establish a Neuroscience Center of Excellence; Sponsor: Sen. Collins, Susan M. [R-ME]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.6302 — To provide for the establishment of a program at the Centers for Disease Control and Prevention with respect to healthy aging and to authorize grants to health departments to carry out healthy aging programs, and for other purposes; Sponsor: Rep. Frankel, Lois [D-FL-21]; Committees: House - Energy and Commerce

H.R.6304 — To amend the Occupational Safety and Health Act of 1970 to prohibit any emergency temporary standard that includes a vaccine or drug mandate; Sponsor: Rep. Hartzler, Vicky [R-MO-4]; Committees: House - Education and Labor

H.R.6305 — To ensure the security of biomedical research, and for other purposes; Sponsor: Rep. Hudson, Richard [R-NC-8]; Committees: House - Energy and Commerce

H.R.6308 — To amend title XVIII of the Social Security Act to improve the way beneficiaries are assigned under the Medicare shared savings program by also basing such assignment on primary care services furnished by nurse practitioners, physician assistants, and clinical nurse specialists; Sponsor: Rep. Kilmer, Derek [D-WA-6]; Committees: House - Ways and Means; Energy and Commerce

H.R.6309 — To establish a United States strategy to counter threats to supply chains for critical goods, and for other purposes; Sponsor: Rep. Kinzinger, Adam [R-IL-16]; Committees: House - Ways and Means

H.R.6311 — To provide emergency assistance to States, territories, Tribal nations, and local areas affected by substance use disorder, including the use of opioids and stimulants, and to make financial assistance available to States, territories, Tribal nations, local areas, public or private nonprofit entities, and certain health providers, to provide for the development, organization, coordination, and operation of more effective and cost efficient systems for the delivery of essential services to individuals with substance use disorder and their families; Sponsor: Rep. Maloney, Carolyn B. [D-NY-12]; Committees: House - Energy and Commerce; Natural Resources; Judiciary; Oversight and Reform

H.R.6321 — To require the head of each Federal agency, within 100 calendar days, to complete all pending Freedom of Information Act requests related to a drug or medical device to prevent, diagnose, mitigate, or treat COVID-19, gain-of-function or potential pandemic pathogen research, or a policy, rule, or standard requiring COVID-19 vaccination of individuals, and for other purposes; Sponsor: Rep. Roy, Chip [R-TX-21]; Committees: House - Oversight and Reform; Appropriations

H.R.6324 — To direct the Secretary of Education to develop and disseminate an evidence-based curriculum for kindergarten through grade 12 on the dangers of vaping and misusing opioids, synthetic drugs, and related substances; Sponsor: Rep. Vela, Filemon [D-TX-34]; Committees: House - Education and Labor