



Health Policy Briefing

November 8, 2021

House Passes Infrastructure Package, Tees Up Consideration of Reconciliation Package

The House of Representatives passed the \$1 trillion bipartisan infrastructure package on Friday by a vote of 228-206. The bill contains traditional infrastructure-related provisions to fund roads, bridges, transit, and broadband build-out with nearly \$550 billion in new funding. The **Infrastructure Investment and Jobs Act** (H.R. 3684), having previously passed the Senate, will now be sent to the President’s desk to be signed into law.

The House also passed the rule providing for consideration of H.R. 5376, the **Build Back Better Act**. The latest version of the social spending package currently stands at \$1.85 trillion and is expected to be considered the week of November 15 following this week’s House committee work period. The reconciliation bill currently includes the creation of a Medicare hearing benefit, an extension of expanded Affordable Care Act (ACA) insurance subsidies, the creation of subsidized insurance plans for individuals residing in states that have not yet expanded their Medicaid programs, and an expansion of home and community-based care. It also includes a scaled-down paid family and medical leave provision. Prior to the vote, the package was tweaked to hasten the implementation of the new Medicare hearing benefit by one year (up to 2023), provide states with \$50 million in grants to apply for or implement a section 1332 waiver, and to add a Medicare drug price negotiation provision. The drug pricing measure would allow Medicare to directly negotiate the prices of the highest gross spending products in Medicare Part B and Part D, starting in 2025 with up to 10 of the most expensive medicines and increasing to up to 20 of the most expensive medicines by 2028. Negotiation would be restricted to products that have been on the market and passed their initial exclusivity period (defined as nine years for small molecule products and 13 years for biologics). The measure would carve out exceptions for small biotechnology firms.

Manufacturers whose prices increase faster than inflation – tagged to the 2021 rate – would be penalized starting next year. Additionally, Medicare beneficiaries will get a \$2,000 out-of-pocket spending cap per year, and out-of-pocket spending on insulin would be capped for both Medicare and private insurance enrollees. The drug pricing deal reportedly has the support of Sens. Kyrsten Sinema (D-Ariz.) and Bob Menendez (D-N.J.)

Inside

- E&C Panel Advances Nine Health Care Related Bills.....2
- Lawmakers Urge Revision of Surprise Billing Regulation.2
- OSHA, CMS Release Vaccine Mandate Regulations.....3
- Sen. King Seeks to Increase Global Vaccine Availability.....3
- COVID Vaccine Now Available for Children 5-11.....3
- Recently Introduced Health Legislation.....4

as well as the Congressional Progressive Caucus.

Following Democratic electoral losses in Virginia on Tuesday, Sen. Joe Manchin (D-N.J.) argued that the party should pause on advancing the bill. Despite weeks of negotiation with the White House, Manchin has thus far refused to endorse the **Build Back Better Act** and is one of several centrist Democrats calling for a full Congressional Budget Office (CBO) score of the package before any action is taken on the bill. The House version of the legislation will still be subject to negotiation once it passes the lower chamber, with key issues – including the SALT deduction, immigration measures, and paid leave provisions – expected to be revised by the Senate. Senate Majority Leader Chuck Schumer (D-N.Y.) has stated that he will spend this week's recess working to reach a consensus on the reconciliation package with all 50 Senate Democrats.

E&C Panel Advances Nine Health Care Related Bills

The House Energy and Commerce Subcommittee on Health advanced nine bills to the full committee for markup last week, including the **Dr. Lorna Breen Health Care Provider Protection Act** (H.R. 1667). The bill would design a campaign to improve the mental health of health care providers and combat physician suicide. It was previously passed by the Senate in August. Other bills passed by the subcommittee include:

- H.R. 1193, the **Cardiovascular Advances in Research and Opportunities Legacy Act**
- H.R. 3297, the **Public Health Workforce Loan Repayment Act of 2021**
- H.R. 3320, the **Allied Health Workforce Diversity Act of 2021**
- H.R. 3537, the **Accelerating Access to Critical Therapies for ALS Act**
- H.R. 4555, the **Oral Health Literacy and Awareness Act of 2021**
- H.R. 5487, the **Stillbirth Health Improvement and Education for Autumn Act of 2021**
- H.R. 5551, the **Improving the Health of Children Act**
- H.R. 5561, the **Early Hearing Detection and Intervention Reauthorization Act**

Lawmakers Urge Revision of Surprise Billing Regulation

More than 150 members of Congress have signed a [letter](#) to the secretaries of Health and Human Services, Treasury, and Labor expressing concerns with the interim final rule (IFR) released on September 30 to implement the **No Surprises Act**. The lawmakers argue that the parameters of the independent dispute resolution process (IDR) process laid out in the IFR do not reflect the way the law was written. The IFR directs IDR entities to begin with the assumption that the median in-network rate is the appropriate payment amount prior to considering other factors. “The process laid out in the law expressly directs the certified IDR entity to consider each of [the] listed factors should they be submitted, capturing the unique circumstance of each billing dispute without causing any single piece of information to be the default one considered.” The letter, organized by Reps. Brad Wenstrup (R-Ohio) and Tom Suozzi (D-N.Y.), urges the administration to revise the IFR to align with the law as written by specifying that the certified IDR entity should not default to the median in-network rate and should instead consider all the factors outlined in the statute without disproportionately weighting one factor.

OSHA, CMS Release Vaccine Mandate Regulations

The Occupational Safety and Health Administration (OSHA) has released its [emergency temporary standard](#) (ETS) mandating COVID-19 vaccinations or weekly testing of workers at companies with 100 or more employees. The rule requires covered employers to develop, implement, and enforce a mandatory COVID-19 vaccination policy or require employees to undergo regular COVID-19 testing and wear a face covering at work. Each violation of the rule could result in a fine of up to \$13,653, and willful violations could lead to a fine as high as \$136,532. The first compliance deadline is set for December 6, when employers must have established, implemented, and begun enforcing a written vaccination policy; begin providing paid time off for workers to get vaccinated, as well as time off for recovery from side effects; and ensure that those covered employees who are not inoculated are wearing masks, among other requirements. Covered employees must be fully vaccinated or submit to testing starting January 4. States with their own OSHA-approved workplace safety and health plans can decide whether to accept the standard or choose to draft an equivalent or more protective rule. The ETS was announced in conjunction with an [interim final rule with comment period](#) (IFC) from the Centers for Medicare and Medicaid Services (CMS) to require health care workers at approximately 76,000 Medicare and Medicaid participating hospitals and other facilities to be vaccinated. This regulation does not offer an option for workers to get tested regularly instead of vaccination, but (like the ETS) it does provide for medical or religious exemptions. The regulation covers employees, students, people in training, volunteers, and those who provide services under contract, but (like the ETS) it does not apply to people who work only remotely. Facilities that do not comply with the rule could face civil monetary penalties, payment denials, or be terminated from the Medicare and Medicaid programs. The health-care worker vaccine mandate also follows a phased-approach, where all staff must be vaccinated by January 4.

The GOP Doctors Caucus released a [statement](#) in response to the vaccine mandates, arguing that they will alienate Americans and jeopardize patients' access to timely care because of resulting health care professional layoffs and walkouts. The Caucus reiterates its "call for President Biden to abandon this one-size-fits-all edict or, at the very least, create necessary accommodations for those with natural immunity through prior infection or regular testing and monitoring." Senate Republicans are planning to use the Congressional Review Act to force a vote to block the new vaccine mandates. More than 40 Republicans have signed on to the push led by Sen. Mike Braun (R-Ind.) so far. The effort, expected to take place sometime in December, will likely fail in the Democratic-controlled Congress. Over the weekend, a federal appeals court [temporarily halted](#) nationwide implementation of the OSHA ETS, with a response from the Administration due on Monday. Other legal challenges will likely follow.

Sen. King Seeks to Increase Global Vaccine Availability

Sen. Angus King (I-Maine) has sent [letters](#) to Moderna and Pfizer urging the companies to make their COVID-19 vaccines available for generic manufacturing, which would make more doses available to combat the pandemic across the globe. He also asks the manufacturers to consider participating in the World Health Organization's (WHO) South African technology transfer hub and the Pan American Health Organization's Latin American hubs, and to commit to a royalty-free license to the Medicines Patent Pool (MPP) for any additional coronavirus treatments the companies may develop. "Your company has already made a huge contribution to ameliorating the impacts of the pandemic here at home," King writes, "I hope you will now consider this approach to sharing those benefits with the rest of the world."

COVID Vaccine Now Available for Children 5-11

Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky has endorsed the Advisory Committee on Immunization Practices' (ACIP) recommendation that children 5 to 11 years old be vaccinated against COVID-19 with the Pfizer-BioNTech pediatric vaccine, allowing providers to begin vaccinating them as soon as possible. The ACIP recommendation passed by a 14-0 vote. The Pfizer vaccine is the first pediatric COVID vaccine authorized for use in this country. Children will get two injections containing 10 micrograms of antigen – one-third of the size of the adult vaccine dose – given 21 days apart. Trials have shown that vaccination is nearly 91% effective in preventing COVID-19 among children aged 5-11 years, with vaccine side effects being mild, self-limiting, and like those seen in adults and with other vaccines recommended for children. Distribution of pediatric vaccinations across the country started last week, with plans to scale up to full capacity starting this week.

S.3124 — A bill to amend title XI of the Social Security Act to repeal the requirement for unique health identifiers; Sponsor: Sen. Paul, Rand [R-KY]; Committees: Senate – Finance

H.Con.Res.57 — Celebrating the first anniversary of the coalition of signatory countries to the Geneva Consensus Declaration on Promoting Women’s Health and Strengthening the Family; Sponsor: Rep. Banks, Jim [R-IN-3]; Committees: House - Foreign Affairs

H.R.5801 — To amend title XXVII of the Public Health Service Act to apply additional payments, discounts, and other financial assistance towards the cost-sharing requirements of health insurance plans, and for other purposes; Sponsor: Rep. McEachin, A. Donald [D-VA-4]; Committees: House - Energy and Commerce

H.R.5804 — To amend title XVIII of the Social Security Act to improve access to diabetes outpatient self-management training services, to require the Center for Medicare and Medicaid Innovation to test the provision of virtual diabetes outpatient self-management training services, and for other purposes; Sponsor: Rep. Schrier, Kim [D-WA-8]; Committees: House - Energy and Commerce; Ways and Means

H.R.5807 — To establish national data privacy standards in the United States, and for other purposes; Sponsor: Rep. Vela, Filemon [D-TX-34]; Committees: House - Energy and Commerce; Science, Space, and Technology

S.3132 — A bill to amend title XVIII of the Social Security Act to modernize payments for ambulatory surgical centers under the Medicare program, and for other purposes; Sponsor: Sen. Blumenthal, Richard [D-CT]; Committees: Senate – Finance

S.3139 — A bill to ban anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.5811 — To amend the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2022 to prohibit the use of funds related to any rule requiring a COVID-19 vaccination, and for other purposes; Sponsor: Rep. Moolenaar, John R. [R-MI-4]; Committees: House - Energy and Commerce

H.R.5812 — To amend title XI of the Social Security Act to repeal the requirement for unique health identifiers; Sponsor: Rep. Roy, Chip [R-TX-21]; Committees: House - Energy and Commerce; Ways and Means

H.R.5813 — To abolish the Occupational Safety and Health Administration, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Education and Labor

H.R.5816 — To prohibit the federal government, or State or local government or other entity receiving federal funding, from requiring any citizen to be vaccinated, including federal agencies from requiring its employees to take any vaccination, without the citizen being fully advised in writing of all known potential risks from the vaccine and consultation with a physician followed by the voluntary informed consent of the citizen, and for other purposes; Sponsor: Rep. Gohmert, Louie [R-TX-1]; Committees: House - Energy and Commerce

H.R.5818 — To amend title XVIII of the Social Security Act to modernize payments for ambulatory surgical centers under the Medicare program, and for other purposes; Sponsor: Rep. Larson, John B. [D-CT-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.5819 — To amend title 38, United States Code, to increase the amount paid by the Secretary of Veterans Affairs to veterans for improvements and structural alterations furnished as part of home health services; Sponsor: Rep. Lawson, Al, Jr. [D-FL-5]; Committees: House - Veterans’ Affairs

H.R.5820 — To prohibit the use of certain Federal funds to facilitate mandatory vaccination programs, and for other purposes; Sponsor: Rep. Lesko, Debbie [R-AZ-8]; Committees: House - Energy and Commerce

H.R.5823 — To establish a Pandemic Risk Reinsurance Program, and for other purposes; Sponsor: Rep. Maloney, Carolyn B. [D-NY-12]; Committees: House - Financial Services

H.R.5824 — To permit civil actions against employers for COVID-19 vaccination mandates, and for other purposes; Sponsor: Rep. Mast, Brian J. [R-FL-18]; Committees: House – Judiciary

H.R.5829 — To prohibit federally funded COVID-19 vaccine mandates, and for other purposes; Sponsor: Rep. Timmons, William R. IV [R-SC-4]; Committees: House - Energy and Commerce; Oversight and Reform; Education and Labor; Ways and Means

S.3149 — A bill to direct the Secretary of Health and Human Services to establish within the Office of the Director of the Centers for Disease Control and Prevention the Office of Rural Health, and for other purposes; Sponsor: Sen. Merkley, Jeff [D-OR]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.5835 — To prohibit the use of Federal funds to establish, implement, or enforce any vaccine mandate; Sponsor: Rep. Brooks, Mo [R-AL-5]; Committees: House - Energy and Commerce

H.R.5837 — To amend title XVIII of the Social Security Act to expand access to telehealth services relating to substance use disorder treatment, and for other purposes; Sponsor: Rep. Curtis, John R. [R-UT-3]; Committees: House - Energy and Commerce; Ways and Means; Judiciary

H.R.5848 — To direct the Secretary of Health and Human Services to establish within the Office of the Director of the Centers for Disease Control and Prevention the Office of Rural Health, and for other purposes; Sponsor: Rep. McEachin, A. Donald [D-VA-4]; Committees: House - Energy and Commerce

H.R.5850 — To ensure an evidence-based funding approach to study the effects of health profession opportunity grant demonstration projects, and to evaluate the demonstration projects; Sponsor: Rep. Schneider, Bradley Scott [D-IL-10]; Committees: House - Ways and Means

H.R.5851 — To void existing non-compete agreements for any employee who is fired for not complying with an employer's COVID-19 vaccine mandate, and for other purposes; Sponsor: Rep. Tenney, Claudia [R-NY-22]; Committees: House - Education and Labor; Energy and Commerce

S.3163 — A bill to improve access to medical examinations required by veterans to obtain disability compensation or pension under laws administered by the Secretary of Veterans Affairs, and for other purposes; Sponsor: Sen. Tester, Jon [D-MT]; Committees: Senate - Veterans' Affairs

S.3166 — A bill to amend title XIX of the Social Security Act to improve coverage of dental and oral health services for adults under Medicaid, and for other purposes; Sponsor: Sen. Cardin, Ben [D-MD]; Committees: Senate – Finance

S.3170 — A bill to ensure that nothing in Federal law, other than an explicit statement in an Act of Congress, shall be construed to provide an executive agency with the authority to mandate, or implement a mandate, that an individual be inoculated by a COVID-19 vaccine, and for other purposes; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate - Homeland Security and Governmental Affairs

S.3174 — A bill to implement the recommendations of the Inspector General of the Department of Defense with respect to mitigation of foreign suppliers in the pharmaceutical supply chain of the Department of Defense; Sponsor: Sen. Rubio, Marco [R-FL]; Committees: Senate - Armed Services

S.3184 — A bill to prohibit certain COVID-19 vaccination mandates for minors, and to require parental consent for COVID-19 vaccination of minors; Sponsor: Sen. Cruz, Ted [R-TX]; Committees: Senate - Health, Education, Labor, and Pensions

S.3189 — A bill to amend title XX of the Social Security Act to provide a pathway to health careers through health profession opportunity grants; Sponsor: Sen. Heinrich, Martin [D-NM]; Committees: Senate - Finance

S.3193 — A bill to amend title XVIII of the Social Security Act to expand the scope of practitioners eligible for payment for telehealth services under the Medicare program, and for other purposes; Sponsor: Sen. Daines, Steve [R-MT]; Committees: Senate - Finance

S.3194 — A bill to direct the Secretary of Veterans Affairs to submit to Congress a report on mental health care furnished by the Department of Veterans Affairs in certain States and a report on funding by Vet Centers of marketing and outreach; Sponsor: Sen. Boozman, John [R-AR]; Committees: Senate - Veterans' Affairs

S.3195 — A bill to provide consumers with foundational data privacy rights, create strong oversight mechanisms, and establish meaningful enforcement; Sponsor: Sen. Cantwell, Maria [D-WA]; Committees: Senate - Commerce, Science, and Transportation

S.3201 — A bill to establish a joint United States-Taiwan Infectious Disease Monitoring Center to serve as an early warning center in the case of an infectious disease outbreak in the Indo-Pacific region; Sponsor: Sen. Cotton, Tom [R-AR]; Committees: Senate - Foreign Relations

S.3203 — A bill to establish the Commission on the COVID-19 Pandemic; Sponsor: Sen. Feinstein, Dianne [D-CA]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.5857 — To amend the Public Health Service Act to enhance the national strategy for combating and eliminating tuberculosis, and for other purposes; Sponsor: Rep. Bera, Ami [D-CA-7]; Committees: House - Energy and Commerce

H.R.5860 — To exempt essential workers from Federal COVID-19 vaccine mandates; Sponsor: Rep. Burchett, Tim [R-TN-2]; Committees: House - Energy and Commerce; Oversight and Reform

H.R.5869 — To amend the Public Health Service Act to provide for the establishment of a mesothelioma patient registry, and for other purposes; Sponsor: Rep. Katko, John [R-NY-24]; Committees: House - Energy and Commerce

H.R.5870 — To establish a joint United States-Taiwan Infectious Disease Monitoring Center to serve as an early warning center in the case of an infectious disease outbreak in the Indo-Pacific region; Sponsor: Rep. Khanna, Ro [D-CA-17]; Committees: House - Foreign Affairs

H.R.5872 — To amend the Federal Food, Drug, and Cosmetic Act to treat as misbranded cosmetics with packaging or labeling using the term “natural” unless the cosmetic meets certain standards, and for other purposes; Sponsor: Rep. Maloney, Sean Patrick [D-NY-18]; Committees: House - Energy and Commerce

H.R.5874 — To promote the leadership of the United States in global innovation by establishing a robust patent system that restores and protects the right of inventors to own and enforce private property rights in inventions and discoveries, and for other purposes; Sponsor: Rep. Massie, Thomas [R-KY-4]; Committees: House - Judiciary

H.R.5875 — To amend title VII of the Public Health Service Act to increase retention of the rural health care workforce, and for other purposes; Sponsor: Rep. McKinley, David B. [R-WV-1]; Committees: House - Energy and Commerce

H.R.5883 — To establish a value-based care program to exempt eligible rural health clinics from certain payment limitations, and for other purposes; Sponsor: Rep. Sewell, Terri A. [D-AL-7]; Committees: House - Energy and Commerce; Ways and Means