



Health Policy Briefing

December 14, 2020

Pfizer COVID Vaccine Receives EUA

Pfizer Inc.'s coronavirus vaccine has received an emergency use authorization (EUA) from the Food and Drug Administration (FDA). Operation Warp Speed official Army Gen. Gustave F. Perna stated over the weekend that the first vaccines will be distributed today, echoing earlier remarks by U.S. Department of Health and Human Services (HHS) Secretary Alex Azar.

The FDA's advisory panel voted to back the Pfizer shot by a vote of 17 to 4, with one abstention, earlier in the week – signaling that the benefits of the product outweigh the risks for individuals age 16 and older. Much of the panel's discussion centered on whether there was enough evidence to support the vaccine's use in 16 and 17 year olds. The Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) voted during an emergency meeting on Saturday to recommend that people age 16 and older receive the Pfizer vaccine. ACIP recommended that care providers monitor people with a history of anaphylaxis for 30 minutes after giving them a shot. The group also recommended letting pregnant women, lactating women, and immunocompromised people decide whether to get a vaccine given the lack of specific data on how it performs in these populations.

Defense officials announced that a group of senior leaders, including Defense Secretary Chris Miller, will be the first in the military to receive a COVID-19 vaccine as a part of an effort to build confidence in a vaccine and encourage other personnel to get the shot. The Pentagon is currently preparing to accept the first doses of the Pfizer vaccine and to distribute it to high-priority officials, who are likely to include Deputy Defense Secretary David Norquist, Joint Chiefs Chairman Gen. Mark Milley, Vice Chairman Gen. John Hyten, and Senior Enlisted Adviser Ramón Colón-López. While the vaccine will initially be voluntary while it is under EUA, Pentagon officials have stated that once full approval is granted by the FDA that the department may require mandatory vaccination.

The FDA's advisory panel will meet on December 17 to evaluate Moderna's vaccine, and ACIP will next meet on December 18 and 20 to discuss vaccine distribution.

Inside

- [Compromise Reached on Surprise Billing Fix.....](#)2
- [Government Funding Deadline Extended to Dec. 18; Ongoing Negotiations on COVID Package.....](#)2
- [Senate Passes Several Health Bills.....](#)2
- [Clyburn Requests Details on Political Meddling at CDC.....](#)3
- [Biden Outlines Pandemic Response Plans for First 100 Days.....](#)3
- [HHS Finalizes Rule on 340B Disputes.....](#)3
- [President Continues Push for \\$200 Drug Discount Cards.....](#)3
- [Hart Health Strategies COVID-19 Resources.....](#)4
- [Upcoming Congressional Hearings and Markups.....](#)4
- [Recently Introduced Health Legislation.....](#)4

Compromise Reached on Surprise Billing Fix

On Friday, key congressional lawmakers released [legislative text](#) and a [summary](#) of their negotiated agreement to protect patients from surprise insurance gaps and end surprise medical billing. All four health care committees of jurisdiction – led by House Ways and Means Chair Richard Neal (D-Mass.), House Energy and Commerce Chair Frank Pallone (D-N.J.), House Education and Labor Chair Bobby Scott (D-Va.), and Senate Health, Education, Labor, and Pensions (HELP) Chair Lamar Alexander (R-Tenn.) – have agreed to the proposal, which would use an independent dispute resolution (IDR) process without benchmark pay rates to resolve disputes over out-of-network bills between providers and payers. The arbiter would be directed to consider the median in-network payment rate for the service in question, information related to the providers' experience, the complexity of the service, and the market share of the parties and their previous contracting history. The IDR would be binding, and there would be no monetary threshold for seeking arbitration. Patients would be held harmless from surprise medical bills and only be responsible for the in-network payment rate, unless they are notified about receiving out-of-network services 72 hours before receiving care. The agreement includes provisions to improve the accuracy of provider directory information. Also, a ban on air ambulance surprise bills is included in the deal. The legislation would extend mandatory funding for community health centers, the National Health Service Corps, and the Teaching Health Center Graduate Medical Education Program at current levels through fiscal year (FY) 2024. House Speaker Nancy Pelosi (D-Calif.) has said she will push for the measure's passage before the end of the year, but it remains unclear whether Senate Majority Leader Mitch McConnell (R-Ky.) will support the inclusion of the measure in a year-end legislative package.

Government Funding Deadline Extended to Dec. 18; Ongoing Negotiations on COVID Package

In advance of the December 11 deadline, Congress passed a one-week stop-gap spending bill, extending the deadline for funding the federal government for fiscal year (FY) 2021 until December 18. Negotiators are still trying to reach a deal on a roughly \$1.4 trillion omnibus package that would include all 12 appropriations bills. Lawmakers also continue to negotiate a bipartisan coronavirus relief bill, which may be attached to the appropriations package. An agreement was reportedly reached on Sunday evening to vote on employer liability protections and state and local government aid provisions as a separate bill. If the agreement holds, the larger of the two proposals would include \$748 billion for enhanced unemployment insurance, small-business relief, and vaccine distribution funding, while the separate \$160 billion measure would contain liability protections and state and local government aid. Complete details of each measure are expected to be released soon. Treasury Secretary Steven Mnuchin made his own \$916 billion proposal on behalf of Republicans last week that was rejected by Democrats for failing to include additional money for supplemental unemployment benefits.

Sens. Josh Hawley (R-Mo.) and Bernie Sanders (I-Vt.) have warned that they will use the funding deadline to force a vote on a second round of stimulus checks for individuals. Their proposal would provide a \$1,200 check to individuals making up to \$75,000. House Majority Leader Steny Hoyer (D-Md.) has advised members that pending an agreement on the omnibus and further coronavirus relief legislation, votes in the House could occur as early as 6:30 p.m. on Tuesday. No votes are expected in the House until agreement has been reached on the omnibus or coronavirus legislation.

Senate Passes Several Health Bills

The Senate passed several health-related bills by unanimous consent last week. The ***Orange Book Transparency Act*** (H.R. 1503) is aimed at improving the database of generic drug approvals and patents and increasing pharmaceutical competition. The chamber also passed an amended version of the ***Safeguarding Therapeutics Act*** (H.R. 5663), which would give the FDA the authority to destroy counterfeit medical devices. Both measures were subsequently approved by the House of Representatives. The Senate also cleared the ***Purple Book Continuity Act*** (H.R. 1520) which relates to the published list of licensed biological products and the ***Food Allergy Safety, Treatment, Education, and Research (FASTER) Act*** (S. 3451), which would add sesame to the list of major food allergens that are required to be identified on labels, starting in 2023, and would require a report and recommendations on federal food allergy regulations. The House passed a similar measure (H.R. 2117) earlier this year. Finally, the Senate amended and passed the ***Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies (TRANSPLANT) Act*** (H.R. 4764) which reauthorizes the C.W. Bill Young Cell Transplantation Program.

Clyburn Requests Details on Political Meddling at CDC

House Select Subcommittee on the Coronavirus Crisis chairman Jim Clyburn (D-S.C.) is requesting details into allegations that CDC Director Robert Redfield covered up attempted political meddling into the agency's scientific work by Trump administration officials. His [letter](#) to Redfield and HHS Secretary Alex Azar requests documents and communications related to efforts to delete, conceal, or withhold an email from HHS senior advisor Paul Alexander demanding that the CDC insert new language in a previously published scientific report on coronavirus risks to children or "pull it down and stop all reports immediately." Clyburn states that failure to produce the evidence in question could result in a subpoena.

Biden Outlines Pandemic Response Plans for First 100 Days

President-elect Joe Biden has pledged to administer 100 million coronavirus vaccinations and to reopen schools during his first 100 days in office. During a speech in which Biden introduced his administration's first health care appointments and nominees, the President-elect also repeated his promises to mandate face coverings on airplanes, in federal buildings, and other places under the federal government's control. The 100 million vaccine figure is in keeping with the vaccine supplies that have already been procured by the government, which will cover the vaccination of 50 million people since Pfizer and Moderna vaccines require two doses.

HHS Finalizes Rule on 340B Disputes

HHS published a final [rule](#) instructing the Secretary to assemble representatives from key agencies, including the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA), to resolve disputes in the program between hospitals or clinics and pharmaceutical manufacturers. The Affordable Care Act (ACA) called for the development of a process to address such disputes, but this is the first effort that has been taken to fulfil that requirement.

President Continues Push for \$200 Drug Discount Cards

Work continues on a revised version of President Trump's proposal to send Medicare beneficiaries \$200 in drug discount cards. The plan would send a letter to 39 million beneficiaries within the next week, with the drug-discount cards being distributed later in December and in January. The plan was circulated inside the administration last week with instructions to expedite its approval. The Special Interest Group for Inventory Information Approval System Standards (SIGIS), which works with the Internal Revenue Service (IRS) to set the standards for health benefit cards, has raised concerns that the plan is not aligned with other regulated discount cards used for medical goods and services because the White House intends the cards to be used exclusively for drugs. The Trump administration, however, continues to urge SIGIS to reconsider its position and disregard the regulations in question.

Hart Health Strategies COVID-19 Resources

Hart Health Strategies Inc. continues to update the following resources related to the coronavirus pandemic. Please remember to clear your cache to ensure you download the most recent documents.

- [COVID-19 Testing](#)
- [Disaster Primer](#)
- [Federal Relief Overview](#)
- [Health Care Workers on the Front Lines](#)
- [Hospice and Palliative Care](#)
- [Nursing Resources](#)
- [Personal Protective Equipment](#)
- [Physician Provisions](#)
- [Re-Opening America](#)
- [Small Business Resources](#)
- [Small Business - Paycheck Protection Program](#)
- [Small Business – PPP FAQ](#)
- [State Resources](#)
- [Tax Provisions](#)
- [Telehealth Overview](#)

Upcoming Congressional Hearings and Markups

Senate Finance Subcommittee on Health Care hearing to examine the Alzheimer's crisis, focusing on testing and treatment pipelines and fiscal implications; 2:30 p.m., WEBEX; December 16

House Oversight and Reform Committee hearing “The Role of Purdue Pharma and the Sackler Family in the Opioid Epidemic;” 9:00 a.m., December 17

Recently Introduced Health Legislation

H.R.8892 — To amend title XVIII of the Social Security Act to support rural residency training funding and promote partnerships with urban teaching hospitals; Sponsor: Rep. Wenstrup, Brad R. [R-OH-2]; Committees: House - Energy and Commerce; Ways and Means

H.R.8894 — To repeal the authority of the Food and Drug Administration to require that drugs be dispensed only upon prescription, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Energy and Commerce

H.R.8897 — To direct the Secretary of Defense to carry out a program for the development of rapid and cost-effective medical countermeasures to pandemics, and for other purposes; Sponsor: Rep. Gosar, Paul A. [R-AZ-4]; Committees: House - Armed Services

H.R.8898 — To require the submission of a report to the Congress on parasitic disease among poor Americans; Sponsor: Rep. Johnson, Henry C. “Hank,” Jr. [D-GA-4]; Committees: House - Energy and Commerce

H.R.8905 — To amend the Federal Food, Drug, and Cosmetic Act to reduce the threat of counterfeit drugs to the pharmaceutical supply chain, and to make the pharmaceutical supply chain more robust, while ensuring the authenticity, content, purity, and manufacturing location and batch number of drugs (including COVID-19 therapeutics and vaccines) and allowing patient verification of authenticity, and for other purposes; Sponsor: Rep. Van Drew, Jefferson [R-NJ-2]; Committees: House - Energy and Commerce

S.4980 — *A bill to amend the Public Health Service Act to direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to support research and programmatic efforts that will build on previous research on the effects of adverse childhood experiences; Sponsor: Sen. King, Angus S., Jr. [I-ME]; Committees: Senate - Health, Education, Labor, and Pensions*

H.R.8906 — *To amend title XXIX of the Public Health Service Act to reauthorize the program under such title relating to lifespan respite care; Sponsor: Rep. Langevin, James R. [D-RI-2]; Committees: House - Energy and Commerce*

H.R.8918 — *To amend the Public Health Service Act to promote healthy eating and physical activity among children; Sponsor: Rep. Cohen, Steve [D-TN-9]; Committees: House - Energy and Commerce*

H.R.8920 — *To establish a program to develop antimicrobial innovations targeting the most challenging pathogens and most threatening infections; Sponsor: Rep. Doyle, Michael F. [D-PA-18]; Committees: House - Armed Services; Homeland Security; Energy and Commerce; Natural Resources; Judiciary; Veterans' Affairs; Ways and Means*

H.R.8921 — *To direct the Secretary of Health and Human Services to reimburse qualified health care providers for the costs of purchasing, leasing, installing, and operating qualified equipment for cold storage of COVID-19 vaccines; Sponsor: Rep. Espaillat, Adriano [D-NY-13]; Committees: House - Energy and Commerce*

H.R.8934 — *To ensure that Medicaid beneficiaries have the opportunity to receive care in a home and community-based setting; Sponsor: Rep. Cartwright, Matt [D-PA-8]; Committees: House - Energy and Commerce*

H.R.8936 — *To amend title XIX of the Social Security Act to provide enhanced Federal matching payments for homecare worker training programs, and for other purposes; Sponsor: Rep. Dingell, Debbie [D-MI-12]; Committees: House - Energy and Commerce*

H.R.8938 — *To direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to establish a standardized procedure for all States to submit weekly reports on hospital policies and metrics related to the response to COVID-19, and for other purposes; Sponsor: Rep. Gabbard, Tulsi [D-HI-2]; Committees: House - Energy and Commerce*

H.R.8942 — *To amend the Public Health Service Act to authorize the Secretary of Health and Human Services to award grants to schools and school-based health centers to increase the number of behavioral health care providers in such schools and health centers, and for other purposes; Sponsor: Rep. Kennedy, Joseph P., III [D-MA-4]; Committees: House - Energy and Commerce*

H.R.8943 — *To direct the President to use authority under the Defense Production Act of 1950 to ensure an adequate supply equipment necessary for limiting the spread of COVID-19, to elevate the Director of the Defense Logistics Agency as the head of the COVID-19 Joint Acquisition Task Force, to require the Director of the Defense Logistics Agency to establish a system for States and localities to access covered items during a covered emergency, and for other purposes; Sponsor: Rep. Larson, John B. [D-CT-1]; Committees: House - Armed Services; Financial Services; Transportation and Infrastructure*

H.R.8950 — *To expand the permissible uses of amounts provided under the Coronavirus Relief Fund; Sponsor: Rep. Thompson, Glenn [R-PA-15]; Committees: House - Oversight and Reform*

S.4989 — *A bill to facilitate nationwide accessibility and coordination of 211 services for information and referral for mental health emergencies, homelessness needs, other human services needs, and for other purposes; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate - Health, Education, Labor, and Pensions*

S.4990 — A bill to require the Office for Civil Rights of the Department of Health and Human Services to conduct a study and issue a report on the de-identification of data pursuant to privacy regulations; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4993 — A bill to amend the Public Health Service Act to promote healthy eating and physical activity among children; Sponsor: Sen. Booker, Cory A. [D-NJ]; Committees: Senate - Health, Education, Labor, and Pensions

S.5000 — A bill to provide support with respect to the prevention of, treatment for, and recovery from, substance use disorder; Sponsor: Sen. Portman, Rob [R-OH]; Committees: Senate - Health, Education, Labor, and Pensions

S.5002 — A bill to improve the quality, appropriateness, and effectiveness of diagnosis in health care, and for other purposes; Sponsor: Sen. Van Hollen, Chris [D-MD]; Committees: Senate - Health, Education, Labor, and Pensions

S.5007 — A bill to amend title XVIII of the Social Security Act to provide for an increase in payment under part B of the Medicare program for certain services in response to COVID-19; Sponsor: Sen. Boozman, John [R-AR]; Committees: Senate - Finance