



Health Policy Briefing

December 20, 2020

Lawmakers Reach Deal on Government Funding/ Coronavirus Relief

Republican and Democratic congressional leadership reached a deal on a nearly \$900 billion coronavirus relief stimulus package ahead of the Sunday night government funding deadline. While the text of the agreement has yet to be finalized, according to statements by senate leadership, the COVID package will include enhanced unemployment relief and \$600 direct impact checks for individuals. It also includes \$25 billion in direct rental assistance, an extension of the moratorium on evictions, and small business relief through \$284 billion for the Paycheck Protection Program (PPP). More than \$30 billion would be provided to support the procurement and distribution of COVID-19 vaccines. The emergency relief bill will not include employer liability protections or direct assistance for state and local governments. The COVID plan will be attached to a \$1.4 trillion spending package to fund the federal government through the end of the fiscal year on September 30, 2021. The final omnibus will include a ban on surprise medical bills. While the details of the surprise billing provision have not yet been released, it is expected to be similar to the compromise reached by the leaders of the House Ways and Means, Energy and Commerce, Education and Labor, and Senate Health, Education, Labor, and Pensions (HELP) committees last week. This evening, Congress passed a 24-hour continuing resolution (CR) to keep the government funded through December 21 to provide additional time to finalize the text of the agreement. A final vote on the omnibus/COVID-19 package is expected sometime tomorrow.

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Moderna COVID Vaccine Granted EUA as Pfizer Begins Distribution

The first COVID-19 vaccine shots were distributed across the country last week. Officials estimate that the first shipment contained roughly 2.9 million doses of the Pfizer-BioNTech vaccine, with an additional 2.9 million doses retained by the government so that the first vaccine recipients can be ensured a second shot. The government will announce new weekly allocations each Friday. According to U.S. Department of Health and Human Services (HHS) Secretary Alex Azar, the plan is to have 20 million people get their first shot in the month of December and their second dose in January. By the end of March, the hope is to have 100 million Americans who have received at least one dose. The Centers for Disease Control and Prevention (CDC) recommended the first vaccines go to health care workers and those in long-term care facilities. Six cases of anaphylaxis among the 272,001 doses of the Pfizer shot administered as of Saturday morning have been identified in the U.S. Pfizer and the FDA are revising fact sheets handed out with the vaccine to provide more detailed instructions for health care providers; the CDC recommends that everyone receive monitoring for 15 minutes after receiving the vaccine, while individuals with a history of severe allergic reactions be monitored for 30 minutes.

According to White House officials, President Trump will receive the vaccine as soon as his medical team recommends it. Vice President Pence, his wife, and Surgeon General Jerome Adams were vaccinated on Friday during a televised event, and members of Congress have also begun to receive the new COVID-19 vaccine at the recommendation of the attending physician as a part of continuity of government protocols. President-elect Biden and his wife will receive their first dose of the vaccine on Monday, while Vice President-elect Harris and her husband will get their first shots the following week. Supreme Court justices have been told by the Capitol physician's office that they will be eligible to receive their shots in the coming days.

The Food and Drug Administration (FDA) granted emergency use authorization (EUA) on Friday to Moderna for the use of its coronavirus vaccine in people 18 years of age and older, making it the second vaccine to be cleared by the agency since the start of the pandemic. The Moderna EUA follows a 20-0 vote, with one abstention, from the FDA's independent advisory panel that the known and potential benefits of the vaccine outweigh the known and potential risks. Similar to the shot produced by Pfizer Inc. and BioNTech, the vaccine uses mRNA technology and is administered in a two-dose regimen. Moderna's vaccine, however, does not need the special equipment that Pfizer's requires to be kept at an extremely cold temperature.

The CDC's Advisory Committee on Immunization Practices (ACIP) voted 11-9 over the weekend to recommend Moderna's vaccine. Delivery of the Moderna product to the U.S. will begin immediately. Moderna expects to be able to produce 20 million doses for the U.S. by the end of the year, and another 85 million to 100 million doses in the U.S. in the first quarter. The company plans to seek full approval of the vaccine next year.

Senate Passes Additional Health Legislation

The Senate approved several pieces of health-related legislation by unanimous consent last week. The ***School-Based Allergies and Asthma Management Program Act*** (H.R. 2468) encourages schools to implement management plans to help students identify and control their asthma and allergies and reduce absenteeism. The ***Advancing Research to Prevent Suicide Act*** (H.R. 4704) directs the National Science Foundation to support research on the science of suicide. The ***Ensuring Innovation Act*** (S. 1636) amends the Food, Drug, and Cosmetic Act with respect to chemical exclusivity and aims to ensure that exclusivity is not awarded to products which do not represent a true innovation. The ***Data Mapping to Save Moms' Lives Act*** (S. 3152) requires the Federal Communications Commission (FCC) to incorporate maternal health outcomes into its broadband health maps. The ***Cannabidiol and Marijuana Research Expansion Act*** (S. 2032) expands research on cannabis and marijuana. H.R.7898 requires HHS to consider certain recognized security practices of covered entities and business associates when making certain determinations. The ***Henrietta Lacks Enhancing Cancer Research Act*** (H.R. 1966) requires the Government Accountability Office (GAO) to complete a report reviewing how federal agencies address barriers to participation in federally-funded cancer clinical trials by individuals from underrepresented populations.

Steering Committee Selects New E&C Democrats

The House Democratic Steering Committee nominated appointments to several committees for the 117th Congress last week, including the Energy and Commerce Committee. The Steering Committee approved the following new members to E&C: Angie Craig (Minn.), Lizzie Fletcher (Texas), Kathleen Rice (N.Y.), Kim Schrier (Wash.), and Lori Trahan (Mass.). The nominations will now be sent to the full Democratic Caucus for approval.

Senators Begin Becerra Nomination Process

Senate panels have begun their vetting of President-elect Joe Biden's cabinet picks, including nominee for Secretary of the HHS Xavier Becerra. The Senate Finance Committee has sent its questionnaire to the HHS nominee, and Senate Finance Committee Ranking Member Ron Wyden (D-Ore.) and Senate HELP Committee Ranking Member Patty Murray (D-Wash.) – met with Becerra virtually last week. The ongoing coronavirus pandemic was the focus of their conversation, but Sen. Wyden also discussed the need to lower drug prices with the HHS nominee.

Clyburn Probes Pfizer Vaccine Procurement

House Select Subcommittee on the Coronavirus Crisis Chair Jim Clyburn (D-S.C.) is [asking](#) White House officials whether the U.S. government opted against purchasing additional doses of the Pfizer vaccine. According to a New York Times report, the federal government chose to forego the opportunity to purchase up to 500 million additional doses of its vaccine earlier this year. The panel's letter to HHS Secretary Alex Azar and Department of Defense (DOD) Acting Secretary Christopher Miller requests a response and a briefing by December 23, 2020.

Krishnamoorthi Requests Details on Navarro Contracts

House Oversight and Reform Subcommittee on Economic and Consumer Policy Chair Raja Krishnamoorthi (D-Ill.) is [demanding](#) that White House Trade Czar Peter Navarro provide any information on pandemic-related government contracts in which he played a role. Krishnamoorthi argues that Navarro's involvement in ventilator procurement resulted in the federal government overpaying by hundreds of millions of dollars. Navarro was the chief negotiator of a \$646.7 million ventilator contract with Philips Respironics.

E&C Republicans Praise Regulatory Review Rule

Republican leadership of the House Energy and Commerce Committee sent a [letter](#) to HHS expressing support for a proposed rule that would provide for HHS to review each of its regulations every 10 years, requiring regulations that are more than 10 years old to be reviewed within the first two years of the rule's enactment. Regulations that are not reviewed during the provided window would expire. "HHS regulations have a real-world impact on jobs, the quality of life, and the cost of living of the American people. As a matter of good government, it is important that regulations are monitored to find out if they are actually achieving their projected benefits. The proposed rule would incentivize HHS to conduct retrospective regulatory reviews to ensure regulations are delivering the projected benefits rather than measuring the effectiveness of the implementation of the regulation," the members write. The letter to HHS Secretary Alex Azar was signed by Ranking Member Greg Walden (R-Ore.), incoming ranking member for the 117th Congress Cathy McMorris Rodgers (R-Wash.), Health Subcommittee Chair Michael Burgess (R-Texas), and Oversight and Investigations Chair Brett Guthrie (R-Ky.).

NIH Aims to Curb Foreign Influence in Research

According to a new [report](#) from the Government Accountability Office (GAO), the National Institutes of Health (NIH) plans to amend its regulations and procedures to require biomedical researchers to disclose non-financial conflicts of interest with the goal of curbing foreign influences. The NIH has identified 455 researchers of possible concern and has worked with the Department of Justice (DOJ) to investigate six criminal cases. These cases include scientists who failed to disclose foreign ties, those who recreated findings from their U.S. research in labs in other countries, or people who stole confidential grant applications during the peer review process.

Provider Relief Fund Phase 3 General Distribution

On December 16, HHS [announced](#) the Phase 3 General allocation distribution of the Provider Relief Fund (PRF). While the original allocation was for \$20 billion, HHS increased the total to \$24.5 billion so that all health care providers could receive “up to 88 percent of their reported losses,” taking into account prior distributions. According to HHS, distribution of the additional funding to 70,000 providers began immediately and will continue through January. As detailed within the application instructions, all providers receiving more than \$10,000 are subject to key reporting requirements, with the first deadline for reporting February 15, 2021. For the updated reporting elements, visit [here](#), along with a summary of those requirements [here](#). In addition, as noted within the reporting requirements document, all providers that expend more than \$750,000 in Federal funds (including PRF and the Paycheck Protection Program (PPP) funds) will be subject to additional audit requirements. For additional information, visit the [Reporting Requirements and Auditing](#) page and read the [Auditing and Reporting Requirements FAQs](#). More information related to this program can be found on the [PRF website](#).

Becerra and State AGs Comment On 340B

California attorney general and President-elect Biden’s nominee for U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra has sent a [letter](#) to HHS Secretary Alex Azar regarding disputes between providers and pharmaceutical manufactures participating in the 340B drug discount program. The letter was signed by 28 other state AGs. “Drug manufacturers are, without justification, flouting discounted pricing requirements for low-income patients and/or unreasonably conditioning 340B pricing on data demands,” the letter states. “Each day that drug manufacturers violate their statutory obligations, vulnerable patients and their health care centers are deprived of the essential health care resources that Congress intended to provide.” The letter urges HHS to use its authority and any available measures, including imposition of civil penalties, to hold drug manufacturers in violation of the law directly accountable.

CBO Corrects 2020 Revenue Forecast

The Congressional Budget Office’s (CBO) revenue forecast for 2020 was off by 9 percent – almost twice as much as usual – as a result of the coronavirus pandemic. According to a new [report](#) from the agency, taxes paid by individuals were 16 percent higher than anticipated, despite wages falling more than predicted, while corporate receipts were also underestimated by 12.5 percent. CBO explains that in both cases, fewer people took advantage of tax incentives created in response to the pandemic than expected. Payroll taxes were also two percent higher than what the CBO had originally forecast.

HealthCare.gov Enrollment Increases by Over 6%

Enrollment in HealthCare.gov has increased 6.6 percent over last year according to recently released federal [data](#). More than 8.2 million people signed up for health care coverage through the Affordable Care Act (ACA) exchange during the enrollment period that ended last week, growing 6.3 percent over 2019 and 2.2 percent over 2018. Eleven states plus Washington, D.C. have extended their own open enrollment periods, with some not closing until the end of January.

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](#)

Recently Introduced Health Legislation

H.R.8953 — *To amend the Public Health Service Act to authorize grants for graduate medical education partnerships in States with a low ratio of medical residents relative to the general population; Sponsor: Rep. Castor, Kathy [D-FL-14]; Committees: House - Energy and Commerce*

H.R.8958 — *To require the Secretary of Health and Human Services to publish guidance for States on strategies for maternal care providers participating in the Medicaid program to reduce maternal mortality and severe morbidity with respect to individuals receiving medical assistance under such program; Sponsor: Rep. Kelly, Robin L. [D-IL-2]; Committees: House - Energy and Commerce*

H.R.8966 — *To provide for a vaccine safety public awareness campaign; Sponsor: Rep. Wenstrup, Brad R. [R-OH-2]; Committees: House - Energy and Commerce*

H.R.8967 — *To require the Secretary of Health and Human Services to award a contract to an eligible nonprofit entity to establish and maintain a health care claims database for purposes of lowering Americans' health care costs, and for other purposes; Sponsor: Rep. Beyer, Donald S., Jr. [D-VA-8]; Committees: House - Armed Services; Education and Labor; Oversight and Reform; Energy and Commerce; Ways and Means*

H.R.8971 — *To authorize assistance to aid in the prevention and treatment of obstetric fistula in foreign countries, and for other purposes; Sponsor: Rep. Maloney, Carolyn B. [D-NY-12]; Committees: House - Foreign Affairs*

H.R.8981 — *To prohibit discrimination on the basis of mental or physical disability in cases of anatomical gifts and organ transplants; Sponsor: Rep. Herrera Beutler, Jaime [R-WA-3]; Committees: House - Energy and Commerce*

H.R.8987 — *To amend the Public Health Service Act to incentivize the manufacture of certain medicines in the United States and to enhance the security of the United States pharmaceutical supply chain, and for other purposes; Sponsor: Rep. Joyce, John [R-PA-13]; Committees: House - Energy and Commerce; Ways and Means*

S.5027 — A bill to authorize the Director of the Centers for Disease Control and Prevention to award grants to eligible State, Tribal, and territorial public health agencies to develop and administer a program for digital contact tracing for COVID-19, and for other purposes; Sponsor: Sen. Schatz, Brian [D-HI]; Committees: Senate - Health, Education, Labor, and Pensions

S.5034 — A bill to empower communities to establish a continuum of care for individuals experiencing mental or behavioral health crisis, and for other purposes; Sponsor: Sen. Cortez Masto, Catherine [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

S.5044 — A bill to amend title XVIII of the Social Security Act to establish requirements with respect to the use of prior authorization under Medicare Advantage plans, and for other purposes; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Finance

S.5051 — A bill to amend title XVIII of the Social Security Act to provide for Medicare coverage of multi-cancer early detection screening tests; Sponsor: Sen. Crapo, Mike [R-ID]; Committees: Senate - Finance