HHS | Hart Health Strategies Inc.

Health Policy Briefing

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Negotiations on Stimulus Continue After Trump Reversal

President Trump announced last week that he had ordered his officials and Republicans in Congress to stop negotiations on the next coronavirus stimulus until after the election, and to instead focus on confirming his nomination of Amy Coney Barrett to the Supreme Court. Prior to the President's announcement, House Speaker Nancy Pelosi (D-Calif.) and Treasury Secretary Steven Mnuchin were in the midst of negotiations on the $2.2 trillion aid proposal from Democrats and the $1.6 trillion proposal backed by the White House. In a letter to colleagues, Pelosi stated that the remaining areas of disagreement included funding for unemployment insurance, money for schools and state and local governments, amounts for the Child Tax Credit and Earned Income Tax Credit, restrictions on the use of money for testing, and a $44 billion gap on appropriated discretionary funding.

The President reversed course on Friday, endorsing a $1.8 trillion offer, and negotiations between Pelosi and Mnuchin took place over the weekend. The White House proposal has been met with concern by Senate Republicans, who are unsure whether to support the overall cost of the measure and stand in opposition to some of its provisions, including the expansion of Affordable Care Act (ACA) tax credits. The Senate is in recess until October 19 and the House is in recess until mid-November, but lawmakers have been told they can be called back with 24 hours-notice to vote on a stimulus deal.

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Senators Request Change to Provider Relief Fund Reporting Requirements

Separate groups of Senate Republicans and Democrats have sent letters to U.S. Department of Health and Human Services (HHS) Secretary Alex Azar calling on the administration to change the reporting requirements for CARES Act Provider Relief Fund (PRF) grants, which could require some hospitals to return millions of dollars to the government. As part of the newly released reporting requirements, HHS made technical changes to the definition and calculation of "expenses" and "lost revenue" attributable to COVID-19 for relief fund recipients. Senators urge Azar to "reinstate the original June requirements for determining lost revenue in order to prevent unnecessary financial uncertainty for hospitals." The Republican letter was signed by 30 senators, and the Democratic letter was signed by 22 senators.

Now Open: Phase 3 Application Portal for the Provider Relief Fund

On October 1, the U.S. Department of Health and Human Services (HHS) announced a schedule for distribution of an additional $20 billion in funds from the CARES Act Provider Relief Fund (PRF) "that considers financial losses and changes in operating expenses caused by the coronavirus" (also known as the Phase 3 distribution). **Eligible providers have an application deadline of November 6, 2020**. The application portal is located here, and HHS has detailed the general process for applying here, including application instructions and sample application form. In addition, HHS has recently posted a fact sheet, toolkit and presentation on Phase 3 as well as updating its FAQs. HHS is hosting a webcast on October 15 at 3 pm ET. Click here to register for the webcast.

All providers receiving more than $10,000 are subject to key reporting requirements, with the first deadline for reporting February 15, 2021. For the 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 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 Provider Relief Fund website.

Lawmakers Warn Against Administration's New LDT Policy

Democratic leadership of the House Energy and Commerce Committee have written to U.S. Department of Health and Human Services (HHS) Secretary Alex Azar raising significant concerns about the decision to allow laboratory-developed tests (LDTs) to come to market without review by the Food and Drug Administration (FDA), characterizing the move as a "grave mistake." The FDA announced last week via an update to its General FAQs that it will no longer be reviewing LDTs, even if requested by the lab sponsor, in line with Secretary Azar's decision. "This new policy," the lawmakers argue, "could lead to numerous faulty tests on the market, raising serious concerns about the reliability of tests used to detect COVID-19…This decision will increase the chances of false negative results, endangering countless lives, and weakening our understanding of COVID-19 as we head into fall and winter."

Oversight Panel Investigates Political Interference at FDA, CDC

House Oversight and Reform Subcommittee on Economic and Consumer Policy Chairman Raja Krishnamoorthi (D-Ill.) is adding to a growing number of probes investigating political influence into scientific decisions being made by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) related to the coronavirus pandemic. The letter addressed to FDA Commissioner Stephen Hahn and CDC Director Robert Redfield Krishnamoorthi requests information detailing changes made by the White House during its review process of the agencies' communications. The subcommittee asks the agencies to respond by October 19.

E&C Asks for Probe of HHS Cybersecurity Abilities

Bipartisan leadership of the House Energy and Commerce Committee are asking the Government Accountability Office (GAO) to evaluate the U.S. Department of Health and Human Services' (HHS) cybersecurity incident response capabilities. Their request is based on the agency's own expressed concerns and recent past cybersecurity incidents. "Given the types of information created, stored, and shared on the information systems owned and operated by HHS, it is important that the agency implement effective incident response handling processes and procedures to address persistent cyber-based threats," the lawmakers stress, especially in the midst of the COVID-19 pandemic.

E&C GOP Request Information on HHS Program Support Center

Republican leadership of the House Energy and Commerce Committee sent a letter to U.S. Department of Health and Human Services (HHS) Secretary Alex Azar to share their concerns about the HHS Program Support Center (PSC), which was created to provide comprehensive acquisition management services for HHS and federal agencies. The PSC recently abruptly terminated several agreements facilitated between non-HHS agencies. The lawmakers question whether HHS contracting for non-HHS agencies is appropriate and legal. "Even if HHS believed that the PSC had the legal authority to administer contracts for other agencies, it is not clear why the PSC did not have policies, procedures, and internal controls in place to support this activity. This not only has ramifications for the PSC's non-HHS agency contract actions valued at more than a half billion dollars in FY 2019, but possibly for other HHS revolving funds that might be used to support non-HHS agencies," the letter states. Ranking Member Greg Walden (R-Ore.) and Oversight and Investigations Subcommittee Ranking Member Brett Guthrie (R-Ky.) request information about how the PSC works and what fees it charges.

2nd Presidential Debate Cancelled

The Commission on Presidential Debates has canceled the second Presidential debate of this election cycle originally scheduled for October 15 between President Trump and Joe Biden. The President objected to participating in a virtual debate, after the event format was changed from an in-person town hall in Miami following his diagnosis with COVID-19.

Whistleblower Scientist Bright Resigns from NIH

Dr. Rick Bright submitted his resignation from the National Institutes of Health (NIH) last week. Bright is the former director of the Biomedical Advanced Research and Development Authority (BARDA) and the person at the center of a whistleblower complaint against the administration's hydroxychloroquine strategy. Bright claims that NIH leadership opposed his recommendations related to the COVID-19 pandemic response for political reasons and sidelined him from doing meaningful work at the agency. Bright was transferred to NIH from BARDA this spring after raising concerns about political interference in scientific decision-making.

Providers Call for Fix to MPFS Budget Neutrality

A coalition representing 47 organizations and 1.4 million physician and non-physician providers have sent a letter to Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma expressing concerns about the proposed budget neutrality reduction proffered by the agency in its 2021 Medicare Physician Fee Schedule (PFS) proposed rule. The organizations warn that the change could jeopardize the financial viability of providers, reduce access to medically necessary specialty services, and decrease lifesaving cancer screening services. The letter argues that CMS has significant administrative discretion in administering the budget neutrality provision, and that the administration could mitigate the impact of budget neutrality by utilizing funds outside of the PFS under the unique circumstances of the current public health emergency (PHE).

FDA Releases Vaccine Guidance

The Food and Drug Administration (FDA) has released the standards it will use in the emergency use authorization (EUA) of an eventual COVID-19 vaccine. The guidance will require manufacturers to monitor clinical trial participants for a median of two months after administering the last shot, a time frame which could be shortened depending on the data. The White House temporarily blocked the agency from publishing the guidance last week, following insistence from President Trump that a vaccine could be available before the November 3 election. While administration officials claimed that the pharmaceutical industry had expressed opposition to the FDA benchmarks, the FDA stated that it had heard no such complaints and the industry has publicly supported the agency's expectations for demonstrating safety and efficacy. The guidance decreases the likelihood that any vaccine will receive an EUA before the election.

Eli Lilly Requests EUA for Monoclonal Antibody Treatment

Eli Lilly is requesting the Food and Drug Administration (FDA) issue an emergency use authorization (EUA) for its coronavirus monoclonal antibody treatment known as bamlanivimab. The company seeks to use the treatment on high-risk patients recently diagnosed with mild-to-moderate COVID-19. According to data from its phase II clinical trial published by the company, patients who received any dose of the antibody were less likely to be hospitalized or visit the emergency room. A phase III study for the prevention of COVID in residents and staff at long-term care (LTC) facilities is ongoing. If Eli Lilly receives the EUA, it says it could supply as many as one million doses before the end of the year. The company plans to ask for an emergency authorization for its combination monoclonal antibody treatment next month.

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.Res.1176 —Supporting the designation of October 3, 2020, as National Ostomy Awareness Day; Sponsor: Rep. Payne, Donald M., Jr. [D-NJ-10]; Committees: House - Oversight and Reform

H.R.8505 —To amend title XVIII of the Social Security Act to provide for a one-year waiver of budget neutrality adjustments under the Medicare physician fee schedule, and for other purposes; Sponsor: Rep. Burgess, Michael C. [R-TX-26]; Committees: House - Ways and Means; Energy and Commerce; Appropriations

H.R.8506 —To improve the provision of health care and other benefits from the Department of Veterans Affairs for veterans who were exposed to toxic substances, and for other purposes; Sponsor: Rep. Bilirakis, Gus M. [R-FL-12]; Committees: House - Veterans' Affairs

H.R.8508 —To require the President to use authorities under the Defense Production Act of 1950 to require emergency production of the supplies necessary for distributing and administering the COVID-19 vaccine, and for other purposes; Sponsor: Rep. Crist, Charlie [D-FL-13]; Committees: House - Financial Services

H.R.8525 — To amend title XIX of the Social Security Act to provide for coverage under the Medicaid program of non-invasive prenatal genetic screening; Sponsor: Rep. Speier, Jackie [D-CA-14]; Committees: House - Energy and Commerce

H.R.8527 —To address the high costs of health care services, prescription drugs, and health insurance coverage in the United States, and for other purposes; Sponsor: Rep. Westerman, Bruce [R-AR-4]; Committees: House - Ways and Means; Rules; Judiciary; Energy and Commerce; House Administration; Oversight and Reform; Education and Labor; Budget; Armed Services

H.R.8528 —To extend certain provisions relating to telehealth services, and for other purposes; Sponsor: Rep. Williams, Roger [R-TX-25]; Committees: House - Ways and Means; Energy and Commerce

S.4796 — A bill to address the high costs of health care services, prescription drugs, and health insurance coverage in the United States, and for other purposes; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate – Finance

H.Res.1181 — Honoring Rosalynn Smith Carter's 50 years of mental health advocacy; Sponsor: Rep. Dingell, Debbie [D-MI-12];Committees: House - Energy and Commerce

H.Res.1182 — Recognizing the roles and the contributions of America's certified nurse-midwives and certified midwives in providing high-quality, evidence-based, cost-effective, and essential sexual and reproductive health care services to women and pregnant people; Sponsor: Rep. Roybal-Allard, Lucille [D-CA-40]; Committees: House - Energy and Commerce

H.R.8529 — To amend title XIX of the Social Security Act to prohibit additional rebates under the Medicaid program for certain noninnovator multiple source drugs; Sponsor: Rep. Butterfield, G. K. [D-NC-1]; Committees: House - Energy and Commerce

H.R.8536 — To amend the Fair Credit Reporting Act to delay the reporting of medical debt by consumer reporting agencies, and for other purposes; Sponsor: Rep. Gallagher, Mike [R-WI-8]; Committees: House - Financial Services

H.R.8546 — To amend titles XIX and XXI of the Social Security Act to give States the option to extend the Medicaid drug rebate program to the Children's Health Insurance Program, and for other purposes; Sponsor: Rep. Wild, Susan [D-PA-7]; Committees: House - Energy and Commerce