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Health Policy Briefing

November 23, 2020

House Democrats Pick Leadership for 117th Congress

House Democrats have nominated current Speaker Nancy Pelosi (D-Calif.) to continue to lead the party for another two years. Her selection took place by voice vote. To secure the position of speaker during the 117th Congress, she will need the support of the majority of the full House come January. Majority Leader Steny Hoyer (D-Md.), Majority Whip Jim Clyburn (D-S.C.), and House Democratic Caucus Chairman Hakeem Jeffries (D-N.Y.) were also reelected to their leadership posts. Rep. Katherine Clark (D-Mass.) defeated Rep. David Cicilline (D-R.I.) in the race for assistant Speaker. She will replace Rep. Ben Ray Lujan (D-N.M.), who has been elected to the Senate. The race for Democratic Congressional Campaign Committee (DCCC) chair has been postponed until the week after Thanksgiving to give the candidates, Rep. Sean Patrick Maloney (D-N.Y.) and Rep. Tony Cardenas (D-Calif.), additional time to campaign. Current DCCC chair Cheri Bustos (D-Ill.) did not seek a second term. Please see HERE for Hart Health Strategies Inc. updated 2020 Political/Elections Overview document.

White House Objection Complicates Spending Talks

White House negotiators are demanding cuts to domestic spending ahead of the December 11 deadline to fund the federal government. Treasury Secretary Steven Mnuchin expressed objections to the proposal to exempt $12.5 billion in spending for the Department of Veterans Affairs (VA) from the budget cap established by the 2019 debt ceiling deal. The money would provide for expanded health care for veterans as required by the 2018 VA Mission Act. Efforts are currently underway to pass a full-year omnibus measure, but negotiations could be stalled by the need to find domestic spending cuts to offset the VA money, a move which is opposed by Democrats and would increase the likelihood of another short-term spending measure.

Inside

COVID Stimulus Negotiations Remain Stalled

Senate Minority Leader Chuck Schumer (D-N.Y.) called on Majority Leader Mitch McConnell (R-Ky.) last week to resume negotiations on a coronavirus stimulus package. McConnell has repeatedly dismissed the $2.4 trillion bill that Democratic leadership wish to use as a starting point for negotiations. White House Chief of Staff Mark Meadows signaled that any future talks on a COVID stimulus package will be led by Congress and not the White House. Previously, negotiations had taken place between Meadows, Treasury Secretary Steven Mnuchin, and House Speaker Nancy Pelosi (D-Calif.).

White House Releases Major Drug Pricing Regulations

The administration has released two major regulations aimed at lowering drug prices. The so-called "rebate rule" would remove safe harbor protection from antikickback law for after-sale rebates paid by manufacturers to pharmacy benefit managers (PBMs) in Medicare Part D. Instead, upfront discounts will be eligible for safe harbor protection. The rule will also allow for discounts to go directly to the patient at the pharmacy counter. The Department of Health and Human Services (HHS) had appeared to scrap the rule last year out of concerns that it would raise premiums for program beneficiaries. The PBM industry has threatened lawsuits if the administration follows through with the regulation. Meanwhile, the so-called "most favored nation" interim final rule would tie federal reimbursement for drugs administered in doctors' offices and outpatient departments to the lowest price paid among certain other countries. The policy would be implemented over the course of seven years through a demonstration model and initially apply to 50 single-source drugs comprising a high percentage of Part B drug spending. It would also replace the current add-on percentage-based payment with a flat fee. The seven-year demo will be nationwide and mandatory, to begin in January. In the rule, the Centers for Medicare and Medicaid Services (CMS) acknowledges that it is difficult to accurately estimate the financial impact of the model, but estimates that it will save more than $85 billion over seven years, net of associated premium savings.

CMS Issues Stark, Anti-Kickback Reform Final Rule

The Centers for Medicare and Medicaid Services (CMS) released its Stark and anti-kickback final rule, which has been under review since July. The Physician Self-Referral Law, also known as the "Stark Law," generally prohibits providers from making referrals to an entity for certain health care services if the provider has a financial relationship with the entity. The new regulation finalizes new, permanent exceptions for value-based arrangements that will permit health care providers to design and enter into value-based arrangements, add additional guidance on key requirements of the exceptions to the physician self-referral law, and finalize protection for non-abusive, beneficial arrangements.

White House Finalizes OPO Rule

The White House has finalized a rule aimed at increasing the number of organs available for transplant and shortening transplant wait times. The regulation from the Centers for Medicare and Medicaid Services (CMS) would require organ procurement organizations (OPOs) to be more transparent about their performance and establish more stringent quality measurements. The rule is a part of President Trump's July 2019 Executive Order on Advancing American Kidney Health. It would require each OPO to track the number of usable organs procured, the number that are actually transplanted, and the number donated for research.

House Dems Continue Push to Begin Presidential Transfer of Power

A group of top House Democrats have sent a letter to the General Services Administration (GSA) demanding a briefing on the status of the decision to allow President-elect Joe Biden and his transition team to access government services and facilities. GSA Administrator Emily Murphy has yet to ascertain that Joe Biden was the winner of the November 3 presidential election. Oversight and Reform Committee Chair Carolyn Maloney (D-N.Y.), Appropriations Chair Nita Lowey (D-N.Y.), Financial Services Subcommittee Chair Mike Quigley (D-Ill.), and Government Operations Subcommittee Chair Gerald Connolly (D-Va.) argue that the blocking of transition activities are "impairing the incoming administration's ability to respond to the coronavirus pandemic, hampering its ability to address our nation's dire economic crisis, and endangering our national security." House Energy and Commerce Chair Frank Pallone (D-N.J.) had also sent a letter to the President earlier in the week urging him to begin the transition process for the sake of the government's COVID-19 response. While the transition team cannot contact federal agencies to discuss their policies and operations, Biden's team has begun to contact congressional lawmakers and staff in order to prepare for the incoming administration.

Health Care Groups Push for Presidential Transition

The American Hospital Association (AHA), the American Medical Association (AMA), and the American Nurses Association (ANA) sent a letter to President Trump calling on the administration to share information related to its coronavirus response with President-elect Joe Biden and his transition team. The organizations stress the importance of cooperation and coordination in order to avoid any lapse in the ability to care for patients. "Real-time data and information on the supply of therapeutics, testing supplies, personal protective equipment, ventilators, hospital bed capacity and workforce availability to plan for further deployment of the nation's assets needs to be shared to save countless lives," the letter states.

House Passes 10 Health Care Related Measures

Last week, the House of Representatives passed the following health care related bills by voice vote under suspension of the rules:

- H.R. 4499 – NIMHD Research Endowment Revitalization Act of 2020
- H.R. 5668 – Making Objective Drug Evidence Revisions for New (MODERN) Labeling Act of 2020
- H.R. 4712 – Fairness in Orphan Drug Exclusivity Act
- H.R. 2466 – State Opioid Response Grant Authorization Act of 2020
- H.R. 2281 – Easy MAT for Opioid Addiction Act
- H.R. 2117 – Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2020
- H.R. 5855 – Bipartisan Solution to Cyclical Violence Act of 2020
- H.R. 3878 – Block, Report, And Suspend Shipments Act of 2020
- H.R. 4806 – Debarment Enforcement of Bad Actor Registrants (DEBAR) Act of 2020
- H.R. 4812 – Ensuring Compliance Against Drug Diversion Act of 2019

Grassley, Warren Request Release of Hearing Aid Regulations

Senate Finance Committee Chair Chuck Grassley (R-Iowa) and Sen. Elizabeth Warren (D-Mass.) sent a letter to the Food and Drug Administration (FDA) urging the agency to issue an overdue rule to overhaul over-the-counter (OTC) hearing aid regulations. The update, which would change how certain hearing aids are categorized and institute new patient safety protections, was required by August 18, 2020 as a part of the ***FDA Reauthorization Act of 2017***. The lawmakers write that the FDA should "make issuing the OTC hearing aid regulations a priority, consistent with the law."

E&C Republicans Ask for Info on Lab Capacity

House Energy and Commerce Committee Ranking Member Greg Walden (R-Ore.), along with Rep. Michael Burgess (R-Texas) and Brett Guthrie (R-Ky.), sent a letter to the Centers for Disease Control and Prevention (CDC) requesting full, updated data on domestic lab capacity with BioSafety Level 3 (BSL-3) status. "The lack of information on BSL-3 laboratory capacity is of concern because it may be contributing to delays and bottlenecks in preclinical COVID-19 research. Although the BSL-3 laboratory capacity is not fully known, the extraordinary demand for COVID-19 preclinical research may have overwhelmed the known, available capacity," the lawmakers state. "It is critical for the nation's response to the pandemic to have the best understanding of the totality of such research assets in the U.S. in order to improve access for researchers, maximize research opportunities for identifying medical advances for COVID-19, bring in any underutilized laboratories to help relieve burdens on overworked research entities, and understand through traditional gap analysis whether there is appropriate high-containment laboratory capacity for biodefense strategic planning."

Hoyer Urges Strengthening of Whistleblower Protections

House Majority Leader Steny Hoyer (D-Md.) has sent a letter to House Rules Committee Chair Jim McGovern (D-Mass.) urging the panel to adopt a new prohibition on lawmakers revealing the identities of whistleblowers under the protection of federal law, making the disclosure of a whistleblower's identity a violation of the House Code of Official Conduct. "While its application would only extend to the House," Hoyer writes, "it is my hope that the Senate would follow the House's example and adopt a similar provision in its own rules." The Majority Leader states that he will work with the Rules Committee to ensure that his proposed rule is written precisely enough to hold violators accountable without impinging on lawmakers' ability to work with whistleblowers and conduct oversight.

FDA Grants EUA for Lilly COVID Treatment

The Food and Drug Administration (FDA) has granted an emergency use authorization (EUA) to Eli Lilly's rheumatoid arthritis drug barticitnib, in combination with Gilead'sremdesivir, for the treatment of COVID-19. The combination has been shown to reduce time to recovery. The decision is based on a trial sponsored by the National Institutes of Health (NIH) which found that the two drugs decreased deaths compared to patients who only received remdesivir, and reduced hospital recovery time by a day.

Moderna Releases Promising Vaccine Data

Moderna Inc. has released interim results for its COVID vaccine suggesting that it is 94.5 percent effective and may block severe cases of the disease. The data from a preliminary analysis of the company's large late-stage clinical trial comes just a week after Pfizer Inc. and BioNTech SE announced that their vaccine candidate had a similarly positive record. Both vaccines rely on messenger RNA (mRNA) technology that has thus far never been used in an approved vaccine. The Moderna product does not require storage in the special facilities necessary for the Pfizer vaccine. In Moderna's 30,000 person trial, only five volunteers who received two doses of the vaccine over four weeks became sick, compared with 90 COVID cases in participants who received the placebo. There were no severe coronavirus cases among vaccine recipients, compared to 11 cases in people who received the placebo. Moderna stated that an emergency use authorization (EUA) is expected following a final analysis of 151 cases and two months of follow-up safety data which will be completed later this month. There have been no significant safety concerns so far. The company hopes to manufacture 20 million doses by the end of this year, with the initial doses going to the U.S.

In related news, the Food and Drug Administration (FDA) announced that the Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet on December 10 to discuss the request for EUA of Pfizer's COVID-19 vaccine. The agency will issue a ***Federal Register*** notice this week with details of the meeting, which will include information about a public docket for comments. The meeting will be webcast live.

More Lawmakers Test Positive for COVID

A new group of federal lawmakers announced that they had tested positive for coronavirus last week. Rep. Cheri Bustos (D-Ill.), Rep. Ed Perlmutter (D-Colo.), Sen. Rick Scott (R-Fla.),and Rep. Don Young (R-Alaska), the oldest and longest-serving member of the House, have each tested positive and are isolating and working from home. Senate Finance Committee Chair Chuck Grassley (R-Iowa) has also tested positive for the virus and is working from home. His positive test required him to miss his first roll call vote in more than 27 years, ending his 8,927 consecutive voting streak. A total of 82 members of Congress have contracted the virus, quarantined, or come into contact with someone with the disease this year, according to govtrack.us, and more than two dozen lawmakers have tested positive or were diagnosed with a presumed infection.

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 Homeland Security and Governmental Affairs hearing to examine COVID-19, focusing on essential components of a solution; 10:00 a.m., 342 Dirksen Bldg.; December 1

Recently Introduced Health Legislation

H.Res.1223 — Supporting the goals of World AIDS Day; Sponsor: Rep. Lee, Barbara [D-CA-13]; Committees: House - Foreign Affairs; Energy and Commerce

H.R.8755 — 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: Rep. Sherrill, Mikie [D-NJ-11]; Committees: House - Energy and Commerce; Ways and Means

S.4900 — A bill to require a pilot program on activities under the Transition Assistance Program for a reduction in suicide among veterans, and for other purposes; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Veterans' Affairs

H.R.8756 — To amend title XVIII of the Social Security Act to ensure adequate payment for certain physicians' services furnished under part B of the Medicare program during the COVID-19 public health emergency; Sponsor: Rep. Riggleman, Denver [R-VA-5]; Committees: House - Energy and Commerce; Ways and Means

H.R.8780 — To amend title XVIII of the Social Security Act to provide for additional requirements with respect to electrodiagnostic services under the Medicare program; Sponsor: Rep. Walden, Greg [R-OR-2]; Committees: House - Energy and Commerce; Ways and Means

H.Con.Res.124 — Expressing the sense of Congress that public health professionals should be commended for their dedication and service to the United States on Public Health Thank You Day, November 23, 2020; Sponsor: Rep. Wittman, Robert J. [R-VA-1]; Committees: House - Energy and Commerce

S.Res.777 — A resolution expressing the sense of the Senate on the need for common sense solutions to improve health care delivery and affordability for all people of the United States; Sponsor: Sen. Perdue, David [R-GA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4919 — A bill to provide for a study by the National Academies of Sciences, Engineering, and Medicine on the potential benefits on population health outcomes of incorporating into the Federal legislative process tools that measure the impacts of proposed legislation (including in areas outside of health care) on health and health disparities, and for other purposes; Sponsor: Sen. Cardin, Benjamin L. [D-MD]; Committees: Senate - Health, Education, Labor, and Pensions