



Health Policy Briefing

July 27, 2020

Lawmakers Continue Negotiations on Next COVID Package

Senate Republicans remain at work on the next round of aid to strengthen the economy and support the country's health care infrastructure in response to the COVID-19 pandemic. Senate Majority Leader Mitch McConnell (R-Ky.) has previewed the Republican proposal, highlighting jobs, health care, schools, and liability protections as the four major themes of the forthcoming stimulus package. McConnell has said that the bill will include another round of loans for the Paycheck Protection Program (PPP), another round of stimulus checks for individual Americans, and provisions to protect seniors from a potential increase in their health insurance premiums. Congressional Republicans and the White House, however, are still at odds on several policies, including stimulus check eligibility and a possible payroll tax cut. The White House has expressed reservations about including additional resources for testing and contact tracing, which McConnell has indicated will be included in the legislation. Despite these reservations, the White House announced the award of \$7.6 million to expand the availability of high-capacity testing machines made by Hologic. The House New Democrat Coalition has also characterized new funding for testing and contact tracing as essential for the next pandemic package. Senate Democrats have raised concerns that the Republican proposal does not include hazard pay for workers, adequate support for state and local governments, or maintain enhanced unemployment benefits. House Speaker Nancy Pelosi (D-Calif.) has stated she would like to reach an agreement by the end of the week, although Treasury Secretary Steven Mnuchin intimated that expiring provisions, such as unemployment insurance may pass this week while other parts of the legislation will continue to be negotiated through the August recess.

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President Signs New EOs on Drug Pricing

On Friday, President Trump released several new executive orders to lower drug prices. He also previewed a most favored nations order, which would cap the price Medicare pays for Part B drugs based on the costs charged in comparable foreign countries. The policy goes into effect on August 25 if the pharmaceutical industry does not reach an alternative agreement with the administration in the meantime. The [*Executive Order on Access to Affordable Life-saving Medications*](#) provides for the U.S. Department of Health and Human Services (HHS) Secretary to take action to ensure that future grants to federally-qualified health centers (FQHCs) are conditioned on the FQHC having established practices to make insulin and injectable epinephrine available at the 340B discounted price to individuals with low incomes who (1) have cost-sharing for insulin or injectable epinephrine; (2) have a high unmet deductible; or (3) have no health insurance. Further detail on who would qualify is to be established by the Secretary. The [*Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen*](#) directs the HHS Secretary to complete the rulemaking process he commenced to eliminate safe harbor protection from antikickback law for payments from manufacturers to insurers, pharmacy benefit managers (PBMs), and pharmacies in Part D and establish new safe harbors for discounts to the patient at the point-of-sale. The HHS Secretary, prior to taking this action, must publicly confirm that “the action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients’ total out-of-pocket costs.” The [*Executive Order on Increasing Drug Importation to Lower Prices for American Patients*](#) instructs the HHS Secretary to take action to complete the previous importation rulemaking process to allow importation of certain drugs from Canada. Additionally, he must facilitate the granting of waivers of the current prohibition on importation of drugs, “provided such importation poses no additional risk to public safety and results in lower costs to American patients[.]” Finally, he must take action to authorize the re-importation of insulin products upon a finding that it is required for emergency medical care.

House Passes First Set of FY21 Spending Bills

The House of Representatives approved a \$259.5 billion spending package last week to fund Agriculture-Food and Drug Administration (FDA), Interior-Environment, Military Construction-Veterans Affairs, and State-Foreign Operations for fiscal year 2021 (FY21). The four-bill minibus ([H.R.7608](#)) was approved by a 224-189 vote. It is the first appropriations measure passed by either chamber of Congress this year. Prior to passage, lawmakers added a package of amendments that included changes to prevent the U.S. from withdrawing from the World Health Organization (WHO) and to emphasize the need for a binational COVID-19 testing strategy with Mexico. The House plans to vote on a seven-bill spending package (H.R.7617) this week that includes Defense, Commerce-Justice-Science, Energy and Water, Financial Services, Homeland Security, Labor-Health and Human Services-Education, and Transportation-Housing and Urban Development FY21 appropriations. These programs are currently funded through September 30, 2020.

HHS Provides Additional Clarity Regarding the Reporting Requirements Under the CARES Act Provider Relief Fund

Congress has appropriated approximately \$175 billion for the CARES Act Provider Relief Fund. Thus far, including the additional \$5 billion allocation for nursing homes announced last week, the U.S. Department of Health and Human Services (HHS) has allocated approximately \$132 billion. One key element of receiving the funds, per the Terms and Conditions, are extensive reporting requirements. Last week, HHS posted a document providing additional clarity regarding those [reporting requirements](#). As part of the notice, HHS stated: “The purpose of this notice is to inform Provider Relief Fund (PRF) recipients that received one or more payments exceeding \$10,000 in the aggregate from the PRF of the timing of future reporting requirements. Detailed instructions regarding these reports will be released by **August 17, 2020**.” (emphasis added) These revised requirements have lowered the threshold – from \$150,000 in the Terms and Conditions to \$10,000 in the notice. In addition, the notice altered the timeframe for reporting – from 10 days after each calendar quarter to two new reporting deadlines. All recipients must submit an initial report by **February 15, 2021**, and this can be a final report if all funds have been expended by December 31, 2020. Otherwise, the final report deadline is **July 31, 2021**. The portal for report submission will be open as of **October 1, 2020**.

NAM Panel to Draft COVID Vaccine Distribution Plan

A committee at the National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine (NAM) is working to [develop a distribution plan](#) for an eventual COVID-19 vaccine. The panel is charged with recommending criteria to equitably distribute the vaccine among groups of recipients, accounting for health disparities, risk, and access for communities of color. The committee, which is led by former Centers for Disease Control and Prevention (CDC) director William Foege, met for the first time on July 24. A final report is expected in the early fall. The Trump administration's goal is to deliver 300 million doses of vaccine by January 2021.

HHS Extends Emergency Declaration

The U.S. Department of Health and Human Services (HHS) [officially](#) extended the COVID-19 public health emergency declaration for another 90 days ahead of its expiration on Saturday. The renewal provides for the extension of a number of requirements instituted in response to the coronavirus pandemic, including that payers cover COVID-19 testing without cost-sharing, waivers for the provision of telehealth, and the 20 percent add-on Medicare payment for treating COVID-19 inpatients. The latest renewal will expire in October without another extension.

Draft 2020 Democratic Platform Released

The Democratic Party released its [draft 2020 Platform](#) in advance of this week's meeting of the party's full Platform Committee. The 80-page document offers a range of ideas in several policy areas including economic policy, health care, criminal justice reform, climate change, voting rights, education policy, and foreign trade and international diplomacy.

On the health care front, the draft platform recommits the party to getting the Affordable Care Act (ACA) back to full strength as a means to provide universal health care coverage. The drafters also wish to add a public option to the ACA to ensure that private insurers are properly motivated to provide "affordable, quality coverage to every American."

According to the document, the public option will provide at least one plan choice without deductibles, will be administered by the Centers for Medicare and Medicaid Services (CMS), will cover all primary care without any co-payments, and will control costs for other treatments by negotiating prices with doctors and hospitals, just like Medicare does on behalf of older people. Everyone will be eligible to choose the public option or another ACA marketplace plan. To help close the persistent racial gap in insurance rates, Democrats will expand funding for ACA outreach and enrollment programs, in order for every American to be aware of their options for securing quality, affordable coverage.

Democrats also aspire to give wide latitude to states who want to use ACA waivers in their quest to experiment with statewide universal health care approaches.

The draft platform also promises "aggressive action" to address the issue of prescription drug affordability by allowing Medicare to negotiate prescription drug prices for all public and private insurers, for families and business – as well as older Americans – no matter where they get their drug coverage.

In addition to focusing on Medicare, the platform drafters pledge to prevent the price of brand-name and outlier generic drugs from rising faster than inflation and will crack down on anti-competitive efforts to manipulate the patent system or collude on prices. This includes eliminating tax breaks for prescription drug advertisements.

Finally, the draft platform pledges to support policies to increase the number of primary care physicians, registered nurses and dentists and also pledges to outlaw the practice of surprise medical billing.

The draft platform is scheduled to be considered by the full Platform Committee today. The Platform Committee consists of 180 delegates who can amend the draft party platform prior to placing it before Democratic National Convention next

month.

The Democratic Platform Committee is chaired by Atlanta Mayor Keisha Lance Bottoms, who is also on the short list of potential nominees for Vice President.

E&C Leaders Sharply Criticize Azar's Leadership Role in COVID Response

House Energy and Commerce Committee Chair Frank Pallone (D-N.J.) and Oversight Subcommittee Chair Diana DeGette (D-Colo.) have sent a [letter](#) to U.S. Department of Health and Human Services (HHS) Secretary Alex Azar sharply criticizing his role in the administration's response to the COVID-19 pandemic. The lawmakers assert that Azar has promoted politics over science and allowed officials to repeatedly undermine key public health guidance from the Centers for Disease Control and Prevention (CDC). "It is time for you to either stand up to protect public health or step aside as the nation's top health official," the Committee leaders write. The letter goes on to detail several examples where Azar failed to defend the CDC against attacks from the White House.

Booker Leads Letter to Reverse Trump's WHO Decision

A group of thirty-four Democratic senators, led by Cory Booker (D-N.J.) are [calling](#) on the Trump administration to reverse its decision to withdraw the United States from the World Health Organization (WHO). "Now is not the time to take our eyes off the ball and engage in attacks on the one global institution that is working day-in and day-out to counter the threat posed by this disease," the lawmakers argue, "we...urge you to reverse this short-sighted and dangerous decision, and to commit to reengagement with the WHO – and Congress - on collective efforts to address the COVID-19 pandemic."

FDA Announces New Regulations for Prescription Opioids

The Food and Drug Administration (FDA) [announced](#) last week that it will begin requiring opioid manufacturers to include information about the overdose antidote naloxone on product labeling. The agency is also recommending that health care professionals discuss the availability of naloxone with patients and caregivers as a part of prescribing opioid pain medicine and medicine to treat opioid use disorder (OUD), both when beginning and when renewing treatment. The U.S. saw a [record](#) 71,000 overdose deaths in 2019, and early data for the first four months of 2020 shows an 11.4 percent year-over-year increase in fatalities.

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](#)
- [Timeline for Implementation](#)

Upcoming Congressional Hearings and Markups

Senate Homeland Security and Governmental Affairs Committee hearing “Oversight of COVID-19 Financial Relief Packages;” 10:00 a.m., virtual; July 28

Senate Finance Committee hearing “Part 1: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic;” 10:15 a.m., 215 Dirksen Bldg.; July 28

Joint Economic Committee hearing “Reducing Uncertainty and Restoring Confidence during the Coronavirus Recession;” 2:30 p.m., virtual; July 28

House Energy and Commerce Subcommittee on Health hearing “Improving Access to Care: Legislation to Reauthorize Key Public Health Programs;” 10:00 a.m., Cisco Webex; July 29

House Veterans’ Affairs Health Subcommittee hearing “Who’s in Charge? Examining Oversight of State Veterans Homes During the COVID-19 Pandemic;” 10:00 a.m., 210 House Visitors Center; July 29

Senate Veterans’ Affairs Committee hearing “VA Telehealth During and Beyond COVID-19: Challenges and Opportunities in Rural America;” 3:00 p.m., G50 Dirksen Bldg.; July 29

Senate Finance Committee hearing “Part 2: Protecting the Reliability of the U.S. Medical Supply Chain During the COVID-19 Pandemic;” 9:30 a.m., 215 Dirksen Bldg.; July 30

House Oversight and Reform Select Subcommittee on the Coronavirus Crisis hearing “The Urgent Need for a National Plan to Contain the Coronavirus;” 9:00 a.m., 2154 Rayburn Bldg.; July 31

Recently Introduced Health Legislation

H.R.7674 — To require the Director of the Centers for Disease Control and Prevention to create a standardized method for State, Tribal, and local health departments to report to the Centers with respect to COVID-19, and for other purposes; Sponsor: Rep. Beyer, Donald S., Jr. [D-VA-8]; Committees: House - Energy and Commerce

H.R.7676 — To amend the Public Health Service Act to provide for hospital and insurer price transparency; Sponsor: Rep. Flores, Bill [R-TX-17]; Committees: House - Energy and Commerce

H.R.7678 — To amend the National Defense Authorization Act for Fiscal Year 2020 to direct the Secretary of Defense to include a description of programs to address and reduce the stigma associated with seeking assistance for mental health or suicidal thoughts in a report; Sponsor: Rep. Brindisi, Anthony [D-NY-22]; Committees: House - Armed Services

H.R.7686 — To amend the Public Health Service Act to establish a program to provide full compensation to any essential COVID-19 frontline worker who was seriously injured or died as a result of having COVID-19, and for other purposes; Sponsor: Rep. Kennedy, Joseph P., III [D-MA-4]; Committees: House - Energy and Commerce

H.R.7689 — 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: Rep. McBath, Lucy [D-GA-6]; Committees: House - Energy and Commerce

S.4216 — A bill to direct the Secretary of Health and Human Services and the Comptroller General of the United States to conduct studies and report to Congress on actions taken to expand access to telehealth services under the Medicare,

Medicaid, and Children's Health Insurance programs during the COVID-19 emergency; Sponsor: Sen. Fischer, Deb [R-NE]; Committees: Senate – Finance

S.4217 — A bill to amend the Small Business Act to include hospitals serving rural areas or areas of persistent poverty in the paycheck protection program, and for other purposes; Sponsor: Sen. Wicker, Roger F. [R-MS]; Committees: Senate - Small Business and Entrepreneurship

S.4225 — A bill to establish authority to destroy counterfeit devices offered for import, and for other purposes; Sponsor: Sen. Enzi, Michael B. [R-WY]; Committees: Senate - Health, Education, Labor, and Pensions

S.4230 — A bill to amend title XVIII of the Social Security Act to expand access to mental health services and certain evaluation and management services furnished through telehealth under the Medicare program; Sponsor: Sen. Wyden, Ron [D-OR]; Committees: Senate – Finance

S.4231 — A bill to strengthen and sustain on-shore manufacturing capacity and State stockpiles, and to improve the Strategic National Stockpile; Sponsor: Sen. Alexander, Lamar [R-TN]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.1057 — Expressing the sense of the House of Representatives that in order to effectively address the high prevalence of those suffering from mental health conditions and substance use disorders, the United States needs to make historic financial investments into mental health and substance use disorder care and finally acknowledge such care as a priority in health care equal to physical health, and for other purposes; Sponsor: Rep. Kennedy, Joseph P., III [D-MA-4]; Committees: House - Energy and Commerce

H.Res.1059 — Supporting the goals and ideals of National Clinicians HIV/AIDS Testing and Awareness Day, and for other purposes; Sponsor: Rep. Waters, Maxine [D-CA-43]; Committees: House - Energy and Commerce

H.R.7695 — To require the Secretary of Health and Human Services to collect, analyze, and report qualitative and quantitative data on the use of telehealth during the COVID-19 public health emergency; Sponsor: Rep. Curtis, John R. [R-UT-3]; Committees: House - Ways and Means; Energy and Commerce

H.R.7701 — To establish programs related to prevention of prescription opioid misuse, and for other purposes; Sponsor: Rep. Cartwright, Matt [D-PA-8]; Committees: House - Ways and Means; Judiciary; Energy and Commerce; Education and Labor

H.R.7714 — To amend the Internal Revenue Code of 1986 to reduce the floor on the deduction for medical expenses; Sponsor: Rep. Schweikert, David [R-AZ-6]; Committees: House - Ways and Means

S.Res.653 — A resolution expressing the sense of the Senate that a United States withdrawal from the World Health Organization undermines United States global health leadership and the international COVID-19 response; Sponsor: Sen. Cardin, Benjamin L. [D-MD]; Committees: Senate - Foreign Relations

S.4240 — A bill to prohibit the use of funds to withdraw the United States from the World Health Organization; Sponsor: Sen. Coons, Christopher A. [D-DE]; Committees: Senate - Foreign Relations

S.4242 — A bill to establish programs related to prevention of prescription opioid misuse, and for other purposes; Sponsor: Sen. Durbin, Richard J. [D-IL]; Committees: Senate – Finance

S.4246 — A bill to provide that the rules entitled “Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” and “Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” shall have no force or effect, and for other purposes;

Sponsor: Sen. Murray, Patty [D-WA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4248 — A bill to establish a grant program to provide funds for health care entities to establish or improve bias and anti-racism training to help reduce racial and ethnic disparities in COVID-19 testing, treatment, health outcomes, and vaccine access; Sponsor: Sen. Harris, Kamala D. [D-CA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4249 — A bill to ensure the protection of human genetic information collected as a result of diagnostic testing for COVID-19; Sponsor: Sen. Tillis, Thom [R-NC]; Committees: Senate - Health, Education, Labor, and Pensions

S.4253 — A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the listing of patents in the Orange Book; Sponsor: Sen. Murray, Patty [D-WA]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.7718 — To address the health needs of incarcerated women related to pregnancy and childbirth, and for other purposes; Sponsor: Rep. Bass, Karen [D-CA-37]; Committees: House - Judiciary

H.R.7722 — To limit the price of insulin drugs accessible for participants, beneficiaries, and enrollees enrolled in group or individual health insurance coverage and group health plans and for uninsured individuals who have diabetes, and for other purposes; Sponsor: Rep. Fortenberry, Jeff [R-NE-1]; Committees: House - Energy and Commerce; Education and Labor

H.R.7723 — To establish the position of Interagency Coordinator for Behavioral Health to coordinate the programs and activities of the Federal Government relating to mental health, and for other purposes; Sponsor: Rep. Kennedy, Joseph P., III [D-MA-4]; Committees: House - Energy and Commerce

H.R.7732 — To direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to carry out a national campaign to increase awareness and knowledge of the virus that causes COVID-19; Sponsor: Rep. Wasserman Schultz, Debbie [D-FL-23]; Committees: House - Energy and Commerce

S.Res.655 — A resolution declaring racism a public health crisis; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Health, Education, Labor, and Pensions

S.4259 — A bill to codify a statutory definition for long-term care pharmacies; Sponsor: Sen. Scott, Tim [R-SC]; Committees: Senate - Finance

S.4262 — A bill to direct the Secretary of Health and Human Services to develop an action plan, make targeted grants, and develop public awareness campaigns with respect to COVID-19 and the disproportionate impact of the COVID-19 pandemic on racial and ethnic minorities and other vulnerable populations; Sponsor: Sen. Menendez, Robert [D-NJ]; Committees: Senate - Health, Education, Labor, and Pensions

S.4264 — A bill to require personal protective equipment to be acquired from domestic producers for the Strategic National Stockpile; Sponsor: Sen. Graham, Lindsey [R-SC]; Committees: Senate - Finance

S.4269 — A bill to amend the Public Health Service Act to improve maternal health and promote safe motherhood; Sponsor: Sen. Kaine, Tim [D-VA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4274 — A bill to amend title XI of the Social Security Act to exclude discounts for covered part D drugs from the anti-kickback prohibition, and for other purposes; Sponsor: Sen. Paul, Rand [R-KY]; Committees: Senate - Finance

S.4282 — A bill to amend the Community Mental Health Service Block Grant to authorize a set-aside for crisis care services, and for other purposes; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.4289 — A bill to require the Secretary of Health and Human Services to collect, analyze, and report qualitative and quantitative data on the use of telehealth during the COVID-19 public health emergency; Sponsor: Sen. Young, Todd [R-IN]; Committees: Senate – Finance

H.Res.1064 — Supporting the goals and ideals of Black, indigenous, and people of color (“BIPOC”) Mental Health Awareness Month in July 2020; Sponsor: Rep. Johnson, Eddie Bernice [D-TX-30]; Committees: House - Oversight and Reform

H.R.7750 — To prohibit unfair or deceptive acts or practices in connection with the public health emergency resulting from COVID-19, and for other purposes; Sponsor: Rep. Lujan, Ben Ray [D-NM-3]; Committees: House - Energy and Commerce

H.R.7757 — To codify a statutory definition for long-term care pharmacies; Sponsor: Rep. Schrader, Kurt [D-OR-5]; Committees: House - Ways and Means; Energy and Commerce

H.R.7758 — To provide for assistance to rural health, education, and public safety facilities affected by the COVID-19 pandemic, and for other purposes; Sponsor: Rep. Scott, Austin [R-GA-8]; Committees: House – Agriculture

H.R.7759 — To amend title XVIII of the Social Security Act to authorize the Secretary of Health and Human Services to forgive the repayment, extend the timeline of repayment, and lower the interest rate of Medicare hospital accelerated payments made during the COVID-19 public health emergency, and for other purposes; Sponsor: Rep. Smith, Jason [R-MO-8]; Committees: House - Ways and Means

H.R.7760 — To make a supplemental appropriation for the COVID-19 Telehealth Program of the Federal Communications Commission for the fiscal year ending September 30, 2020; Sponsor: Rep. Spanberger, Abigail Davis [D-VA-7]; Committees: House - Budget; Appropriations

H.R.7767 — To amend the Internal Revenue Code of 1986 to provide for credits against tax for domestic medical and drug manufacturing and advanced medical manufacturing equipment; Sponsor: Rep. Wenstrup, Brad R. [R-OH-2]; Committees: House - Ways and Means

S.Res.657 — A resolution supporting the goals and ideals of Black, indigenous, and people of color (“BIPOC”) Mental Health Awareness Month in July 2020; Sponsor: Sen. Cortez Masto, Catherine [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

S.4295 — A bill to amend title XVIII of the Social Security Act to ensure access to certain drugs and devices under the Medicare program; Sponsor: Sen. Paul, Rand [R-KY]; Committees: Senate – Finance

S.4313 — A bill to establish a grant program for purposes of providing training to physicians on the health effects of exposure to perfluoroalkyl and polyfluoroalkyl substances; Sponsor: Sen. Shaheen, Jeanne [D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

S.4315 — A bill to authorize the Secretary of Health and Human Services to award grants to eligible entities to conduct testing and contact tracing for COVID-19, and related activities such as supported isolation, through mobile health units and, as necessary, at individuals’ residences, and for other purposes; Sponsor: Sen. King, Angus S., Jr. [I-ME]; Committees: Senate - Health, Education, Labor, and Pensions