



Health Policy Briefing

September 14, 2020

White House Releases “Most Favored Nation” Drug Pricing Order

The White House released its latest executive order (E.O.) on drug pricing on Sunday that would ensure that Medicare pay no more than the lowest price for a drug than it is sold for in any Organisation for Economic Co-operation and Development (OECD) country with a comparable per capita GDP. The E.O. directs the U.S. Department of Health and Human Services (HHS) to immediately begin a demonstration project to test the “most favored nation” approach under Medicare Part B. A similar model would be implemented for Medicare Part D for those products without competition for which patients pay prices higher than in comparable OECD nations. The President had previewed a version of the directive last month, but provided industry time to propose an alternative policy before moving forward. The President’s deadline passed, however, without pharmaceutical companies and the administration reaching an agreement on an alternative plan.

Democrats Block Slimmed-Down COVID Package

On Thursday, the Senate rejected a narrow coronavirus stimulus bill offered by Senate Republicans by a vote of 52-47, failing to achieve the needed 60-vote procedural threshold. Sen. Rand Paul (R-Ky.) was the only Republican to vote against the legislation. The package, with a cost of approximately \$500 billion, included a \$300 increase in weekly federal unemployment benefits through December 27, liability protections from coronavirus-related lawsuits, and extended the Paycheck Protection Program (PPP). It also included \$16 billion for testing, contact tracing, and surveillance and \$31 billion in funding for vaccine, therapeutic, and diagnostic development.

Democrats hoped that by blocking the scaled-down bill they would force Republicans back to the negotiating table on a more comprehensive solution. The parties remain at odds on several issues, including unemployment insurance and funding for state and local governments. The \$3.5 trillion **HEROES Act** was passed by the House of Representatives in May, and Senate Republican

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leadership introduced the \$1.1 trillion **HEALS Act** in late July. There are no talks currently scheduled between Democratic leadership and the White House, however, increasing the chances that Congress will not reach a deal until after the November presidential election. Congress is currently scheduled to recess in early October. Currently, no House votes are scheduled from October 5 to November 15. The Senate's current calendar includes a recess from October 12 to November 6.

Meanwhile, House Speaker Nancy Pelosi (D-Calif.) and Treasury Secretary Steven Mnuchin have agreed to use a stopgap spending measure to avoid a government shutdown come the end of the fiscal year on September 30th but have yet to determine the timetable for the continuing resolution (CR). The expectation is that a deal would fund the federal government through the beginning of December. The House's last scheduled day in session is December 10, while Senate Majority Leader Mitch McConnell (R-Ky.) is targeting December 18 for adjournment.

COVID Vaccine Trial Halted, CEOs Pledge Commitment to Safety

AstraZeneca announced that it has halted its COVID-19 vaccine clinical trial to review safety data while investigating a single adverse event that occurred in a person enrolled in one of its studies. The company characterized the pause as a routine action taken so that an independent review of a potentially unexplained illness could be conducted. This is the first safety issue that has arisen for the several coronavirus vaccines in late-stage trials. AstraZeneca's vaccine is being developed in partnership with scientists at Oxford University. Phase three trials are currently taking place in the U.S., U.K., Brazil, and South Africa. It is one of the vaccines receiving support from the White House's Operation Warp Speed; the federal government has agreed to pay up to \$1.2 billion toward the development and manufacturing of 300 million doses.

The CEOs of AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson, Merck, Moderna Inc., Novavax Inc., Pfizer Inc., and Sanofi have signed a [pledge](#) outlining their commitment to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles. The companies pledge to always make the safety and well-being of vaccinated individuals their top priority, continue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes, to only submit for approval or emergency use authorization (EUA) after demonstrating safety and efficacy through a phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities, and to work to ensure a sufficient supply and range of vaccine options, including those suitable for global access.

Lawmakers Call for Speedy Approval of Rapid COVID Tests

Fourteen bipartisan House lawmakers have sent a [letter](#) to Administrator of Food and Drugs Stephen Hahn calling for expedited authorization and lower sensitivity standards for rapid, in-home COVID-19 tests. The letter was led by Reps. Ro Khanna (D-Calif.) and Rodney Davis (R-Ill.). The lawmakers underscore the promise of low-cost, saliva-based, self-administered tests in supporting the affordable and frequent testing that is necessary for Americans to return to a normal way of life. They urge the FDA to "utilize its existing authority and consider options such as providing an expedited pathway for authorization" for the tests.

Lawmakers Press White House for Vaccine Distribution Plans

House Oversight and Reform Chair Carolyn Maloney (D-N.Y.), Economic and Consumer Policy Subcommittee Chair Raja Krishnamoorthi (D-Ill.), and Coronavirus Crisis Select Subcommittee Chair Jim Clyburn (D-S.C.) have [written](#) to the U.S. Department of Health and Human Services (HHS) requesting written information as well as a staff briefing on the administration's plans to distribute an eventual COVID-19 vaccine. The letter expresses concerns that the White House has not yet begun to engage with communities of color about a vaccine or determined how vaccine prioritization decisions will be made. The lawmakers request the information within three weeks. Senate Appropriations Subcommittee Health and Human Services Chairman Roy Blunt (R-Mo.) also sent a [letter](#) to Centers for Disease Control and Prevention (CDC) Director Robert Redfield requesting information about the agency's plans for distributing an eventual COVID-19 vaccine in a fair and equitable way. Blunt's panel plans to hold a hearing later this month on vaccine development and distribution.

Energy and Commerce Advances 26 Health Bills

The House Energy and Commerce Committee considered 26 health bills during a September 9 markup. Legislation included H.R. 1379, the *Ensuring Lasting Smiles Act*; H.R. 4078, the *EARLY Act Reauthorization*; H.R. 4861, the *Effective Suicide Screening and Assessment in the Emergency Department Act*; as well as bills to expand access to mental health services, combat the opioid epidemic, reauthorize key public health programs, and provide access to marijuana for research. During the markup, Chairman Frank Pallone (D-N.J.) stated his hope that the bills can be considered by the full House.

Democrats Release Report Questioning CMS Administrator Verma's Spending

Democrats have released a [report](#) detailing Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma's nearly \$6 million in spending on private communications consultants. The report follows a 17-month probe into the CMS administrator and calls on the Government Accountability Office (GAO) to investigate potential violations of federal spending laws. The report was compiled by the staff of House Energy and Commerce Committee Chair Frank Pallone (D-N.J.), House Oversight and Reform Committee Chair Carolyn Maloney (D-N.Y.), Senate Finance Committee Ranking Member Ron Wyden (D-Ore.), and Senate Health, Education, Labor, and Pensions (HELP) Ranking Member Patty Murray (D-Wash.). "Congress did not intend for taxpayer dollars to be spent on handpicked communications consultants to promote Administrator Verma's public profile and personal brand," the lawmakers said in a statement.

Senator Murray Calls for FDA Action on E-Cigarettes

Following the passage of the deadline for manufacturers of e-cigarettes and other tobacco products to file marketing applications with the FDA, Senator Patty Murray (D-Wash.), ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee called on the Food and Drug Administration to immediately clear the market of those products that failed to comply. She also called on the FDA to ensure transparency in this effort.

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 Appropriations Committee hearing to examine the Department of Health and Human Services' Coronavirus response, focusing on a review of efforts to date and next steps; 10:00 a.m., G50 Dirksen Bldg.; September 16

House Oversight and Reform Committee markup of legislation including: H.R. 4774, Internet of Things Cybersecurity Training for Federal Employees Act; H.R. 7496, COVID PREPARE Act; and H.R. 7548, PPE Buy America Act; 10:00 a.m., 2154 Rayburn Bldg.; September 16

House Veterans' Affairs Subcommittee on Oversight and Investigations hearing "Modernizing VA's Medical Supply Chain: Lessons Learned From the Pandemic;" 2:00 p.m., 210 House Visitors Center; September 16

Senate HELP Committee hearing "COVID-19: An Update on the Federal Response;" 10:00 a.m., G50 Dirksen Bldg.; September 23

Senate Judiciary Committee hearing "Examining Threats to American Intellectual Property: Cyber-attacks and Counterfeits During the COVID-19 Pandemic;" 2:30 p.m., 226 Dirksen Bldg.; September 23

Senate Armed Services Readiness and Management Support Subcommittee hearing "Supply Chain Integrity;" 9:15 a.m., G50 Dirksen Bldg.; October 1

Recently Introduced Health Legislation

H.R.8179 — To make hemp, cannabidiol derived from hemp, and any other ingredient derived from hemp lawful for use under the Federal Food, Drug, and Cosmetic Act as a dietary ingredient in a dietary supplement. Sponsor: Rep. Schrader, Kurt [D-OR-5]; Committees: House - Energy and Commerce

H.R.8178 — To amend the Public Health Service Act to provide for public health research and investment into understanding and eliminating structural racism and police violence. Sponsor: Rep. Pressley, Ayanna [D-MA-7]; Committees: House - Energy and Commerce

H.R.8177 — To amend title XVIII of the Social Security Act to remove from the list of drugs excluded from coverage under the Medicare prescription drug program prescription oral vitamins and mineral products indicated for the treatment of iron deficiency anemia in individuals with chronic kidney disease. Sponsor: Rep. O'Halleran, Tom [D-AZ-1]; Committees: House - Ways and Means; Energy and Commerce

H.R.8173 — To direct the Secretary of Veterans Affairs to conduct a study on the connection between living at high altitude and suicide risk factors among veterans. Sponsor: Rep. McAdams, Ben [D-UT-4]; Committees: House - Veterans' Affairs

H.R.8172 — To direct the Secretary of Veterans Affairs to use accredited commercial institutional review boards to review research proposal protocols of the Department, and to establish an Office of Research Reviews in the Department of Veterans Affairs. Sponsor: Rep. Luria, Elaine G. [D-VA-2]; Committees: House - Veterans' Affairs

H.R.8168 — To require the guidance of the Food and Drug Administration on reducing the risk of human immunodeficiency virus (HIV), hepatitis A, and hepatitis B transmission by blood and blood products (including the donor history questionnaire) to be based on an individual risk assessment of sexual behaviors upon which all donors are evaluated equally, without regard to sexual orientation or gender identity, and for other purposes. Sponsor: Rep. Demings, Val Butler [D-FL-10]; Committees: House - Energy and Commerce

H.R.8167 — To amend the Paycheck Protection Program and Health Care Enhancement Act to expand the appropriations under the Public Health and Social Services Emergency Fund to include the scale up of testing by veterinary and biotechnology company laboratories, and for other purposes. Sponsor: Rep. Crist, Charlie [D-FL-13]; Committees: House - Energy and Commerce

H.R.8158 — To amend title XVIII of the Social Security Act to waive budget neutrality for oxygen under the Medicare program, and for other purposes. Sponsor: Rep. McMorris Rodgers, Cathy [R-WA-5]; Committees: House - Ways and Means; Energy and Commerce

H.R.8156 — 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

H.R.8153 — To direct the Secretary of Commerce, in consultation with the Federal Trade Commission, to conduct a study and submit to Congress a report on the state of the blockchain technology and use in consumer protection, and for other purposes. Sponsor: Rep. Soto, Darren [D-FL-9]; Committees: House - Energy and Commerce

H.R.8149 — To direct the Secretary of Veterans Affairs to carry out an initiative to identify and validate brain and mental health biomarkers among veterans. Sponsor: Rep. Lamb, Conor [D-PA-17]; Committees: House - Veterans' Affairs

H.R.8147 — To direct the Secretary of Veterans Affairs to expand an existing pilot program, and to establish a new pilot program, related to complementary and integrative health services for veterans. Sponsor: Rep. Lamb, Conor [D-PA-17]; Committees: House - Veterans' Affairs

H.R.8145 — To provide for a staffing improvement plan and occupational series for licensed professional mental health counselors and marriage and family therapists of Department of Veterans Affairs, and for other purposes. Sponsor: Rep. Hayes, Jahana [D-CT-5]; Committees: House - Veterans' Affairs

H.R.8144 — To direct the Secretary of Veterans Affairs to submit to Congress a plan to address staffing of mental health providers of the Department of Veterans Affairs. Sponsor: Rep. Hayes, Jahana [D-CT-5]; Committees: House - Veterans' Affairs

H.R.8141 — To amend the Public Health Service Act to reduce health inequities experienced by individuals who are members of historically racial and ethnic minority groups under State plans under the community mental health services block grant program. Sponsor: Rep. Cardenas, Tony [D-CA-29]; Committees: House - Energy and Commerce

H.R.8139 — To amend title XIX of the Social Security Act to remove direct sales of drugs near expiration during the COVID-19 emergency from the calculation of certain pricing metrics under the Medicaid program. Sponsor: Rep. Bilirakis, Gus M. [R-FL-12]; Committees: House - Energy and Commerce

H.R.8138 — To amend the Orphan Drug Act with respect to the definition of medical food. Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Ways and Means; Energy and Commerce; Armed Services

H.Res.1096 — Expressing support for the designation of the week of August 25 through August 31, 2020, as "Black Breastfeeding Week" to bring national attention to the United States maternal child health crisis in the Black community and the important role that breastfeeding plays in improving maternal and infant health outcomes. Sponsor: Rep. Adams, Alma S. [D-NC-12]; Committees: Energy and Commerce

H.R.8137 — To amend the Public Health Service Act to ensure accurate and timely reporting of smoking variants through updating the Federal Health IT Strategic Plan. Sponsor: Rep. Trone, David J. [D-MD-6]; Committees: House - Energy and Commerce

H.R.8131 — To amend the Internal Revenue Code of 1986 to establish Hemp Opportunity Zones. Sponsor: Rep. Riggleman, Denver [R-VA-5]; Committees: House - Ways and Means; Agriculture

H.R.8125 — To direct the Secretary of Defense to carry out a pilot program to pre-program suicide prevention resources into smart devices issued to members of the Armed Forces. Sponsor: Rep. Joyce, David P. [R-OH-14]; Committees: House - Armed Services

H.R.8181 — To amend title XVIII to provide for certain Medigap coverage for Medicare beneficiaries with end-stage renal disease, and for other purposes; Sponsor: Rep. Axne, Cynthia [D-IA-3]; Committees: House - Ways and Means; Energy and Commerce

H.R.8190 — To amend the Public Health Service Act to deem any insulin that is determined by the Secretary to be biosimilar to the reference product to be interchangeable with the reference product, and for other purposes; Sponsor: Rep. Grothman, Glenn [R-WI-6]; Committees: House - Energy and Commerce

S.4532 — A bill to amend title XXVII of the Public Health Service Act and the Patient Protection and Affordable Care Act to require coverage of hearing devices and systems in certain private health insurance plans, and for other purposes; Sponsor: Sen. Capito, Shelley Moore [R-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.4533 — A bill to amend the Public Health Service Act to provide for public health research and investment into understanding and eliminating structural racism and police violence; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4536 — A bill to report data on COVID-19 in Federal, State, and local correctional facilities, and for other purposes; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate – Judiciary

S.4539 — A bill to direct the Secretary of Health and Human Services and other Federal officials to compile into a searchable database information relating to Federal support for biomedical research and development related to COVID-19, and for other purposes; Sponsor: Sen. Merkley, Jeff [D-OR]; Committees: Senate - Health, Education, Labor, and Pensions

S.4541 — A bill to amend title XVIII of the Social Security Act to provide for patient protection by limiting the number of mandatory overtime hours a nurse may be required to work in certain providers of services to which payments are made under the Medicare Program; Sponsor: Sen. Merkley, Jeff [D-OR]; Committees: Senate – Finance

S.4542 — A bill to prohibit distribution abroad of COVID-19 vaccines developed with the support of Federal funding until the domestic need for the vaccine has been met; Sponsor: Sen. Tillis, Thom [R-NC]; Committees: Senate - Banking, Housing, and Urban Affairs

S.4545 — A bill to direct the Secretary of Veterans Affairs to establish the Zero Suicide Initiative pilot program of the Department of Veterans Affairs; Sponsor: Sen. Rosen, Jacky [D-NV]; Committees: Senate - Veterans' Affairs

S.4555 — A bill to reauthorize funding for programs to prevent, investigate, and prosecute elder abuse, neglect, and exploitation, and for other purposes; Sponsor: Sen. Wyden, Ron [D-OR]; Committees: Senate – Finance

S.4557 — A bill to support efforts to provide intensive, individualized assistance for enrolling in health care coverage; Sponsor: Sen. Baldwin, Tammy [D-WI]; Committees: Senate - Health, Education, Labor, and Pensions

S.4562 — A bill to amend the Public Health Service Act with respect to the collection and availability of health data with respect to Indian Tribes and Tribal organizations, and for other purposes; Sponsor: Sen. Smith, Tina [D-MN]; Committees: Senate - Indian Affairs