



Health Policy Briefing

May 3, 2021

Biden Delivers First Address to Congress, Unveils American Families Plan

In his first [address](#) to a joint session of Congress, President Joe Biden struck a positive tone in outlining a vision for the nation’s recovery from the COVID-19 pandemic. While health care issues were not a focus of the speech, the President encouraged Americans to get vaccinated and stated that the U.S. “will become an arsenal of vaccines for other countries” as the nation’s own vaccine supply grows to meet domestic demand. The President discussed drug pricing, expressing support for direct negotiation in the Medicare program and urging Congress to act to cut drug prices this year. He suggested that savings could be put toward strengthening the Affordable Care Act (ACA) without spending additional taxpayer money. He also endorsed the creation of the Advanced Research Projects Agency for Health (ARPA-H) during his speech. The agency would be housed within the National Institutes of Health (NIH) and charged with developing breakthrough treatments to prevent, detect, and treat diseases such as Alzheimer’s, diabetes, and cancer.

President Biden went on to unveil his \$1.8 trillion [American Families Plan](#) during his address on Wednesday night. The antipoverty package, which combines \$1 trillion in spending with \$800 billion in tax cuts and credits for middle- and lower-income families, would be funded in part by tax increases on wealthy Americans. It is focused on education, support for children and families, and tax reform, but also contains several health care-related provisions. The American Families Plan would create a \$225 billion national paid family and medical leave program and make permanent ACA premium reductions passed through the **American Rescue Plan**. It would also make investments in maternal health and veteran health care services. The administration notes in its [fact sheet](#) that the President has a plan to further build on the ACA and lower prescription drug costs

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through Medicare price negotiation, the creation of a public option, allowing Medicare enrollment at age 60, and closing the Medicaid coverage gap. These provisions, however, are expected to be advanced separately from the American Families Plan. While progressive Democrats continue to push for Congress to add drug pricing and Medicare-related provisions to the final bill, this could be difficult given Democrats' narrow margins in each chamber and no signs that Republicans will support the initiative.

Senate Passes Extension of Fentanyl Ban

The Senate passed an extension (H.R. 2630) of the current ban on fentanyl analogues that is scheduled to expire on May 6. The ***Extending Temporary Emergency Scheduling of Fentanyl Analogues Act***, which was passed by voice vote, will allow the government to continue to classify fentanyl-like substances as Schedule I controlled substances through October 22, 2021. The bill previously passed the House by voice vote and will now be sent to the President's desk for his signature. The White House has expressed support for an extension to provide time to draft a broader overhaul of the drug policy.

Congressional Schedule

Congress currently stands in recess. The Senate will resume consideration of the nomination of Andrea Palm to serve as Deputy Secretary of Health and Human Services when the chamber returns on May 10.

HELP Announces Effort to Improve Preparedness System

Senate Health, Education, Labor, and Pensions (HELP) Committee Chair Patty Murray (D-Wash.) and Ranking Member Richard Burr (R-N.C.) have sent a Dear Colleague [letter](#) detailing their plans to revamp the nation's pandemic preparedness system. The lawmakers outlined their intention to work on bipartisan, consensus legislative proposals including:

- Strategies for strengthening and modernizing federal public health and medical preparedness and response systems and programs to better support states, localities, and Tribes;
- Ensuring sufficient public health and medical capacity to continue providing critical services to at-risk populations;
- Strengthening readiness within the medical countermeasure enterprise to ensure that countermeasures can be rapidly identified and advanced through clinical development and manufacturing and appropriately deployed and distributed when a new public health threat is identified;
- Modernizing the development of medical countermeasures to address public health threats; and
- Improving and securing the supply chain for the U.S.'s critical medical supplies needed to swiftly address public health threats.

Top Senate Appropriator Releases Earmark Proposal

Senate Appropriations Chair Patrick Leahy (D-Vt.) has released his plan to reverse the decade-long ban on earmarks. The proposal is largely in line with reforms agreed to by both Democrats and Republicans in the House of Representatives. The total amount of money for congressionally-directed spending would be capped at 1% of discretionary spending, and no money could be appropriated to for-profit entities or to the benefit of members or their immediate families. Senators would also be required to publicly post their earmark requests online and the requests will be audited by the Government Accountability Office (GAO). Unlike the House plan, the Senate would not limit the total number of requests each lawmaker can make.

Consideration of Endless Frontier Act Delayed

Committee consideration of Senate Majority Leader Chuck Schumer's (D-N.Y.) ***Endless Frontier Act*** (S. 1260) has been delayed for several weeks. The bipartisan bill aims to respond to China's economic, military, and technological advances. It includes more than \$100 billion in funding for the National Science Foundation to support high-tech research and advanced manufacturing. The legislation was initially slated to be marked up by the Senate Commerce Committee last week but was pushed back for at least two weeks after more than 200 amendments were filed to the bill. Schumer intends to package the ***Endless Frontier Act*** with other China-related legislation prior to consideration on the Senate floor.

Dems Push Manufacturers to Expand International Access to COVID Vaccines

A group of Democratic senators are urging Pfizer, Moderna, and Johnson & Johnson to increase global access to their COVID-19 vaccines. The [letters](#) argue that expanded access is urgently needed to reduce human suffering and prevent unnecessary deaths in places like India, which recently set the record for reaching 400,000 new COVID-19 cases in a single day. Sens. Elizabeth Warren (D-Mass.), Ed Markey (D-Mass.), Tammy Baldwin (D-Wis.), Jeff Merkley (D-Ore.), and Chris Murphy (D-Conn.) suggest that the companies could voluntarily share their vaccine-related intellectual property and other technology with partner companies to expand vaccine development and access.

Warren Requests Investigation into Emergent Biosolutions CEO

Sen. Elizabeth Warren (D-Mass.) has sent a [letter](#) to Securities and Exchange Commission (SEC) Chair Gary Gensler urging him to open an investigation into potential insider trading done by the CEO of Emergent BioSolutions. The Washington Post recently reported that the company's CEO Robert Kramer dumped \$10 million in Emergent shares prior to the company disclosing problems with producing COVID-19 vaccine at its Baltimore facility. "Given my longstanding concerns about pandemic profiteering and the specific troubling new details about Emergent and Mr. Kramer's sales of company stock amidst its vaccine production failures," Warren writes, "I ask that the SEC open an investigation of this matter as rapidly as possible."

Cheri Bustos to Retire from Congress

Rep. Cheri Bustos (D-Ill.) has announced that she will not run for reelection in 2022. Bustos is the former Democratic Congressional Campaign Committee (DCCC) chairwoman. She currently serves on the Agriculture and Appropriations committees. Her congressional district has shifted rightward in recent years.

GAO Releases New Report on Drug Pricing

The Government Accountability Office (GAO) has released a new [report](#) finding that retail drug prices are two to four times higher in the U.S. on average than drug prices in Australia, Canada, and France. GAO's analysis examines 20 selected brand-name prescription drugs. The agency notes that while rebates and confidential discounts offered on some drugs were taken into account for U.S. prices, the publicly available prices for the comparison countries do not reflect such discounts.

CMS Proposed Payment Rule Includes Added GME Slots

The Centers for Medicare and Medicaid Services (CMS) released its fiscal year (FY) 2022 hospital inpatient prospective payment system [proposed rule](#) last week. The regulation would provide acute-care hospitals with a 2.8% increase in Medicare reimbursements and long-term care hospitals with a 1.4% bump. The rule would also implement the distribution of 1,000 more residency slots to qualifying hospitals in rural and underserved areas over the next five years – a provision enacted as part of the ***Consolidated Appropriations Act, 2021***. CMS estimates that these additional graduate medical education (GME) slots will cost approximately \$300 million a year.

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.

- [Disaster Primer](#)
- [Federal Relief Overview](#)
- [Hospice and Palliative Care](#)
- [Nursing Resources](#)
- [Personal Protective Equipment](#)
- [Physician Provisions](#)
- [Re-Opening America](#)
- [Small Business Resources](#)
- [Small Business - Paycheck Protection Program](#)
- [State Resources](#)
- [Tax Provisions](#)
- [Telehealth Overview](#)
- [Testing](#)
- [Vaccines](#)

Upcoming Congressional Hearings and Markups

House Oversight Subcommittee on Economic and Consumer Policy hearing “The Urgent Need to Reform the Organ Transplantation System to Secure More Organs for Waiting, Ailing, and Dying Patients;” 11:00 a.m.; May 4

House Energy and Commerce Subcommittee on Health hearing “Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs;” 11:30 a.m.; May 4

House Veterans’ Affairs Committee hearing on [various legislation](#) related to health care; 10:00 a.m.; May 5

House Education & Labor Subcommittee on Health, Employment, Labor, and Pensions hearing “Lower Drug Costs Now: Expanding Access to Affordable Health Care;” 12:00 p.m.; May 5

House Committee on Oversight and Reform hearing “Birthing While Black: Examining America’s Black Maternal Health Crisis;” 11:00 a.m.; May 6

House Science, Space, & Technology Subcommittee on Research and Technology hearing “National Science Foundation: Advancing Research for the Future of U.S. Innovation Part II;” 11:00 a.m.; May 6

Recently Introduced Health Legislation

S.1362 — A bill to amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of pharmacist services; Sponsor: Sen. Grassley, Chuck [R-IA]; Committees: Senate – Finance

S.1366 — A bill to secure the supply of drugs in the United States, and for other purposes; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.1367 — A bill to require a report on foreign investment in the pharmaceutical industry of the United States; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate - Banking, Housing, and Urban Affairs

H.R.2831 — To amend the Federal Food, Drug, and Cosmetic Act to provide for the prompt approval of drugs when safety information is added to labeling, and for other purposes; Sponsor: Rep. Barragan, Nanette Diaz [D-CA-44]; Committees: House - Energy and Commerce

H.R.2843 — To amend subsection (q) of section 505 of the Federal Food, Drug, and Cosmetic Act to clarify the process for denying certain petitions whose primary purpose is to delay the approval of an application submitted under subsection (b)(2) or (j) of such section 505, and for other purposes; Sponsor: Rep. Levin, Andy [D-MI-9]; Committees: House - Energy and Commerce

H.R.2846 — To amend title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes; Sponsor: Rep. McKinley, David B. [R-WV-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.2853 — To amend the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, and for other purposes; Sponsor: Rep. Schrader, Kurt [D-OR-5]; Committees: House - Energy and Commerce

H.R.2855 — To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to add a new set of measures to the 5-star rating system under the Medicare Advantage program in order to encourage increased access to biosimilar biological products; Sponsor: Rep. Tonko, Paul [D-NY-20]; Committees: House - Energy and Commerce; Ways and Means

S.1374 — A bill to direct the Director of the National Science Foundation to support STEM education and workforce development research focused on rural areas, and for other purposes; Sponsor: Sen. Wicker, Roger F. [R-MS]; Committees: Senate - Commerce, Science, and Transportation

S.1383 — A bill to amend the Public Health Service Act to direct the Secretary of Health and Human Services to develop best practices for the establishment and use of behavioral intervention teams at schools, and for other purposes; Sponsor: Sen. Cornyn, John [R-TX]; Committees: Senate - Health, Education, Labor, and Pensions

S.1388 — A bill to require the Federal Trade Commission to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations, and for other purposes; Sponsor: Sen. Grassley, Chuck [R-IA]; Committees: Senate – Judiciary

S.1390 — A bill to amend the Elementary and Secondary Education Act of 1965 to improve mental health services for students, and for other purposes; Sponsor: Sen. Kennedy, John [R-LA]; Committees: Senate - Health, Education, Labor, and Pensions

S.1391 — A bill to amend the Public Health Service Act to provide best practices on student suicide awareness and prevention training and condition State educational agencies, local educational agencies, and tribal educational agencies receiving funds under section 520A of such Act to establish and implement a school-based student suicide awareness and prevention training policy; Sponsor: Sen. Kennedy, John [R-LA]; Committees: Senate - Health, Education, Labor, and Pensions

S.1397 — 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

S.1399 — A bill to amend the Internal Revenue Code of 1986 to allow qualified distributions from health savings accounts for certain home care expenses; Sponsor: Sen. Sinema, Kyrsten [D-AZ]; Committees: Senate - Finance

S.Res.184 — A resolution designating the week of May 2, 2021 through May 8, 2021, as “Tardive Dyskinesia Awareness Week”; Sponsor: Sen. Murphy, Christopher [D-CT]; Committees: Senate - Judiciary

S.Res.188 — A resolution expressing appreciation and recognition for the Trump Administration for the creation of Operation Warp Speed and the historic development of a COVID-19 vaccine; Sponsor: Sen. Marshall, Roger W. [R-KS]; Committees: Senate - Health, Education, Labor, and Pensions

S.1410 — A bill to codify the temporary scheduling order for fentanyl-related substances by adding fentanyl-related substances to schedule I of the Controlled Substances Act; Sponsor: Sen. Cotton, Tom [R-AR]; Committees: Senate - Judiciary

S.1424 — A bill to amend the Internal Revenue Code of 1986 to permit high deductible health plans to provide chronic disease prevention services to plan enrollees prior to satisfying their plan deductible; Sponsor: Sen. Thune, John [R-SD]; Committees: Senate - Finance

S.1425 — A bill to enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition, and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes; Sponsor: Sen. Klobuchar, Amy [D-MN]; Committees: Senate - Judiciary

S.1427 — A bill to establish a demonstration project to increase access to biosimilar biological products under the Medicare program; Sponsor: Sen. Cornyn, John [R-TX]; Committees: Senate - Finance

S.1428 — A bill to prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products; Sponsor: Sen. Klobuchar, Amy [D-MN]; Committees: Senate - Judiciary

S.1434 — A bill to require the Food and Drug Administration to revoke the approval of one opioid pain medication for each new opioid pain medication approved; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.1436 — A bill to direct the Secretary of Health and Human Services to amend the mission statement of the Food and Drug Administration; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.1438 — A bill to amend title XVIII of the Social Security Act to provide for the distribution of additional residency positions to help combat the opioid crisis; Sponsor: Sen. Hassan, Margaret Wood [D-NH]; Committees: Senate - Finance

S.1439 — A bill to establish procedures regarding the approval of opioid drugs by the Food and Drug Administration; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.2862 — To require the Secretary of Health and Human Services to conduct a national suicide prevention media campaign, and for other purposes; Sponsor: Rep. Beyer, Donald S., Jr. [D-VA-8]; Committees: House - Energy and Commerce

H.R.2868 — 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.2869 — To require the Secretary of Health and Human Services to establish a demonstration project to increase access to biosimilar biological products under the Medicare program; Sponsor: Rep. Cardenas, Tony [D-CA-29]; Committees: House - Energy and Commerce; Ways and Means

H.R.2870 — To amend the Public Health Service Act to provide for stockpiles to ensure that all Americans have access to generic drugs at risk of shortage, and for other purposes; Sponsor: Rep. Carter, Earl L. "Buddy" [R-GA-1]; Committees: House - Energy and Commerce

H.R.2873 — To amend the Federal Trade Commission Act to prohibit product hopping, and for other purposes; Sponsor: Rep. Cicilline, David N. [D-RI-1]; Committees: House - Judiciary

H.R.2877 — To amend the Public Health Service Act to direct the Secretary of Health and Human Services to develop best practices for the establishment and use of behavioral intervention teams at schools, and for other purposes; Sponsor: Rep. Ferguson, A. Drew, IV [R-GA-3]; Committees: House - Energy and Commerce

H.R.2881 — To amend title XVIII of the Social Security Act to provide for an option for individuals who are ages 50 to 64 to buy into Medicare, to provide for health insurance market stabilization, and for other purposes; Sponsor: Rep. Higgins, Brian [D-NY-26]; Committees: House - Energy and Commerce; Ways and Means

H.R.2883 — To enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes; Sponsor: Rep. Jeffries, Hakeem S. [D-NY-8]; Committees: House - Judiciary

H.R.2884 — To amend title 35, United States Code, to clarify and improve the process for subsection (k) applicants to resolve patent infringement claims for biological products (commonly known as the "patent dance"), and for other purposes; Sponsor: Rep. Johnson, Henry C. "Hank," Jr. [D-GA-4]; Committees: House - Judiciary

H.R.2891 — To prohibit prescription drug companies from compensating other prescription drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market; Sponsor: Rep. Nadler, Jerrold [D-NY-10]; Committees: House - Judiciary; Energy and Commerce

H.R.2898 — To amend the Internal Revenue Code of 1986 to allow qualified distributions from health savings accounts for certain home care expenses; Sponsor: Rep. Porter, Katie [D-CA-45]; Committees: House - Ways and Means

H.R.2903 — To amend title XVIII of the Social Security Act to expand access to telehealth services, and for other purposes; Sponsor: Rep. Thompson, Mike [D-CA-5]; Committees: House - Energy and Commerce; Ways and Means

S.Res.193 — A resolution supporting the designation of the week of May 2, 2021, as “Children’s Mental Health Awareness Week” and the day of May 9, 2021, as “Children’s Mental Health Awareness Day”; Sponsor: Sen. King, Angus S., Jr. [I-ME]; Committees: Senate - Health, Education, Labor, and Pensions

S.1450 — A bill to amend title XVIII of the Social Security Act to provide for expanded coverage of services furnished by genetic counselors under part B of the Medicare program, and for other purposes; Sponsor: Sen. Barrasso, John [R-WY]; Committees: Senate - Finance

S.1451 — A bill to amend the Foreign Assistance Act of 1961 to implement policies to end preventable maternal, newborn, and child deaths globally; Sponsor: Sen. Collins, Susan M. [R-ME]; Committees: Senate - Foreign Relations

S.1456 — A bill to direct the Secretary of Health and Human Services to enter into a 10-year arrangement with the National Academy of Sciences to conduct and update biennially a study on the effects of State legalized marijuana programs, and for other purposes; Sponsor: Sen. Menendez, Robert [D-NJ]; Committees: Senate - Health, Education, Labor, and Pensions

S.1457 — A bill to establish programs to address addiction and overdoses caused by illicit fentanyl and other opioids, and for other purposes; Sponsor: Sen. Markey, Edward J. [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.1462 — A bill to amend the Federal Food, Drug, and Cosmetic Act to simplify the generic drug application process; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Health, Education, Labor, and Pensions

S.1463 — A bill to amend the Federal Food, Drug, and Cosmetic Act to modernize therapeutic equivalence rating determinations; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Health, Education, Labor, and Pensions

S.1467 — A bill to direct the Secretary of Veterans Affairs to carry out a series of clinical trials on the effects of cannabis on certain health outcomes of veterans with chronic pain and post-traumatic stress disorder, and for other purposes; Sponsor: Sen. Tester, Jon [D-MT]; Committees: Senate - Veterans’ Affairs

S.1468 — A bill to direct the Secretary of Veterans Affairs to expand the Rural Access Network for Growth Enhancement Program of the Department of Veterans Affairs and to direct the Comptroller General of the United States to conduct a study to assess certain mental health care resources of the Department of Veterans Affairs available to veterans who live in rural areas; Sponsor: Sen. Tester, Jon [D-MT]; Committees: Senate - Veterans’ Affairs

S.1476 — A bill to amend title XIX of the Social Security Act to enable greater participation by seniors and Medicare beneficiaries in State Medicaid programs for working people with disabilities; Sponsor: Sen. Portman, Rob [R-OH]; Committees: Senate - Finance

S.1486 — A bill to eliminate discrimination and promote women’s health and economic security by ensuring reasonable workplace accommodations for workers whose ability to perform the functions of a job are limited by pregnancy, childbirth, or a related medical condition; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate - Health, Education, Labor, and Pensions

S.1491 — A bill to amend the Public Health Service Act to improve obstetric care in rural areas; Sponsor: Sen. Smith, Tina [D-MN]; Committees: Senate - Health, Education, Labor, and Pensions

S.1508 — A bill to provide for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes; Sponsor: Sen. Marshall, Roger W. [R-KS]; Committees: Senate - Health, Education, Labor, and Pensions

S.1512 — A bill to amend title XVIII of the Social Security Act to expand access to telehealth services, and for other purposes; Sponsor: Sen. Schatz, Brian [D-HI]; Committees: Senate - Finance

S.1521 — A bill to require certain civil penalties to be transferred to a fund through which amounts are made available for the Gabriella Miller Kids First Pediatric Research Program at the National Institutes of Health, and for other purposes; Sponsor: Sen. Kaine, Tim [D-VA]; Committees: Senate - Health, Education, Labor, and Pensions

S.1523 — A bill to amend title XI of the Social security Act and title XXVII of the Public Health Service Act to establish requirements with respect to prescription drug benefits; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.1524 — A bill to amend the Public Health Service Act to provide for hospital and insurer price transparency; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions