



## Health Policy Briefing

March 14, 2022

### Congress Passes \$1.5 Trillion Omnibus Bill

Congress has passed a \$1.5 trillion spending bill (H.R. 2471) that will fund the federal government through the remainder of the fiscal year (FY) 2022 and includes \$13.6 trillion to respond to Russia's invasion of Ukraine. The defense portion of the package passed on a 361 to 69 vote in the House of Representatives and the domestic agency funding passed on a 260 to 171 vote. The package later cleared the Senate in a 68-31 vote. The legislation provides \$730 billion for non-defense discretionary spending, a 6.7% increase, and features the first earmark spending since the practice was banned in 2011. The bill includes at least 2,727 earmarks totaling \$4.2 billion. Democrats had pushed to include \$15.6 billion in emergency COVID-19 funding in the omnibus package, but that money was ultimately struck from the bill in response to disagreements over how to offset its cost. The initially proposed legislation would have clawed back \$7 billion in an unused state and local coronavirus aid.

Under the spending bill, the U.S. Department of Health and Human Services (HHS) will receive \$108.3 billion, an \$11.3 billion increase over FY21. The National Institutes of Health would receive \$45 billion in funding, a \$2.25 billion increase compared to FY21 enacted levels. The government spending deal includes \$1 billion to fund the Advanced Research Projects Agency for Health (APRA-H). The bill also provides the Food and Drug Administration (FDA) with new authority to regulate synthetic nicotine and e-cigarette products. The bill includes an extension of many Medicare telehealth waiver authorities, such as the expansion of originating sites and eligible practitioners, an extension of telehealth services to Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs), and use of telehealth in recertification for hospice care five months beyond the conclusion of the current public health emergency

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(PHE). The omnibus also includes a temporary measure to allow employers to resume covering telehealth for employees with health savings accounts (HSAs) before annual deductibles are met. Such flexibility was instituted through prior COVID response legislation but expired at the end of 2021. The new provision will not cover the first quarter of 2022 and applies only to the period from April 1 through December 31, 2022. The omnibus also provides for a mandated Medicare Payment Advisory Commission (MedPAC) study on the impact of telehealth on Medicare spending and beneficiary care.

Congress also passed a four-day stopgap spending bill to extend government funding beyond the expiration of the prior continuing resolution (CR) at midnight on March 11. This stopgap through March 15 was signed into law by President Joe Biden on Friday, providing time for the 2,700-page omnibus bill to be proofread, printed, and signed into law.

## House to Consider Standalone COVID Bill This Week

Democrats will vote this week on a \$15.6 billion standalone measure (H.R. 7007) providing money for pandemic testing and treatment. The **COVID Supplemental Appropriations Act** would be partially offset by rescinding \$8.6 billion in unobligated money from previous pandemic relief laws, including \$4.85 billion from the Paycheck Protection Program. It includes \$10.6 billion for the Public Health and Social Services Emergency Fund, much of which will be made available to the Biomedical Advanced Research and Development Authority (BARDA) to procure vaccines and therapeutics. \$750 million would be allocated for the development of vaccines targeting emerging coronavirus variants, and \$4.45 billion would go toward global health programs. An additional \$425 million would be set aside for international disaster assistance. The bill's potential to pass the evenly divided Senate remains unclear. Republicans have asked for more information on previously appropriated, unspent funds before they will agree to provide more money for COVID-19 relief. The bill will not be fully offset, as the initially proposed state and local clawback has been stripped from the legislation. The administration has stated that this \$15 billion request will only be enough to support COVID operations in the short term and that an additional funding request should be expected.

## HELP Leadership Introduces ARPA-H, Pandemic Preparedness Legislation

Senate Health, Education, Labor, and Pensions (HELP) Committee Chair Patty Murray (D-Wash.) and Ranking Member Richard Burr (R-N.C.) introduced legislation last week to establish the Advanced Research Projects Authority for Health (ARPA-H). The **ARPA-H Act** would house the new agency within the National Institutes of Health (NIH). ARPA-H, which was first proposed in President Joe Biden's fiscal year (FY) 2022 budget, would focus on transforming and advancing cutting-edge biomedical research. The latest omnibus government funding bill included \$1 billion for the creation of ARPA-H.

Murray and Burr also officially introduced the **PREVENT Pandemics Act** last week, ahead of the bill's scheduled markup on March 15. The bill includes several measures that were not a part of the previously released discussion draft, including a provision to strengthen security in high-level biocontainment labs. It also adds a proposal to prevent undue foreign influence in biomedical research, adding a statutory requirement for researchers funded by the NIH to disclose participation in foreign talent programs.

## House Democrats Meet for Policy Retreat

House Democratic lawmakers convened in Philadelphia last week for a caucus retreat to prioritize their legislative agenda before the November midterm elections. The caucus discussed the pursuit of various parts of their Build Back Better tax and social spending package, legislation focused on U.S. competitiveness with China, and a voting rights bill that is less comprehensive than the legislation Congress failed to pass earlier this year. Lawmakers are considering restarting negotiations on a scaled-back version of Build Back Better, which could be passed through the budget reconciliation process requiring only a simple majority to clear the Senate.

## Senate Democrats to Hold Hearings on Cost-Cutting Proposals

In a Dear Colleague letter sent last week, Senate Majority Leader Chuck Schumer (D-N.Y.) announced that many Senate committees will hold hearings and mark ups in March and April on Democrats' cost-cutting proposals. The Senate Finance Committee has already scheduled a March 16 hearing on lowering the cost of prescription drugs. Witnesses from the American Action Forum, Information Technology and Innovation Foundation, and National Multiple Sclerosis Society are set to testify.

## Grassley Asks FTC to Reconsider PBM Study

Sen. Chuck Grassley (R-Iowa) has sent a letter to Federal Trade Commission (FTC) Chair Lina Khan urging the agency to investigate pharmacy benefit managers (PBMs). Grassley argues that there is "widespread bipartisan support" for a probe into whether PBMs are "causing Americans to pay higher prices for prescription drugs." The FTC recently deadlocked along party lines about whether to launch a study of U.S. PBMs. Republican commissioners voted against the proposal because, as drafted, it would not consider concerns with the impact of PBMs on out-of-pocket costs for consumers. Grassley encouraged FTC commissioners to find common ground on a meaningful study, pointing out that a more targeted focus "on the impact of PBMs on consumers and the out-of-pocket costs of their prescription drugs appears to be an area of agreement." He also suggested that the FTC could study whether PBMs use formulary designs to depress the market share of low-cost prescription drugs.

## Wyden Continues AbbVie Investigation

Senate Finance Committee Chair Ron Wyden (D-Ore.) has sent a letter to AbbVie Inc. demanding that the manufacturer explain the tax implications of having the company's unit in Bermuda hold its intellectual property for the rheumatoid arthritis medication Humira. Wyden asserts that no Humira manufacturing, packaging, or distribution takes place in Bermuda. His letter states that AbbVie's effective tax rate was 12.5%, compared to the 21% statutory corporate rate. "The lack of transparency into this arrangement raises important questions related to where income associated with the U.S. Humira net revenues is being recognized for tax purposes," Wyden writes. The letter asks technical questions of the company about how it books revenue.

## Lawmakers Request Money for Long COVID Research

A group of two dozen lawmakers in the House of Representatives [wrote](#) to Senate and House leadership urging the inclusion of funds for research on long-COVID in future COVID-19 relief packages. The letter cites estimates that 10% of documented COVID-19 survivors, 7.8 million people, are afflicted with long-COVID. "Congress must use every available tool to immediately respond to this crisis within a crisis," the Democrats led by Rep. Ayanna Pressley (D-Mass.) wrote.

## Democrats Push for Public Option in FY23 WH Budget

Sens. Sheldon Whitehouse (D-R.I.), Sherrod Brown (D-Ohio), Michael Bennet (D-Colo.), and Tim Kaine (D-Va.) have sent a [letter](#) to the White House urging the administration to include a proposal to add a publicly administered health insurance option to the Affordable Care Act's (ACA) marketplaces in their fiscal year (FY) 2023 budget proposal. The letter cites data indicating that 31.1 million Americans remain uninsured, and that coverage disparities persist among Hispanic, Black, Asian, American Indian, and Alaska Native communities. "A public option would promote competition, improve health equity, and guarantee access to stable, low-cost, high-quality health insurance plans nationwide," the lawmakers argue.

## Lawmakers Push for Value-Based Care Incentives

A bipartisan group of lawmakers led by Reps. Suzan DelBene (D-Wash.), Markwayne Mullin (R-Okla.), Ami Bera, M.D. (D-Calif.), Mike Kelly (R-Pa.), Peter Welch (D-Vt.), Darin LaHood (R-Ill.), and Brad Wenstrup (R-Ohio) have sent a [letter](#) to the U.S. Department of Health and Human Services (HHS) calling on Secretary Xavier Becerra to deliver better health outcomes for Medicare beneficiaries and increase incentives for value-based care. The lawmakers ask Becerra to make modifications to the Medicare Shared Savings Program (MSSP) and implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) that will increase provider participation in alternative payment models (APMs). “Adoption of value-based payments has played a critical role in slowing health care spending while improving quality over the last decade,” the letter states. “Moving forward, we must continue to prioritize policies that incentivize responsible cost-savings and advance quality care for seniors, as intended by Congress.” The letter was signed by 41 members of the House of Representatives.

## E&C Members Request Information on COVID-19 and Mental Health

A bipartisan group of House Energy and Commerce Committee members is [requesting](#) information from the Substance Abuse and Mental Health Services Administration (SAMHSA) about the impact of the COVID-19 pandemic on the mental health and well-being of Americans. The letter cites data from various sources regarding increased levels of mental health issues in the United States since the start of the coronavirus pandemic. The lawmakers outline a list of questions to the agency about increased levels of distress, anxiety, and suicide-related behaviors, requesting a response by March 22.

## Schultz, DeGette Urge FDA to Deny E-Cig Applications

Reps. Debbie Wasserman Schultz (D-Fla.) and Diana DeGette (D-Colo.) have sent a letter to the Food and Drug Administration (FDA) asking the agency to deny all e-cigarette applications for non-tobacco vapes. The letter was signed by more than 50 other lawmakers. It has been more than six months since the FDA’s deadline for completing pre-market tobacco reviews of e-cigarettes. Many of the product’s most popular brands remain on the market while awaiting the FDA’s decision.

## DeLauro, Obama Announce Breakthrough COVID Cases

Rep. Rosa DeLauro (D-Conn.) announced that she has tested positive for COVID-19. DeLauro is vaccinated and boosted and stated that she is only experiencing mild symptoms. She plans to isolate and work remotely from her home in Connecticut for the time being. Former President Barack Obama announced that, despite being vaccinated and boosted, he has tested positive but has mild symptoms and otherwise feels fine. Obama says his wife, Michelle, has tested negative and calls on people to get vaccinated even as cases go down.

## MDUFA V Framework Submitted to Congress

An agreement has been reached between the Food and Drug Administration (FDA) and the medical device industry on the framework for the latest Medical Device User Fee Agreement (MDUFA). The new five-year deal reportedly contains up to \$1.9 billion in total revenue and would pave the way for a Total Product Life Cycle Advisory Program pilot funded through a combination of new money and MDUFA IV carryover funds. It also includes goals for increasing agency staffing. The full MDUFA V commitment letter was formally transmitted to lawmakers as the latest step in the reauthorization process last week, but the letter is not public. The agency and industry had missed the January 15 statutory deadline to submit an agreement to Congress. Congress must adopt the new user fee agreements spanning fiscal years (FY) 2023 through 2027 before the current deals expire on September 30.

## OSHA to Increase Inspections of High Hazard Health Facilities

The Occupational Safety and Health Administration (OSHA) has announced an enforcement memorandum for a short-term increase in highly focused inspections directed at hospitals and skilled nursing care facilities that treat or handle COVID-19 patients. The goal of this effort is to control the spread of COVID-19 and future variants of the coronavirus and to protect the health and safety of workers who remain at heightened risk of contracting the virus. OSHA will expand its presence in high-hazard health care facilities between March 9 and June 9, 2022, working to verify readiness to address any ongoing or future COVID-19 surges. Follow-up inspections will be conducted at sites that were previously issued citations and where complaints were received but the agency did not conduct in-person inspections.

## Moderna to Coordinate with COVAX to Supply Vaccine

Moderna stated last week that it does not have plans to ever enforce its COVID-19 vaccine patents against manufacturers based in or producing in 92 low- and middle-income countries. The nations covered are members of the Gavi COVAX Advance Market Commitment, which aims to secure financing for coronavirus vaccines in those nations. In other countries not covered by the commitment, “Moderna remains willing to license its technology for COVID-19 vaccines to manufacturers in these countries on commercially reasonable terms.”

## Upcoming Congressional Hearings and Markups

Senate Health, Education, Labor, and Pensions Committee markup of the ***PREVENT Pandemics Act***; 10:00 a.m.; March 15

Senate Finance Committee hearing “Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare;” 10:00 a.m.; March 16

House Ways and Means Worker & Family Support Subcommittee hearing “Improving Family Outcomes through Home Visiting;” 10:00 a.m.; March 16

House Veterans’ Affairs Health Subcommittee hearing on H.R. 4993, the ***Veterans Emergency Care Reimbursement Act***; H.R. 5738, ***Lactation Spaces for Veteran Moms Act***; H.R. 5754, ***Patient Advocate Tracker Act***; H.R. 5819, ***Autonomy for Disabled Veterans Act***; H.R. 5941, ***Fairness for Rural Veterans Act***; H.R. 6647, to make certain improvements relating to the eligibility of veterans to receive reimbursement for emergency treatment furnished through the Veterans Community Care program; H.R. 6823, ***Elizabeth Dole Home and Community Based Services for Veterans and Caregivers Act***; Discussion Draft, ***Long-term Care Veterans Choice Act***; 2:00 p.m.; March 16

Small Business Subcommittee on Oversight, Investigations, and Regulations hearing “An Empirical Review of the Paycheck Protection Program;” 10:00 a.m.; March 16

Senate Armed Services Subcommittee on Personnel hearing to receive testimony on the health effects of exposure to airborne hazards, including toxic fumes from burn pits; 3:00 p.m.; March 16

House Energy and Commerce Subcommittee on Health hearing “The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight;” 10:30 a.m.; March 17

House Veterans’ Affairs Committee hearing “Building a Better VA: Addressing Healthcare Workforce Recruitment and Retention Challenges;” 2:00 p.m.; March 17

H.Res.967 — Raising awareness of the impact of COVID-19 on bereaved children; Sponsor: Rep. Watson Coleman, Bonnie [D-NJ-12]; Committees: House - Energy and Commerce

H.R.6946 — To amend the Controlled Substances Act with respect to fentanyl-related substances, and for other purposes; Sponsor: Rep. Pappas, Chris [D-NH-1]; Committees: House - Energy and Commerce; Judiciary

H.R.6948 — To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to promulgate rules to update certain regulations relating to human cells, tissues, and cellular and tissue-based products, and for other purposes; Sponsor: Rep. Crenshaw, Dan [R-TX-2]; Committees: House - Energy and Commerce

H.R.6963 — To amend the Federal Food, Drug, and Cosmetic Act to strengthen requirements for postapproval studies for drugs approved using accelerated approval, and for other purposes; Sponsor: Rep. Pallone, Frank, Jr. [D-NJ-6]; Committees: House - Energy and Commerce

S.3778 — A bill to amend titles XVIII and XIX of the Social Security Act to make premium and cost-sharing subsidies available to low-income Medicare part D beneficiaries who reside in Puerto Rico or another territory of the United States; Sponsor: Sen. Menendez, Robert [D-NJ]; Committees: Senate - Finance

S.3782 — A bill to prohibit the delivery of opioids by means of the dark web, and for other purposes; Sponsor: Sen. Hassan, Margaret Wood [D-NH]; Committees: Senate - Judiciary

H.R.6972 — To amend the Federal Food, Drug, and Cosmetic Act to establish additional authorities of the Food and Drug Administration regarding the conduct of pediatric investigations of molecularly targeted drugs to treat cancer, and for other purposes; Sponsor: Rep. Butterfield, G. K. [D-NC-1]; Committees: House - Energy and Commerce

H.R.6973 — To amend the Federal Food, Drug, and Cosmetic Act to clarify the conditions under which the Secretary of Health and Human Services can approve generic drug applications with labeling temporarily different than the brand name drug, and for other purposes; Sponsor: Rep. Carter, Earl L. "Buddy" [R-GA-1]; Committees: House - Energy and Commerce

H.R.6980 — To direct the Secretary of Health and Human Services to conduct a pilot program under which the Secretary increases the conduct of unannounced inspections of foreign human drug establishments and evaluates the differences between inspections of domestic and foreign human drug establishments, including the impact of announcing inspections to persons who own or operate foreign human drug establishments in advance of an inspection; Sponsor: Rep. Hudson, Richard [R-NC-8]; Committees: House - Energy and Commerce

H.R.6988 — To amend the Federal Food, Drug, and Cosmetic Act to authorize a program to support the adoption of, and improve the development of, innovative approaches to pharmaceutical product design and manufacturing, and for other purposes; Sponsor: Rep. Levin, Mike [D-CA-49]; Committees: House - Energy and Commerce

H.R.6991 — To establish the policy of the Department of Veterans Affairs on medicinal cannabis, and for other purposes; Sponsor: Rep. Moulton, Seth [D-MA-6]; Committees: House - Veterans' Affairs

H.R.6996 — To amend the Federal Food, Drug, and Cosmetic Act with respect to the accelerated approval of a product for a serious or life-threatening disease or condition, and for other purposes; Sponsor: Rep. McMorris Rodgers, Cathy [R-WA-5]; Committees: House - Energy and Commerce

H.Res.974 — Supporting the goals and ideals of National Women and Girls HIV/AIDS Awareness Day; Sponsor: Rep. Lee, Barbara [D-CA-13]; Committees: House - Energy and Commerce; Foreign Affairs

H.Res.975 — Expressing the mental health impacts of recurrent climate-related disasters on youth; Sponsor: Rep. Thompson, Mike [D-CA-5]; Committees: House - Energy and Commerce

H.R.7006 — To amend the Federal Food, Drug, and Cosmetic Act to improve inspections of foreign drug manufacturing establishments, and for other purposes; Sponsor: Rep. Griffith, H. Morgan [R-VA-9]; Committees: House - Energy and Commerce

H.R.7008 — To improve patient access to emerging medication therapies by clarifying the scope of permitted health care economic and scientific information communications between biopharmaceutical manufacturers and population health decision makers, and for other purposes; Sponsor: Rep. Guthrie, Brett [R-KY-2]; Committees: House - Energy and Commerce

H.R.7011 — To amend title V of the Social Security Act to support stillbirth prevention and research, and for other purposes; Sponsor: Rep. Adams, Alma S. [D-NC-12]; Committees: House - Energy and Commerce

H.R.7032 — To amend section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) with respect to a process to inform persons submitting an abbreviated application for a new drug whether the new drug is qualitatively or quantitatively the same as a listed drug, and for other purposes; Sponsor: Rep. Kuster, Ann M. [D-NH-2]; Committees: House - Energy and Commerce

H.R.7035 — To amend the Federal Food, Drug, and Cosmetic Act to require prompt reports of marketing status by holders of approved applications for biological products, and for other purposes; Sponsor: Rep. Manning, Kathy E. [D-NC-6]; Committees: House - Energy and Commerce

H.R.7045 — To eliminate the opt-out for nonfederal governmental health plans; Sponsor: Rep. Porter, Katie [D-CA-45]; Committees: House - Energy and Commerce

H.R.7047 — To amend title III of the Public Health Service Act with respect to the determination by the Secretary regarding certain biosimilar application elements, and for other purposes; Sponsor: Rep. Schrader, Kurt [D-OR-5]; Committees: House - Energy and Commerce

H.R.7048 — To prohibit the Secretary of Veterans Affairs from replacing physician anesthesiologists with certified registered nurse anesthetists under the health care system of the Department of Veterans Affairs, and for other purposes; Sponsor: Rep. Scott, David [D-GA-13]; Committees: House - Veterans' Affairs

H.R.7051 — To amend titles XVIII and XIX of the Social Security Act to provide for coverage of prescription digital therapeutics under such titles, and for other purposes; Sponsor: Rep. Thompson, Mike [D-CA-5]; Committees: House - Energy and Commerce; Ways and Means

H.R.7053 — To amend title XVIII of the Social Security Act to extend acute hospital care at home waiver flexibilities; Sponsor: Rep. Wenstrup, Brad R. [R-OH-2]; Committees: House - Ways and Means; Energy and Commerce

S.3791 — A bill to amend titles XVIII and XIX of the Social Security Act to provide for coverage of prescription digital therapeutics under such titles, and for other purposes; Sponsor: Sen. Capito, Shelley Moore [R-WV]; Committees: Senate - Finance

S.3792 — A bill to amend title XVIII of the Social Security Act to extend acute hospital care at home waiver flexibilities; Sponsor: Sen. Carper, Thomas R. [D-DE]; Committees: Senate - Finance

S.3793 — A bill to amend title XI of the Social Security Act to recommend the Center of Medicare and Medicaid Innovation test the effect of technology-enabled care interventions in the home to coordinate care over time and across settings, improve quality, and lower costs for certain Medicare Advantage beneficiaries, and for other purposes; Sponsor: Sen. Scott, Tim [R-SC]; Committees: Senate – Finance

S.3796 — A bill to eliminate the opt-out for nonfederal governmental health plans; Sponsor: Sen. Murphy, Christopher [D-CT]; Committees: Senate - Health, Education, Labor, and Pensions

S.3797 — A bill to amend title V of the Social Security Act to support stillbirth prevention and research, and for other purposes; Sponsor: Sen. Merkley, Jeff [D-OR]; Committees: Senate – Finance

S.3799 — A bill to prepare for, and respond to, existing viruses, emerging new threats, and pandemics; Sponsor: Sen. Murray, Patty [D-WA]; Committees: Senate - Health, Education, Labor, and Pensions

S.3800 — A bill to amend to Public Health Services Act to establish and support a network of Centers for Public Health Preparedness and Response; Sponsor: Sen. Marshall, Roger [R-KS]; Committees: Senate - Health, Education, Labor, and Pensions

S.3809 — A bill to require the Comptroller General of the United States to conduct a study relating to COVID-19 immunity resulting from a prior infection, vaccination, or both, and the COVID-19 pandemic; Sponsor: Sen. Braun, Mike [R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.3810 — A bill to amend the Countermeasure Injury Compensation Program with respect to COVID-19 vaccines; Sponsor: Sen. Lee, Mike [R-UT]; Committees: Senate - Health, Education, Labor, and Pensions

S.3814 — A bill to moderate biosurveillance capabilities and infectious disease data collection, and improve epidemic forecasting and outbreak analytics; Sponsor: Sen. Hickenlooper, John W. [D-CO]; Committees: Senate - Health, Education, Labor, and Pensions

S.3819 — A bill to establish an Advanced Research Projects Authority for Health within the National Institutes of Health; Sponsor: Sen. Murray, Patty [D-WA]; Committees: Senate - Health, Education, Labor, and Pensions

S.3820 — A bill to amend title 38, United States Code, to increase the rate of pay for certain nurses and other medical positions of the Department of Veterans Affairs, and for other purposes; Sponsor: Sen. Blumenthal, Richard [D-CT]; Committees: Senate - Veterans' Affairs