



Health Policy Briefing

May 8, 2023

HELP Drug Pricing, PBM Markup Rescheduled

The Senate Health, Education, Labor, and Pensions (HELP) Committee markup of four drug pricing related bills was postponed last week after a disagreement between panel Democrats and Republicans about the process by which the legislation was brought forth for consideration. Republicans argued that several amendments filed by Democrats contained policies that committee leadership agreed to set aside during their initial bipartisan negotiations on the package of bills, some of which had been awaiting scores from the Congressional Budget Office and technical assistance from federal agencies. HELP Committee members also questioned why the markup was taking place prior to a related hearing scheduled for May 10 in which the nation's largest insulin manufacturers and pharmacy benefit managers have agreed to testify. The markup has been rescheduled for Thursday, May 11.

Appropriations Markups to Begin Mid-May

Senate Appropriations Chair Patty Murray (D-Wash.) announced plans for her panel to begin marking up fiscal year (FY) 2024 spending legislation on May 18th. Negotiations between Murray and Ranking Member Susan Collins (R-Maine) on top-line spending levels are still ongoing. House Appropriations Committee leadership recently announced its own FY 2024 appropriations markup schedule as well: the first subcommittee markups will be held May 17th and 18th, with the first full committee markups tentatively planned for May 23rd, 24th, and 25th. The remaining subcommittee markups will be held June 7th and 8th, with the full committee completing consideration of the measures June 13th, 14th, and 15th.

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E&C Republicans Probe Viral Manipulation Research, CDC Reorganization

Top Republicans on the House Energy and Commerce Committee are [asking](#) the Government Accountability Office to evaluate the benefits and risks of predictive field research programs for viruses. The letter comes as a part of the panel's investigation into the origins of COVID-19. The letter was signed by Chair Cathy McMorris Rodgers (R-Wash.), Health Subcommittee Chair Brett Guthrie (R-Ky.), and Oversight and Investigations Subcommittee Chair Morgan Griffith (R-Va.). The lawmakers have also [asked](#) acting director of the National Institutes of Health (NIH) Lawrence Tabak to supply details about all internal and external NIH research projects involving virus manipulation.

Rodgers, Guthrie, and Griffith also sent a [letter](#) to the Centers for Disease Control and Prevention (CDC) requesting information related to its Moving Forward Initiative which has resulted in the agency undertaking a large-scale reorganization. The letter criticizes the CDC for conducting the initiative "largely in secret," providing just a 10-day notice and comment period and only convening a single related public meeting. The agency used the findings of the Moving Forward Initiative to justify its request to Congress for additional authority to mandate data reporting from state, local, territorial, and tribal public health agencies. "The CDC must provide the Committee with more than a cursory, summarized overview of the findings of the Moving Forward Initiative before the Committee can even begin to consider the agency's request for additional authority," the lawmakers state.

Wyden, Matsui, McHenry Urge Bakers to Comply with Spirit of Sesame Labeling Law

Sen. Ron Wyden (D-Ore.), Rep. Doris Matsui (D-Calif.), and Rep. Patrick McHenry (R-N.C.) have sent a [letter](#) to the American Bakers Association urging its members to stop unnecessarily adding sesame to baked goods in order to protect consumers with a sesame allergy. "The dangerous practice of adding sesame to baked goods that have not previously contained the ingredient, often without notice, undermines the trust that people with food allergies place in the food industry," the letter states. The lawmakers argue that "instead of acting to protect consumers, manufacturers are adding trace amounts of sesame to their baking products since the passage of the ***FASTER Act***. It appears that this is being done to avoid the costs associated with the processes and systems controls necessary to ensure safe baking practices." The ***Food Allergy Safety, Treatment, Education, and Research (FASTER) Act***, which became law in April 2021, requires manufacturers to ensure that products containing sesame are appropriately labeled.

Finance Committee Explores Prevalence of Mental Health Ghost Networks

The Senate Finance Committee released a 'secret shopper' [report](#) last week which found that most Medicare Advantage plan mental health provider directories contain misleading or false contact information. In a study of directories across 12 different plans in six states, Finance majority staff found that more than 80% of mental health care providers listed as in-network were in fact not available to the plan's enrollees. The report recommends increased oversight and audits of health plan directories, and suggests fining plans that do not have accurate directories. The committee released the report prior to a hearing on the prevalence of these so-called ghost networks on Wednesday, May 10.

Sen. Ben Cardin Will Not Seek Reelection

Sen. Ben Cardin (D-Md.), 79, announced last week that he will not seek re-election in 2024. Cardin was first elected to the Senate in 2006 following 17 years representing Maryland's Third Congressional District in the House of Representatives. He currently serves as Chair of the Small Business and Entrepreneurship Committee and is a senior member of the Senate Foreign Relations, Finance, and Environment and Public Works committees. Rep. David Trone (D-Md.) and Montgomery County Council member Will Jawando (D) have announced that they will run for Cardin's Senate seat, and Prince George's County Executive Angela Alsobrooks (D) is also considering a bid in the 2024 election.

WHO Declares End of COVID-19 Global Health Emergency; U.S. PHE to End May 11

At the recommendation of the World Health Organization's (WHO) COVID-19 Emergency Committee, WHO Director-General Tedros Adhanom Ghebreyesus has declared an end to COVID-19 as a Public Health Emergency of International Concern. WHO officials were careful to emphasize that while the emergency phase of the coronavirus pandemic is over, COVID-19 remains a global public health threat. "COVID has changed our world and it has changed us," Tedros said. "If we all go back to how things were before COVID-19, we will have failed to learn our lessons and we will have failed future generations."

As previously announced, the Biden administration will officially terminate the U.S. COVID-19 public health emergency (PHE) on May 11. The end of the PHE declaration will result in a restructured federal COVID-19 response that shifts much of the responsibility for vaccine and treatment distribution to the private sector. People without health insurance will continue to be able to access vaccines and treatments at no out-of-pocket cost through 2024. Vaccines will remain free in Medicare, Medicaid, and the Children's Health Insurance Program, but beneficiaries of these programs could face increased cost sharing for COVID-19 tests and treatments. Certain other flexibilities and regulatory authorities instituted in response to the COVID-19 PHE have already been de-linked from the emergency declaration. The ***Consolidated Appropriations Act, 2023***, for example, extended certain telehealth policies and hospital at home waivers through 2024.

Experts have warned that there is an approximately 20% chance of an outbreak rivaling the intensity of the omicron variant occurring in the next two years. It was reported last week that scientists shared their analysis of the possibility of the virus mutating in such a way that evades vaccines and treatments with the Biden administration as it was working to wind down the PHE. The White House declined to comment about the experts' analysis.

Walensky to Leave Post of CDC Director

Rochelle Walensky will leave her position as Director of the Centers for Disease Control and Prevention (CDC), a post she has held since the start of the Biden administration. During her time as director Walensky acknowledged the CDC's shortcomings in response to the COVID-19 pandemic and launched an effort to reorganize and modernize the agency. Walensky plans to step down on June 30 but did not provide a reason behind her decision to resign.

Tanden Tapped as Next Head of the Domestic Policy Council

According to recent reports, President Joe Biden will soon name Neera Tanden as the next Director of the Domestic Policy Council. Tanden will replace Susan Rice, who has announced her plans to leave the administration later this month. Tanden currently serves as White House staff secretary and senior adviser. She was previously nominated to lead the Office of Management and Budget but withdrew from consideration after bipartisan objections to her use of Twitter to criticize political opponents. Biden aide Stef Feldman will replace Tanden as staff secretary.

DEA Temporarily Extends COVID-19 Telehealth Prescribing Flexibilities

The Drug Enforcement Administration (DEA) announced last week that it will continue to permit providers to prescribe controlled substances via telehealth as the agency works to finalize its related proposed regulations in response to the end of the COVID-19 public health emergency (PHE). The rules proposed in February would have allowed doctors to prescribe only an initial 30-day supply of certain DEA-regulated drugs through telehealth. For other drugs – including Adderall – patients would be required to complete an in-person visit with a provider before receiving a prescription. The DEA stated that it received a record number of comments in response to the proposed rules. It did not specify how long the temporary extension of the COVID-19 era flexibilities will last.

In related news, a bipartisan group of senators sent a [letter](#) to the DEA calling on the agency to address gaps in patient access to the opioid use disorder drug buprenorphine. "We are concerned that the DEA has failed to develop and provide sufficiently clear guidance for pharmacists, wholesalers, distributors, and patients for accessing buprenorphine," the lawmakers said in a letter to the agency. The letter was signed by Sens. Maggie Hassan (D-N.H.), Martin Heinrich (D-N.M.), Thom Tillis (R-N.C.), Elizabeth Warren (D-Mass.) and Sheldon Whitehouse (D-R.I.).

New Survey Examines Impact of Pandemic on Nursing Shortages

A new [survey](#) from AMN Healthcare reveals that nearly one-third of nurses nationwide will leave the profession because of the COVID-19 pandemic. The percentage of nurses saying they were satisfied with their choice of career dropped to 71% in 2023, after holding steady at 80% to 85% for the prior decade. The survey of 182,000 nurses also found a decline in the percentage of nurses who are satisfied with the quality of care they provide from 75% to 64%.

Upcoming Congressional Hearings and Markups

House Ways and Means Committee field hearing on “Trade in America: Securing Supply Chains and Protecting the American Worker – Staten Island;” 10:00 a.m.; May 9

House Veterans’ Affairs Subcommittee on Technology Modernization hearing “Electronic Health Record Modernization Deep Dive: Pharmacy;” 3:00 p.m.; May 9

House Transportation & Infrastructure Subcommittee on Highways and Transit hearing “Freight Forward: Overcoming Supply Chain Challenges to Deliver for America;” 10:00 a.m.; May 10

Senate Health, Education, Labor, and Pensions Committee hearing “The Need to Make Insulin Affordable for All Americans;” 1:00 p.m.; May 10

House Ways and Means Subcommittee on Health hearing on Examining Policies that Inhibit Innovation and Patient Access; 2:00 p.m.; May 10

House Select Subcommittee on the Coronavirus Pandemic hearing “Investigating Pandemic Immunity: Acquired, Therapeutic or Both;” 10:00 a.m.; May 11

Senate Health, Education, Labor, and Pensions Committee markup of S. 1067, *Ensuring Timely Access to Generics Act of 2023*, S. 1114, *Expanding Access to Low-Cost Generics Act of 2023*, S. 1214, *RARE Act*, and S. 1339, *Pharmacy Benefit Manager Reform Act*; 10:00 a.m.; May 11

House Energy and Commerce Subcommittee on Health hearing “Preparing for and Responding to Future Public Health Security Threats;” 10:00 a.m.; May 11

Senate Finance Committee hearing “Cross-border Rx: Pharmaceutical Manufacturers and U.S. International Tax Policy;” 10:00 a.m.; May 11

House Energy and Commerce Subcommittee on Oversight and Investigations hearing “Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains;” 10:30 a.m.; May 11

House Transportation & Infrastructure Subcommittee on Railroads, Pipelines, and Hazardous Materials hearing “Getting Back on Track: Exploring Rail Supply Chain Resilience and Challenges;” 2:00 p.m.; May 11

House Oversight and Accountability Subcommittee on Health Care and Financial Services hearing “FDA Oversight Part II: Responsibility for the Infant Formula Shortage;” 2:00 p.m.; May 11

H.R.3030 — 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: Sorensen, Eric [Rep.-D-IL-17]; Committees: House - Energy and Commerce

H.R.3029 — To amend the Internal Revenue Code of 1986 to allow individuals with direct primary care service arrangements to remain eligible individuals for purposes of health savings accounts, and for other purposes. Sponsor: Smucker, Lloyd [Rep.-R-PA-11]; Committees: House - Ways and Means

H.R.3024 — To amend the Family and Medical Leave Act of 1993 to permit additional leave for bone marrow or blood stem cell donation, and for other purposes. Sponsor: Phillips, Dean [Rep.-D-MN-3]; Committees: House - Education and the Workforce; Oversight and Accountability; House Administration

H.R.3023 — To direct the Secretary of Veterans Affairs and the Secretary of Defense to furnish stellate ganglion block to veterans and members of the Armed Forces with post-traumatic stress disorder, and for other purposes. Sponsor: Perry, Scott [Rep.-R-PA-10]; Committees: House - Armed Services; Veterans' Affairs

H.R.3017 — To amend title XVIII of the Social Security Act to improve access to skilled nursing facilities for primary immunodeficiency patients. Sponsor: Matsui, Doris O. [Rep.-D-CA-7]; Committees: House - Ways and Means; Energy and Commerce

H.R.3011 — To establish a task force of the Department of Defense on mental health. Sponsor: Kilmer, Derek [Rep.-D-WA-6]; Committees: House - Armed Services

H.R.3009 — To direct the Secretary of Defense to carry out a pilot program to pre-program suicide prevention resources into certain smart devices issued to members of the Armed Forces. Sponsor: Joyce, David P. [Rep.-R-OH-14]; Committees: House - Armed Services

H.R.3008 — To amend the Federal Food, Drug, and Cosmetic Act to provide for notification by manufacturers of critical essential medicines of increased demand of such drugs, and for other purposes. Sponsor: Jacobs, Sara [Rep.-D-CA-51]; Committees: House - Energy and Commerce

H.R.3004 — To amend the Internal Revenue Code of 1986 to provide for a temporary expansion of health insurance premium tax credits for certain low-income populations, and to amend title XIX of the Social Security Act to establish a Federal Medicaid program. Sponsor: Fletcher, Lizzie [Rep.-D-TX-7]; Committees: House - Ways and Means; Energy and Commerce

H.Res.347 — Expressing support for designation of the month of April 2023 as “Parkinson’s Awareness Month”. Sponsor: Wexton, Jennifer [Rep.-D-VA-10]; Committees: House - Energy and Commerce

H.Res.345 — Recognizing that infertility is a widespread problem that affects populations of diverse ages, races, ethnicities, and genders. Sponsor: Wasserman Schultz, Debbie [Rep.-D-FL-25]; Committees: House - Energy and Commerce

H.Res.338 — 118th Congress (2023-2024) Expressing support for the designation of April 30, 2023, as “National Adult Hepatitis B Vaccination Awareness Day”. Sponsor: Johnson, Henry C. “Hank,” Jr. [Rep.-D-GA-4]; Committees: House - Energy and Commerce

S.1395 — A bill to temporarily suspend the debt limit through December 31, 2024; Sponsor: Schumer, Charles E. [Sen.-D-NY]; Latest Action: Introduced in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time.

S.1403 — A bill to amend the Public Health Service Act to establish a grant program to award grants to accredited public institutions of higher education, and for other purposes; Sponsor: Mullin, Markwayne [Sen.-R-OK]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.348 — Declaring gun violence a public health crisis; Sponsor: Espaillat, Adriano [Rep.-D-NY-13]; Committees: House - Energy and Commerce

H.Res.351 — Recognizing the impact the stigmatization of menstruation has on the lives of women, girls, and people who menstruate, and expressing support for the designation of the month of May as “National Menstrual Health Awareness Month”; Sponsor: Meng, Grace [Rep.-D-NY-6]; Committees: House - Energy and Commerce; Education and the Workforce

H.Res.355 — Supporting the designation of May 2023 as “National Brain Tumor Awareness Month”; Sponsor: Quigley, Mike [Rep.-D-IL-5]; Committees: House - Energy and Commerce

H.R.3055 — To amend the Elementary and Secondary Education Act of 1965 to include certain mental health professionals as specialized instructional support personnel; Sponsor: Harder, Josh [Rep.-D-CA-9]; Committees: House - Education and the Workforce

H.R.3065 — To amend the Public Health Service Act to provide funding for trained school personnel to administer drugs and devices for emergency treatment of known or suspected opioid overdose, and for other purposes; Sponsor: Phillips, Dean [Rep.-D-MN-3]; Committees: House - Energy and Commerce

H.R.3066 — To establish the National Commission on the COVID-19 Pandemic, and for other purposes; Sponsor: Posey, Bill [Rep.-R-FL-8]; Committees: House - Energy and Commerce; Financial Services; Transportation and Infrastructure

H.R.3068 — To prohibit discrimination in health care and require the provision of equitable health care, and for other purposes; Sponsor: Schiff, Adam B. [Rep.-D-CA-30]; Committees: House - Energy and Commerce; Ways and Means

H.R.3069 — To amend title XI of the Social Security Act to improve access to care for all Medicare and Medicaid beneficiaries through models tested under the Center for Medicare and Medicaid Innovation, and for other purposes; Sponsor: Sewell, Terri A. [Rep.-D-AL-7]; Committees: House - Energy and Commerce; Ways and Means

H.R.3073 — 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 promote mental wellness and resilience and prevent and heal mental health, behavioral health, and psychosocial conditions through developmentally and culturally appropriate community programs, and award grants for the purpose of establishing, operating, or expanding community-based mental wellness and resilience programs, and for other purposes; Sponsor: Tonko, Paul [Rep.-D-NY-20]; Committees: House - Energy and Commerce

H.R.3074 — To amend title XIX of the Social Security Act to remove the Medicaid coverage exclusion for inmates in custody pending disposition of charges, and for other purposes; Sponsor: Trone, David J. [Rep.-D-MD-6]; Committees: House - Energy and Commerce

H.R.3076 — To amend title 36, United States Code, to direct the Secretary of Veterans Affairs to establish a flag for next of kin of veterans who die by suicide; Sponsor: Van Drew, Jefferson [Rep.-R-NJ-2]; Committees: House - Judiciary

H.R.3077 — To amend title 38, United States Code, to establish a counseling program for certain survivor of veterans deceased as the result of suicide; Sponsor: Van Drew, Jefferson [Rep.-R-NJ-2]; Committees: House - Veterans' Affairs

- S.1423 — A bill to amend the Public Health Service Act to authorize a scholarship and loan repayment program to incentivize physicians to enter into the field of sickle cell disease research, treatment, and patient care, and for other purposes; Sponsor: Van Hollen, Chris [Sen.-D-MD]; Committees: Senate - Health, Education, Labor, and Pensions
- S.1424 — A bill to amend title XXVII of the Public Health Service Act to improve health care coverage under vision and dental plans, and for other purposes; Sponsor: Manchin, Joe, III [Sen.-D-WV]; Committees: Senate - Health, Education, Labor, and Pensions
- S.1426 — A bill to improve the identification and support of children and families who experience trauma; Sponsor: Durbin, Richard J. [Sen.-D-IL]; Committees: Senate - Health, Education, Labor, and Pensions
- S.1436 — A bill to expand and extend benefits available to veterans in response to the COVID-19 pandemic, and for other purposes; Sponsor: Tester, Jon [Sen.-D-MT]; Committees: Senate - Veterans' Affairs
- S.Res.197 — A resolution designating the week of May 1, 2023, through May 7, 2023, as “Tardive Dyskinesia Awareness Week”; Sponsor: Mullin, Markwayne [Sen.-R-OK]; Committees: Senate – Judiciary
- S.1441 — A bill to establish a Center for Biomedical Innovation and Development in order to accelerate innovation and development of advanced medical countermeasure products; Sponsor: Cornyn, John [Sen.-R-TX]; Committees: Senate - Health, Education, Labor, and Pensions
- S.1446 — A bill to amend the Internal Revenue Code of 1986 to exclude certain Nurse Corps payments from gross income; Sponsor: Merkley, Jeff [Sen.-D-OR]; Committees: Senate – Finance
- S.1447 — A bill to amend the Public Health Service Act to establish a grant program supporting trauma center violence intervention and violence prevention programs, and for other purposes; Sponsor: Cardin, Benjamin L. [Sen.-D-MD]; Committees: Senate - Health, Education, Labor, and Pensions
- S.1450 — A bill to establish a cap on costs for covered prescription drugs under Medicare parts B and D; Sponsor: Sanders, Bernard [Sen.-I-VT]; Committees: Senate – Finance
- S.1451 — A bill to band anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care; Sponsor: Braun, Mike [Sen.-R-IN]; Committees: Senate - Health, Education, Labor, and Pensions
- S.1452 — A bill to promote mental wellness and resilience and prevent and heal mental health, behavioral health, and psychosocial conditions through developmentally and culturally appropriate community programs, and award grants for the purpose of establishing, operating, or expanding community-based mental wellness and resilience programs, and for other purposes; Sponsor: Markey, Edward J. [Sen.-D-MA]; Committees: Senate - Health, Education, Labor, and Pensions