HHS

Hart Health Strategies Inc.



ealth Policy Briefing

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Government Funding Update

The Labor-Health and Human Services (HHS)-Education appropriations bill will face cuts in fiscal year (FY) 2024 under an agreement reached by bicameral appropriations leadership on spending totals for the 12 annual government funding bills. According to Senate Labor-HHS-Education Subcommittee Chair Tammy Baldwin (D-Wis.), the funding will be less than both FY2023 levels (\$209.9 billion in base discretionary funding plus \$4.2 billion in emergency funds) and the Senate's FY 2024 bill, which included \$224.4 billion in discretionary funding. While the funding allocations are not yet publicly available, House Agriculture-Food and Drug Administration (FDA) Subcommittee Ranking Member Sanford Bishop (D-Ga.) has confirmed that the Agriculture-FDA bill will see a bump in funding. Lawmakers have less than one month to negotiate details of the spending bills, as current funding for federal agencies is set to expire on March 1 for some agencies, including the FDA, and March 8 for the remainder, including HHS. Congress faces an effective April 30 deadline to pass the FY 2024 appropriations bills due to a provision in the most recent debt ceiling law that would impose an automatic spending cut on all discretionary funding should a continuing resolution still be in place at that time. In related news, the White House Office of Management and Budget has confirmed that the President will send Congress his FY 2025 budget proposal on March 11, just days after his March 7 State of the Union address and the FY 2024 funding deadlines.

The Senate will vote this week on \$118 billion border deal released on Sunday. The agreement includes \$62 billion in aid for Ukraine, \$14 billion in aid for Israel, and \$10 billion in humanitarian assistance to the Gaza Strip and Ukraine. It also includes the *Fentanyl Eradication and Narcotics Deterrence (FEND)*Off Fentanyl Act. Majority Leader Chuck Schumer (D-N.Y.) plans to hold a procedural vote on the package Wednesday, though it remains unclear if it has the necessary 60 votes to advance.

CMS Makes First Offers in Drug Price Negotiation Program

Last week, the Centers for Medicare and Medicaid Services (CMS) sent its initial price offers for the 10 products selected for the first round of Medicare prescription drug price negotiations to the affected pharmaceutical manufacturers. The companies have until March 2 to accept the offer or

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make a counteroffer, and each company will be able to meet with CMS three times during the negotiation process. The administration will publish final prices by September 1. CMS has not released how much the initial price offers, which are not made public, would generate in savings.

Senate Finance Advances ASPE Nominee

The Senate Finance Committee advanced the nomination of Rebecca Lee Haffajee, JD, PhD, MPH to serve as the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) last week in a 14-13 party line vote. Haffajee has served in this role in an acting capacity since 2021. Her nomination will now be sent to the full Senate for consideration. Prior to joining the administration, Haffajee worked as a policy researcher at the RAND Corporation and an assistant professor at the University of Michigan School of Public Health.

Baldwin Calls for Increased Competition in Asthma-Inhaler Market

Sen. Tammy Baldwin (D-Wis.) has <u>written</u> to the nation's four largest asthma inhaler manufacturers regarding their use of the Food and Drug Administration's (FDA) Orange Book to delay the entrance of generic drug products to the market. The letters from Baldwin to AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, and Teva urge the companies to remove improperly listed patents from the agency's database of patent and exclusivity information for FDA-approved drugs. Her letters highlight that despite warnings from the Federal Trade Commission challenging more than 100 asthma inhaler patents listed in the Orange Book as inaccurate or improper, the companies have not yet removed the patents.

Senate Dems Urge DEA to Deschedule Marijuana

Twelve Senate Democrats, including Majority Leader Chuck Schumer (D-N.Y.), have sent a letter to Attorney General Merrick Garland and Drug Enforcement Administration (DEA) leader Anne Milgram urging the administration to ease cannabis restrictions. The U.S. Department of Health and Human Services recommended in August that the DEA reschedule marijuana from Schedule I to Schedule III, and the agency's review of the recommendation is ongoing. The letter, led by Elizabeth Warren (D-Mass.) and John Fetterman (D-Pa.), urges the DEA to "reach the right conclusion" and deschedule marijuana from the *Controlled Substances Act* altogether "consistent with the clear scientific and public health rationale for removing marijuana from Schedule I, and with the imperative to relieve the burden of current federal marijuana policy on ordinary people and small businesses."

Lawmakers File Brief in Mifepristone Case

A group of 50 senators and 213 members of the House of Representatives have filed a <u>brief</u> in support of the Biden administration ahead of the Supreme Court's consideration of *Food and Drug Administration (FDA) v. Alliance for Hippocratic Medicine*. The case will determine whether the Supreme Court should stay the U.S. District Court for the Northern District of Texas's order blocking the FDA's approval of mifepristone. The lawmakers argue that the "perils of this unwarranted judicial intervention into science-based determinations can hardly be overstated." The Supreme Court is scheduled to hear arguments in the case on March 26.

HHS Finalizes OUD Treatment Rule

The U.S. Department of Health and Human Services (HHS) has made permanent certain COVID-era flexibilities impacting the prescription of buprenorphine. The final <u>rule</u>, which applies to certified opioid treatment programs, will allow the opioid use disorder (OUD) treatment to be prescribed via telehealth, including audio-only visits, without an initiating in-person visit with the prescriber. The regulation also allows providers more flexibility around the provision of unsupervised methadone doses.

Congressional Retirements and Resignations

 \mathbf{A} running list of members of Congress who are retiring or seeking other office can be found below.

SENATE		
Stabenow (D), MI	Braun (R), IN	
Cardin (D), MD	Romney (R), UT	
Carper (D), DE		
Feinstein (D), CA		
Manchin (D), WV		
HOUSE OF REPRESENTATIVES		
Porter (D), CA	Mooney (R), WV	
Lee (D), CA	Banks (R), IN	
Gallego (D), AZ	Spartz (R), IN	
Schiff (D), CA	Bishop (R), NC	
Slotkin (D), MI	Lesko (R), AZ	
Allred (D), TX	Granger (R), TX	
Trone (D), MD	Buck (R), CO	
Blunt Rochester (D), DE	Burgess (R), TX	
Napolitano (D), CA	Santos (R), NY (effective Dec. 1, 2023)	
Wexton (D), VA	Wenstrup (R), OH	
Kim, Andy (D), NJ	McHenry (R), NC	
Jackson, Jeff (D), NC	McCarthy (R), CA (effective Dec. 31, 2023)	
Sarbanes (D), MD	Johnson, Bill (R), OH (effective Jan. 21, 2024)	
Blumenauer (D), OR	Ferguson (R), GA	
Kilmer (D), WA	Curtis (R), UT	
Spanberger (D), VA	Luetkemeyer (R), MO	
Kildee (D), MI	Lamborn (R), CO	
Phillips (D), MN	Bucshon (R), IN	
Cardenas (D), CA	Pence (R), IN	
Eshoo (D), CA	Duncan (R), SC	
Manning (D), NC	Armstrong (R), ND	
Higgins (D), NY (effective Feb. 2, 2024)		
Nickel (D), NC		
Ruppersberger (D), MD		
Sablan (D), MP		

Hart Health Strategies Inc. Upcoming Congressional Hearings and Markups

House Rules Committee meeting to report a Rule for H.R. 485, *Protecting Health Care for All Patients Act*; 4:00 p.m.; February 5

House Budget Committee markup of H.R. 766, *Preventive Health Savings Act*; H.R. 7032, *Congressional Budget Office Data Sharing Act*; H.R. 5301, *Eliminate Useless Reports Act*; 10:00 a.m.; February 6

House Ways and Means Committee hearing "Examining Chronic Drug Shortages in the United States;" 10:00 a.m.; February 6

House Oversight and Accountability Committee markup to consider H.R. 6283, *Delinking Revenue from Unfair Gouging (DRUG) Act*, and other legislation; 10:00 a.m.; February 6

House Energy and Commerce Subcommittee on Oversight and Investigations hearing "Protecting American Health Security: Oversight of Shortcomings in the FDA's Foreign Drug Inspection Program;" 10:30 a.m.; February 6

Senate Health, Education, Labor, and Pensions Committee hearing "Why Does the United States Pay, by Far, the Highest Prices in the World for Prescription Drugs?;" 10:00 a.m.; February 8

Senate Finance Committee hearing "Artificial Intelligence and Health Care: Promise and Pitfalls;" 10:00 a.m.; February 8

Recently Introduced Health Legislation

H.Res.979 — Expressing the sense of the House of Representatives that public health authorities and tobacco control advocates should encourage American innovation and embrace harm reduction as part of the comprehensive United States approach to tobacco control; Sponsor: Reschenthaler, Guy [Rep.-R-PA-14]; Committees: House - Energy and Commerce; Foreign Affairs

H.R.7108 — To support States and high-need local educational agencies in increasing the number of mental health services providers in schools; Sponsor: DeLauro, Rosa L. [Rep.-D-CT-3]; Committees: House - Education and the Workforce

H.R.7119 — To amend titles XVIII and XIX of the Social Security Act to prohibit skilled nursing facilities and nursing facilities from using pre-dispute arbitration agreements with respect to residents of those facilities under the Medicare and Medicaid programs, and for other purposes; Sponsor: Sánchez, Linda T. [Rep.-D-CA-38]; Committees: House - Ways and Means; Energy and Commerce

S.3679 — A bill to reauthorize the Dr. Lorna Breen Health Care Provider Protection Act, and for other purposes; Sponsor: Kaine, Tim [Sen.-D-VA]; Committees: Senate - Health, Education, Labor, and Pensions

S.3680 — A bill to amend the Internal Revenue Code of 1986 to enhance the paid family and medical leave credit, and for other purposes; Sponsor: Fischer, Deb [Sen.-R-NE]; Committees: Senate – Finance

S.3685 — A bill to amend the Family and Medical Leave Act of 1993 to permit leave for bone marrow or blood stem cell donation, and for other purposes; Sponsor: Casey, Robert P., Jr. [Sen.-D-PA]; Committees: Senate - Health, Education, Labor, and Pensions

S.3691 — A bill to amend title XVIII of the Social Security Act to provide for the application of a cost-of-living adjustment to the non-labor related portion for hospital outpatient department services furnished in Alaska and Hawaii; Sponsor: Sullivan, Dan [Sen.-R-AK]; Committees: Senate – Finance

- H.Res.984 Expressing support for the designation of January 30, 2024, as CTE (chronic traumatic encephalopathy) and RHI (repeated head impacts) Awareness Day; Sponsor: Fitzpatrick, Brian K. [Rep.-R-PA-1]; Committees: House Energy and Commerce
- H.R.7136 To require the Secretary of Veterans Affairs to establish a comprehensive standard for timing between referrals and appointments for care from the Department of Veterans Affairs and to submit a report with respect to that standard, and for other purposes; Sponsor: Franklin, C. Scott [Rep.-R-FL-18]; Committees: House Veterans' Affairs
- H.R.7140 To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to require group health plans and health insurance issuers offering group or individual health insurance coverage to disclose the percentage of in-network participation for certain provider types, and for other purposes; Sponsor: Horsford, Steven [Rep.-D-NV-4]; Committees: House Energy and Commerce; Ways and Means; Education and the Workforce
- H.R.7141 To amend titles XIX and XXI of the Social Security Act and title XXVII of the Public Health Service Act to require no-cost coverage of human milk fortifier; Sponsor: McGarvey, Morgan [Rep.-D-KY-3]; Committees: House Energy and Commerce
- H.R.7142 To amend title XVIII of the Social Security Act to ensure appropriate access to non-opioid pain management drugs under part D of the Medicare program; Sponsor: Miller-Meeks, Mariannette [Rep.-R-IA-1]; Committees: House Energy and Commerce; Ways and Means
- H.R.7147 To amend title XI of the Social Security Act to establish a pilot program for testing the use of a predictive risk-scoring algorithm to provide oversight of payments for durable medical equipment and clinical diagnostic laboratory tests under the Medicare program; Sponsor: Schweikert, David [Rep.-R-AZ-1]; Committees: House Energy and Commerce; Ways and Means
- H.R.7148 To amend title XVIII of the Social Security Act to provide for eligibility for coverage of home health services under the Medicare Program on the basis of a need for occupational therapy; Sponsor: Smucker, Lloyd [Rep.-R-PA-11]; Committees: House Ways and Means; Energy and Commerce
- H.R.7149 To amend title XI of the Social Security Act to require the Center for Medicare and Medicaid Innovation to test a model to improve access to specialty health services for certain Medicare and Medicaid beneficiaries; Sponsor: Steel, Michelle [Rep.-R-CA-45]; Committees: House Energy and Commerce; Ways and Means
- H.R.7153 To reauthorize the Dr. Lorna Breen Health Care Provider Protection Act, and for other purposes; Sponsor: Wild, Susan [Rep.-D-PA-7]; Committees: House Energy and Commerce
- S.3700 A bill to permit nurse practitioners and physician assistants to furnish necessary services, appliances, and supplies to individuals receiving medical benefits for illnesses; Sponsor: Hickenlooper, John W. [Sen.-D-CO]; Committees: Senate Health, Education, Labor, and Pensions
- S.3701 A bill to establish education partnership programs between public schools and public health agencies to prevent the misuse and overdose of synthetic opioids by youth, and for other purposes; Sponsor: Hassan, Margaret Wood [Sen.-D-NH]; Committees: Senate Health, Education, Labor, and Pensions
- S.3713 A bill to prohibit the Federal Government from conducting, funding, approving, or otherwise supporting any research involving human fetal tissue that is obtained pursuant to an induced abortion, and to prohibit the solicitation or knowing acquisition, receipt, or acceptance of a donation of such tissue; Sponsor: Hyde-Smith, Cindy [Sen.-R-MS]; Committees: Senate Health, Education, Labor, and Pensions

- H.Con.Res.87 Recognizing the need for research, education, and policy development regarding high-potency marijuana; Sponsor: Sessions, Pete [Rep.-R-TX-17]; Committees: House Energy and Commerce
- H.R.7155 To provide for the establishment, within the Food and Drug Administration, of an Abraham Accords Bureau to promote and facilitate cooperation between the Food and Drug Administration and entities in Abraham Accords countries wishing to work with the agency in order to develop and sell products in the United States, and for other purposes; Sponsor: Harshbarger, Diana [Rep.-R-TN-1]; Committees: House Energy and Commerce
- H.R.7161 To require States to report information on Medicaid payments to abortion providers; Sponsor: Banks, Jim [Rep.-R-IN-3]; Committees: House Energy and Commerce
- H.R.7164 To advance population research for chronic pain; Sponsor: Caraveo, Yadira [Rep.-D-CO-8]; Committees: House Energy and Commerce
- H.R.7174 To amend title XI of the Social Security Act to equalize the negotiation period between small-molecule and biologic candidates under the Drug Price Negotiation Program; Sponsor: McCormick, Richard [Rep.-R-GA-6]; Committees: House Energy and Commerce; Ways and Means
- S.Con.Res.27 A concurrent resolution recognizing the need for research, education, and policy development regarding high-potency marijuana; Sponsor: Ricketts, Pete [Sen.-R-NE]; Committees: Senate Health, Education, Labor, and Pensions
- S.3722 A bill to require a report on access to maternal health care within the military health system, and for other purposes; Sponsor: Rubio, Marco [Sen.-R-FL]; Committees: Senate Armed Services
- S.3725 A bill to amend the Toxic Substances Control Act to codify a Federal cause of action and a type of remedy available for individuals significantly exposed to per- and polyfluoroalkyl substances, to encourage research and accountability for irresponsible discharge of those substances, and for other purposes; Sponsor: Gillibrand, Kirsten E. [Sen.-D-NY]; Committees: Senate Environment and Public Works
- H.Res.992 Recognizing February 4, 2024, as "World Cancer Day", and its theme "Close the Care Gap", to raise awareness about and launch efforts to eliminate racial and ethnic inequities and disparities in cancer care both in the United States and globally; Sponsor: Sewell, Terri A. [Rep.-D-AL-7]; Committees: House Energy and Commerce
- H.R.7183 To prohibit Federal funds from being used to provide certain gender transition procedures to minors; Sponsor: McCormick, Richard [Rep.-R-GA-6]; Committees: House Energy and Commerce
- H.R.7185 To amend the Office of National Drug Control Prevention Act of 1998 to include new requirements for assessments and reports, and for other purposes; Sponsor: Duarte, John S. [Rep.-R-CA-13]; Committees: House Oversight and Accountability; Judiciary
- H.R.7186 To provide for the integration of participant treatment within the Continuum of Care Program with Certified Community Behavioral Health Clinics, and for other purposes; Sponsor: Calvert, Ken [Rep.-R-CA-41]; Committees: House Financial Services
- H.R.7188 To require the Secretary of Health and Human Services to conduct a national, evidence-based education campaign to increase public and health care provider awareness regarding the potential risks and benefits of human cell and tissue products transplants, and for other purposes; Sponsor: Moolenaar, John R. [Rep.-R-MI-2]; Committees: House Energy and Commerce

H.R.7189 — To amend the Public Health Service Act to reauthorize a national congenital heart disease research, surveillance, and awareness program, and for other purposes; Sponsor: Bilirakis, Gus M. [Rep.-R-FL-12]; Committees: House - Energy and Commerce

H.R.7194 — To amend the Toxic Substances Control Act to codify a Federal cause of action and a type of remedy available for individuals significantly exposed to per- and polyfluoroalkyl substances, to encourage research and accountability for irresponsible discharge of those substances, and for other purposes; Sponsor: Dean, Madeleine [Rep.-D-PA-4]; Committees: House - Energy and Commerce; Judiciary

H.R.7207 — To amend title XVIII of the Social Security Act to prohibit the Secretary of Health and Human Services from selecting certain activities relating to the development of anti-racism plans as clinical practice improvement activities under the Medicare program; Sponsor: Palmer, Gary J. [Rep.-R-AL-6]; Committees: House - Energy and Commerce; Ways and Means

H.R.7208 — To reauthorize the Traumatic Brain Injury program; Sponsor: Pascrell, Bill, Jr. [Rep.-D-NJ-9]; Committees: House - Energy and Commerce

H.R.7212 — To address the behavioral health workforce shortages through support for peer support specialists, and for other purposes; Sponsor: Salinas, Andrea [Rep.-D-OR-6]; Committees: House - Energy and Commerce; Education and the Workforce

H.R.7213 — To amend the Public Health Service Act to enhance activities of the National Institutes of Health with respect to research on autism spectrum disorder and enhance programs relating to autism / reauthorize certain programs with respect to autism spectrum disorder, and for other purposes; Sponsor: Smith, Christopher H. [Rep.-R-NJ-4]; Committees: House - Energy and Commerce

H.R.7214 — To require a report on access to maternal health care within the military health system, and for other purposes; Sponsor: Stefanik, Elise M. [Rep.-R-NY-21]; Committees: House - Armed Services

H.R.7215 — To express the sense of Congress that aliens who are present in the United States without lawful status under the immigration laws should not receive any benefit under the Medicare program or under the Medicaid program; Sponsor: Van Drew, Jefferson [Rep.-R-NJ-2]; Committees: House - Energy and Commerce; Ways and Means

H.R.7216 — To direct the Secretary of Health and Human Services to revise regulations to remove the requirement under the Medicare program that an ambulatory surgical center shall report the COVID-19 vaccination status of health care personnel; Sponsor: Van Duyne, Beth [Rep.-R-TX-24]; Committees: House - Energy and Commerce; Ways and Means