HHS

Hart Health Strategies Inc.



Policy Briefi

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Agreement on Topline Funding Numbers

House and Senate Appropriations Committee leaders reached an agreement late Friday night on funding totals for the 12 fiscal year (FY) 2024 appropriations bills. The House and Senate now have approximately 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 and March 8 for the remainder, including the Department of Health and Human Services. 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.

Senate Passes Legislation to Address the Nursing Shortage

The Senate passed the *Train More Nurses Act* (<u>S. 2853</u>) by unanimous consent last week. The legislation aims to strengthen the nursing workforce and improve pathways for licensed practical nurses to become registered nurses. The bill would require the secretaries of Labor and the U.S. Department of Health and Human Services to conduct a study on federal grant programs that support the nursing workforce.

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Administration, Congressional Policymakers Consider MA Program Reforms

The Senate Finance Committee plans to investigate the marketing practices of five Medicare Advantage (MA) third-party marketing organizations: eHealth, GoHealth, Agent Pipeline, SelectQuote, and TRANZACT. Chairman Ron Wyden (D-Ore.) asserts that the sale of beneficiaries' information has "led to a race to the bottom as unscrupulous actors put their own financial interests ahead of seniors' health needs." The panel has sent letters to each of the companies requesting information on their business practices.

The Centers for Medicare and Medicaid Services (CMS) has issued a request for information (RFI) seeking input on the MA program related to "access to care, prior authorization, provider directories, and networks; supplemental benefits; marketing; care quality and outcomes; value-based care arrangements and equity; and healthy competition in the market." The RFI follows a letter from a bipartisan group of senators including Sens. Bill Cassidy (R-La.), Elizabeth Warren (D-Mass.), Marsha Blackburn (R-Tenn.), and Catherine Cortez Masto (D-Nev.) to the agency in December 2023 urging the administration to improve the data collection and reporting practices of MA plans. Responses to the RFI are due on May 29, 2024.

The Medicaid and CHIP Payment and Access Commission (MACPAC) voted on a series of recommendations during its meeting last week to streamline the appeals process for claims denials made by Medicaid managed care organizations (MCOs). The Commission proposed to allow third-party doctors to conduct external medical reviews of MCO claims denials. Similar policies are already in place in 14 states across the nation. The recommendation follows a 2023 report from the U.S. Department of Health and Human Services which found high rates of prior authorization denials by MCOs. The same report found that external medical reviewers made decisions in beneficiaries' favor more often than when MCOs oversaw the claims adjudication process. MACPAC also voted to recommend that CMS issue guidance on MCO denial forms, and that states conduct audits of denials made by MCOs. MACPAC's recommendations will be published in the Commission's March 2024 Report to Congress.

Finance Leaders Consider Policies to Prevent Generic Drug Shortages

Senate Finance Committee Chairman Ron Wyden (D-Ore.) and Ranking Member Mike Crapo (R-Idaho) have released a white paper outlining policy proposals the Committee is exploring to address generic drug shortages through modifications to the Medicare and Medicaid programs. The panel is considering the following areas for legislative development this year:

- Medicare Part A and B payment reforms to stabilize the supply of generic sterile injectable medicines;
- New incentives for providers and other prescription drug supply chain stakeholders to engage in shortage prevention and mitigation activities;
- Reforms or new pilot programs in Medicare Part D to bolster incentives for pharmacies to purchase generic medicines
 from drug manufacturers that invest in shortage mitigation, quality, and drug supply chain resilience; and
- Potential reforms to the Medicaid Drug Rebate Program targeting generic medicines in shortage.

Lawmakers to Launch Digital Health Caucus; HHS Releases Goals for Cybersecurity

Reps. Troy Balderson (R-Ohio) and Robin Kelly (D-Ill.) plan to launch the Congressional Digital Health Caucus during an event hosted by the Consumer Technology Association on Thursday. The caucus will focus on ensuring access to the benefits of digital health tools for all Americans. The event on February 1 will feature speakers from Google, Microsoft, Amazon Web Services, and Hippocratic AI to discuss artificial intelligence in digital health care.

In related news, a bipartisan group of senators have sent a <u>letter</u> to Majority Leader Chuck Schumer (D-N.Y.) calling for the creation of a federal agency responsible for regulating the technology industry. "Congress must create a new agency with the resources and meaningful enforcement authority to regulate these firms in a comprehensive, considered, and continuous manner," the letter states. "We can successfully mitigate the risks of AI while simultaneously addressing the harms American families and businesses experience every day in our digital world." The Majority Leader has recently convened a series of AI Insight Forums underscoring the need for a comprehensive approach to artificial intelligence. The letter, which was signed by Sens. Michael Bennet (D-Colo.), Lindsey Graham (R-S.C.), Elizabeth Warren (D-Mass.), and Peter Welch (D-Vt.), also endorses the *Digital Platform Commission Act* (S. 1671) and the *Digital Consumer Protection Commission Act* (S. 2597) to establish a new enforcement authority to oversee the tech sector.

The U.S. Department of Health and Human Services (HHS) released a set of voluntary cybersecurity performance <u>goals</u> for the health care sector on Wednesday. The measures include both essential goals to strengthen basic cybersecurity as well as enhanced goals to protect against sophisticated cyber-attacks. The goals were accompanied by a new <u>gateway website</u> to help the health care and public health sector implement these practices.

Pharmaceutical Manufacturers Agree to Testify in Feb. 8 Hearing

The CEOs of Johnson & Johnson and Merck have agreed to testify before the Senate Health, Education, Labor and Pensions (HELP) Committee, alongside the CEO of Bristol Meyers Squibb, on the issue of prescription drug pricing during a hearing to be held of February 8. Chairman Bernie Sanders (I-Vt.) had planned to hold a vote this week on issuing subpoenas for the CEOs but canceled the Executive Session explaining that "The use of a subpoena was clearly a last resort and I'm delighted that these CEOs will be coming into our committee voluntarily."

Lawmakers Urge White House to Oppose WTO COVID-19 IP Waiver

A bipartisan group of senators sent a letter to President Joe Biden last week urging the administration to oppose a World Trade Organization (WTO) proposal to waive intellectual property (IP) protections for COVID-19 diagnostics and therapeutics. "Waiving rules meant to incentivize the discovery and production of life-saving medicines will cause investors and innovators to shift their efforts elsewhere," the lawmakers argue. "What is more, allowing foreign competitors to disregard IP protections for made-in-the-USA biomedical technologies would undercut U.S. businesses and undermine the efforts of the workers who brought those technologies to market." The issue will be discussed at a WTO ministerial conference next month. The letter was led by Sens. Mike Crapo (R-Idaho), Chris Coons (D-Del.), Tom Carper (D-Del.), and Thom Tillis (R-N.C.) and signed by 10 other senators.

Congressional Retirements and Resignations

Rep. Kelly Armstrong (R-N.D.) announced his candidacy for Governor of North Dakota last week. Armstrong was first elected to the House of Representatives in 2018 and currently serves on the Energy and Commerce Committee. Rep. Dutch Ruppersberger (D-Md.) announced that he would retire at the end of his term. Ruppersberger has served in the House since 2003 and currently sits on the House Appropriations Committee.

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		

Hart Health Strategies Inc. Upcoming Congressional Hearings and Markups

House Veterans' Affairs Subcommittee on Technology Modernization hearing "The Future of Data Privacy and Artificial Intelligence at VA;" 3:30 p.m.; January 29

House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic hearing "Overseeing the Department of Health and Human Services' Compliance with Congress;" 10:00 a.m.; January 31

House Energy and Commerce Subcommittee on Health hearing "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers;" 10:00 a.m.; January 31

Senate Homeland Security and Governmental Affairs Committee Executive Session to consider nominations and legislation including S. 3558, to prohibit contracting with certain biotechnology providers; 10:15 a.m.; January 31

Senate Veterans' Affairs Committee hearing "Vet Centers: Supporting the Mental Health Needs of Servicemembers, Veterans and their Families;" 3:30 p.m.; January 31

House Judiciary Committee field hearing "Artificial Intelligence and Intellectual Property: Part II – Identity in the Age of AI; 9:00 a.m. PT; Los Angeles, CA; February 2

Senate Health, Education, Labor, and Pensions Committee hearing on the high costs of prescription drugs for patients; 10:00 a.m.; February 8

Recently Introduced Health Legislation

H.R.7059 — To amend the Public Health Service Act to authorize a grant program to increase capacity for providing abortion services and other sexual and reproductive health care, and for other purposes; Sponsor: Caraveo, Yadira [Rep.-D-CO-8]; Committees: House - Energy and Commerce

H.R.7063 — To prohibit Federal funds from being made available to any pregnancy center that diverts people from accessing comprehensive and timely medical care from licensed medical professionals; Sponsor: Landsman, Greg [Rep.-D-OH-1]; Committees: House - Energy and Commerce

H.R.7068 — To amend the Controlled Substances Act to provide for the scheduling of tianeptine as a schedule III substance, and for other purposes; Sponsor: Panetta, Jimmy [Rep.-D-CA-19]; Committees: House - Energy and Commerce; Judiciary

S.Res.530 — A resolution designating January 23, 2024, as "Maternal Health Awareness Day"; Sponsor: Booker, Cory A. [Sen.-D-NJ]; Committees: Senate – Judiciary

S.3638 — A bill to allow health plan policyholders to obtain information about controlled substances prescribed to adult children enrolled in such plan; Sponsor: Vance, J. D. [Sen.-R-OH]; Committees: Senate - Health, Education, Labor, and Pensions

S.3641 — A bill to require the Secretary of Defense to establish a pilot program for evidence-based perinatal mental health prevention for pregnant and postpartum members of the Armed Forces and dependents, and for other purposes; Sponsor: Shaheen, Jeanne [Sen.-D-NH]; Committees: Senate - Armed Services

S.3651 — A bill to amend title XVIII of the Social Security Act to ensure coverage of mental health services furnished through telehealth; Sponsor: Cassidy, Bill [Sen.-R-LA]; Committees: Senate – Finance

S.3653 — A bill to apply user fees with respect to tobacco products deemed subject to the requirements of chapter IX of the Federal Food, Drug, and Cosmetic Act; Sponsor: Shaheen, Jeanne [Sen.-D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.532 — A resolution recognizing and supporting the goals and ideals of National Medicolegal Death Investigation Professionals Week; Sponsor: Cornyn, John [Sen.-R-TX]; Committees: Senate – Judiciary

S.3663 — A bill to provide funding for programs and activities under the SUPPORT for Patients and Communities Act; Sponsor: Shaheen, Jeanne [Sen.-D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.7085 — To prohibit contracting with certain biotechnology providers, and for other purposes; Sponsor: Gallagher, Mike [Rep.-R-WI-8]; Committees: House - Oversight and Accountability

H.R.7087 — To direct the Secretary of Defense to establish a pilot program for evidence-based perinatal mental health prevention for pregnant and postpartum members of the Armed Forces and beneficiaries, and for other purposes; Sponsor: Houlahan, Chrissy [Rep.-D-PA-6]; Committees: House - Armed Services

H.R.7090 — To amend the Internal Revenue Code of 1986 to exclude from gross income certain compensation to clinical trial participants; Sponsor: Kelly, Mike [Rep.-R-PA-16]; Committees: House - Ways and Means

H.R.7091 — To amend title 38, United States Code, to require medical facilities of the Department of Veterans Affairs to share certain data with State cancer registries, and for other purposes; Sponsor: Kiggans, Jennifer A [Rep.-R-VA-2]; Committees: House - Veterans' Affairs; Energy and Commerce

H.R.7093 — To provide for Congressional approval of public health emergency declarations, and for other purposes; Sponsor: Moore, Barry [Rep.-R-AL-2]; Committees: House - Energy and Commerce; Rules