HHS

Hart Health Strategies Inc.



Policy Briefi

March 11, 2024

President Biden Delivers State of the Union Address

Dresident Joe Biden delivered his third <u>State of the Union address</u> on Thursday. During his speech, the President touched on a number of health care issues, focusing particularly on the cost of prescription drugs and reproductive health care. He called on Congress to expand the *Inflation Reduction Act*'s Medicare drug price negotiation program and give Medicare the power to increase the number of drugs eligible for negotiation from the current ten drugs to 500 drugs over the next decade. The President argued that this change "will not only save lives, it will save taxpayers another \$200 billion." He also wishes to cap Medicare co-payments and limit annual out-of-pocket prescription drug spending at \$2,000 a year for all Americans, even those with private insurance, and to extend the price cap on insulin to the private insurance market. The President called on Congress to pass federal legislation protecting abortion rights and guaranteeing nationwide access to in vitro fertilization. He also asked lawmakers to support \$12 billion for women's health research, highlighting the White House Initiative on Women's Health Research that he launched last November, and also called for continued support on Capitol Hill for the Advanced Research Projects Agency for Health (ARPA-H).

President Signs Government Funding Package With Medicare Physician Payment Provision

ongress passed a \$460 ✓ billion appropriations package last week including fiscal year 2024 funding for Agriculture-Food and Drug Administration; Transportation-Housing and Urban Development; Veterans Affairs; Energy; Commerce-Justice; and the Interior. The measure passed the House of Representatives in a 339-85 vote on Wednesday before being approved by the Senate in a 75-22 vote on Friday, thwarting a partial government shutdown set to occur at midnight. The funding agreement includes a provision addressing the

Inside
CMS Announces Advanced Payments in Response to ClearinghouseCyberattack2
HousePassesSevenHealthBills2
Latest Health Legislation Advanced Out of Committee2
Senate Dems Comment on Medicare Advantage Program3
HELP Ranking Member Cassidy Cautions NIH Against Use of March-In Rights
Stakeholder Input Requested on Older Americans Act3
Republicans Seek HHS Briefing on Medicare Catheter Billing Fraud4
Barrasso Announces Bid for Senate GOP Whip4
GAO Issues Report on Biomedical Research Duplication4
Congressional Retirements and Resignations5
Upcoming Congressional Hearings and Markups6
Recently Introduced Health Legislation 6

Medicare physician cut that went into effect on January 1. The provision leaves in place the full Medicare physician cut of 3.37% (relative to 2023 payments) from January 1-March 8, and then, from March 9 through December 31, 2024, subjects physicians to a 1.77% cut (relative to 2023 payments). This results in physicians receiving a more than 2% cut in Medicare reimbursements in 2024 (annualized) relative to 2023. Lawmakers continue negotiations on an agreement for the remaining six appropriations bills, including the U.S. Department of Health and Human Services. Congress has until March 22 to fund those remaining portions of the federal government.

CMS Announces Advanced Payments in Response to Clearinghouse Cyberattack

The U.S. Department of Health and Human Services has expanded the types of providers eligible to receive advanced payment under Federal health programs to support them in the wake of the Change Healthcare cyberattack. The Centers for Medicare and Medicaid Services (CMS) had previously announced that it would consider applications for accelerated payments from Medicare Part A providers; on Saturday, CMS expanded their notice to include Part B providers as well. Affected providers can apply to receive 30 days of relief to be repaid at a later date. For more information, please see the CMS Fact Sheet. However, it remains unclear how much money is available for accelerated payments. CMS is also instructing Medicare contractors to accept paper claims and expedite provider requests to switch to a different processing platform, and is encouraging Medicare Advantage and Medicaid managed care plans to also make prospective payments to impacted providers, as well as to relax their prior authorization requirements.

House Passes Seven Health Bills

The House of Representatives passed a slate of health care related legislation last week under suspension of the rules. The following bills have been sent to the Senate for further consideration.

- The *Action for Dental Health Act* (H.R. 3843) passed 391-32.
- The *Preventing Maternal Deaths Reauthorization Act* (H.R. 3838) passed 382-12.
- The *END FENTANYL Act* (S. 206) passed by voice vote.
- The Firefighter Cancer Registry Reauthorization Act (H.R. 3821) passed 413-7.
- The *Medicaid Primary Care Improvement Act*, as amended (H.R. 3836) passed by voice vote.
- The *Gabriella Miller Kids First Research Act* (H.R. 3391) passed 384-4.
- The **9-8-8** *Lifeline Cybersecurity Responsibility Act of* **2023** (H.R. 498) passed by voice vote.

Latest Health Legislation Advanced Out of Committee

The House Ways and Means Committee advanced several pieces of health care related legislation last week. The *Protecting America's Seniors' Access to Care Act* (H.R. 7513) blocks the Biden administration's proposed nursing home staffing mandate. The bill was advanced in a 26-17 vote, largely along party lines. The *Kidney PATIENT Act* (H.R. 5074) would allow end-stage renal disease patients to access oral-only drugs using Medicare Part D. It was advanced in a 41-1 vote. The *Real Time Benefit Tool Implementation Act* (H.R. 7512) would require CMS to implement a prescriber real-time benefit tool by January 1, 2027. It was advanced in a 42-0 vote.

The Senate Homeland Security and Governmental Affairs Committee advanced legislation last week that would limit contracting with certain Chinese biotech companies in an attempt to prevent foreign adversaries from acquiring Americans' genetic data. The *Prohibiting Foreign Access to American Genetic Information Act of* 2024 (S. 3558) would bar biotech companies controlled by a foreign adversary's government from obtaining federal contracts. It was advanced in an 11-1 vote. Ranking Member Rand Paul (R-Ky.) voted against the legislation, expressing concerns that it could raise costs for consumers. In related news, Chairman of the House Select Committee on the Chinese Communist Party Mike Gallagher (R-Wis.) is requesting that Attorney General Merrick Garland review the Biotechnology Innovation Organization's lobbying on behalf of WuXi Apptec in relation to the *Foreign Agent Registration Act*. WuXi AppTec is a global pharmaceutical, biopharmaceutical, and medical device company with ties to the Chinese Communist Party. Gallagher suggests that the Attorney General recommend that Congress require trade associations lobbying on behalf of companies posing a national security risk register as foreign agents.

Senate Dems Comment on Medicare Advantage Program

A group of Senate Democrats have sent a <u>letter</u> to the Biden administration highlighting challenges and proposed reforms to strengthen the Medicare Advantage (MA) program. The lawmakers urge CMS to:

- 1. Ensure that insurance companies do not prevent older adults and people with disabilities from getting care by putting up obstacles, including onerous prior authorizations, AI algorithms, or limited networks;
- 2. Strengthen provider encounter and patient data collection and transparency to improve public understanding of the effects of insurer-run MA plans on patients and the Medicare program;
- 3. Rein in overpayments to insurers in MA by adjusting benchmarks to compensate for favorable selection and cracking down on deceptive tactics by private insurance companies, including upcoding;
- 4. Address misleading and deceptive marketing practices; and
- 5. Strengthen Medicare for everyone through administrative action, such as by lowering Medicare premiums, and support legislative efforts to expand Medicare benefits, cap out- of-pocket (OOP) costs in TM, and adjust the physician fee schedule to account for increases in provider costs.

The letter was led by Sen. Elizabeth Warren (D-Mass.) and signed by Richard Blumenthal (Conn.), Cory Booker (N.J.), Sherrod Brown (Ohio), Richard Durbin (Ill.), Ed Markey (Mass.), Jeff Merkley (Ore.), Tina Smith (Minn.), Peter Welch (Vt.) and Bernie Sanders (Vt.).

HELP Ranking Member Cassidy Cautions NIH Against Use of March-In Rights

Senate Health, Education, Labor, and Pensions (HELP) Committee Ranking Member Bill Cassidy (R-La.) and sixteen Senate Republicans have sent a letter to National Institutes of Health (NIH) Director Monica Bertagnolli detailing concerns with the administration's proposal to exercise march-in rights under the Bayh-Dole Act to reign in drug prices. "A short-sighted decision to exercise march-in rights would work against your stated goal and jeopardize patient access by discouraging individuals from partnering with NIH to develop new cures and treatments," the letter states. "Not only will this hurt patients, but it will also diminish the return the public gets on the investments Congress makes in NIH each year – something we should all seek to optimize... Agencies, including NIH, should not abuse their authorities to illegally seize intellectual property, and in the process jeopardize the valuable public-private partnerships that make our biomedical research enterprise the best in the world." The Senators are also requesting that the Government Accountability Office (GAO) review whether the administration's proposal meets the definition of a rule under the Congressional Review Act, thus making it possible to be overturned by Congress under a resolution of disapproval.

Stakeholder Input Requested on Older Americans Act

Bipartisan leadership of the Senate HELP Committee issued a <u>request for input</u> from stakeholders as they work to reauthorize the Older Americans Act (OAA). Current authority for the OAA expires on September 30, 2024. The committee is seeking responses on several targeted questions to better understand the impact of the flexibilities granted during the COVID-19 public health emergency. Written responses are due by March 21, 2024 and should be submitted to OAA@help.senate.gov.

Republicans Seek HHS Briefing on Medicare Catheter Billing Fraud

Republicans on the House Energy and Commerce, Ways and Means, and Oversight and Accountability committees were joined by the GOP Doctors Caucus leadership in requesting a briefing from U.S. Department of Health and Human Services (HHS) officials regarding the steps that are being taken to address an alleged catheter billing fraud and how to prevent its reoccurrence. The scheme is estimated to have affected over 450,000 Medicare beneficiaries and totaled at least \$2 billion. "If public reports about the apparent ease with which this fraud was perpetrated are accurate, they raise questions about the efficacy of current Centers for Medicare and Medicaid Services and the HHS Office of the Inspector General fraud detection and prevention measures," the letter states. The lawmakers also highlight stakeholder concerns that a similar increase in fraud has occurred in diabetes supplies, which may be evidence of a new fraud against the Medicare program.

Barrasso Announces Bid for Senate GOP Whip

Senate GOP Conference Chair John Barrasso, MD (R-Wyo.), an orthopaedic surgeon, has announced that he will run for Senate Republican whip, the number two spot in Senate GOP leadership. Barrasso was one of the "Three Johns" considered potential candidates to succeed Sen. Mitch McConnell (R-Ky.) following his announcement that he would step down as Senate GOP leader at the end of this Congress. Former GOP whip John Cornyn (Texas) and current GOP whip John Thune (S.D.) have each confirmed that they will run for the conference's top post.

GAO Issues Report on Biomedical Research Duplication

The GAO has released a new report on actions that are needed to address biomedical research duplication at different HHS agencies. It is the first in a series of reports examining research activities at the Advanced Research Projects Agency for Health (ARPA-H), NIH, Biomedical Advanced Research and Development Authority, and Food and Drug Administration. The report was mandated by Congress in the *Consolidated Appropriations Act*, 2023. GAO outlines the practices in place to avoid unnecessary research duplication, including reviewing project and funding information provided by applicants, consulting with experts and other agencies, and using databases to identify potentially overlapping research.

Congressional Retirements and Resignations

Sen. Kyrsten Sinema (I-Ariz.) announced that she will not run for a second term in the U.S. Senate this November. Her retirement from office leaves Rep. Ruben Gallego (D-Ariz.) and Kari Lake (R) in the race for the Arizona Senate seat. Sinema currently sits on the Appropriations; Homeland Security and Governmental Affairs; Commerce, Science, and Transportation; and Veterans' Affairs committees.

Sen. Bob Menendez (D-N.J.) will not seek reelection this year. Menendez was indicted last week on 12 new felony charges including bribery and extortion. The three-term senator currently serves on the Senate Finance Committee. U.S. Representative Andy Kim (D-N.J.-03) and N.J. First Lady Tammy Murphy are the frontrunners in the race to fill Menendez' seat. The state's primary is scheduled for June 4th.

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		
Butler (D), CA		
Manchin (D), WV		
Sinema (I), AZ		
Menendez (D), NJ		
HOUSE OF REPRESENTATIVES		
Porter (D), CA	Mooney (R), WV	
Lee (D), CA	Banks (R), IN	
Gallego (D), AZ	Bishop (R), NC	
Schiff (D), CA	Lesko (R), AZ	
Slotkin (D), MI	Granger (R), TX	
Allred (D), TX	Buck (R), CO	
Trone (D), MD	Burgess, MD (R), TX	
Blunt Rochester (D), DE	Wenstrup, DPM (R), OH	
Napolitano (D), CA	McHenry (R), NC	
Wexton (D), VA	McCarthy (R), CA (effective Dec. 31, 2023)	
Kim, Andy (D), NJ	Johnson (R), OH (effective Jan. 21, 2024)	
Jackson, Jeff (D), NC	Ferguson, IV, DMD, PC (R), GA	
Sarbanes (D), MD	Curtis (R), UT	
Blumenauer (D), OR	Luetkemeyer (R), MO	
Kilmer (D), WA	Lamborn (R), CO	
Spanberger (D), VA	Bucshon, MD (R), IN	
Kildee (D), MI	Pence (R), IN	
Phillips (D), MN	Duncan (R), SC	
Cardenas (D), CA	Armstrong (R), ND	
Eshoo (D), CA	McMorris Rodgers (R), WA	
Manning (D), NC	Gallagher (R), WI	
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 Energy and Commerce Health Subcommittee markup of 19 legislative proposals to improve the health and wellbeing of patients and caregivers; 10:00 a.m.; March 12

House Ways and Means Committee hearing "Enhancing Access to Care at Home in Rural and Underserved Communities;" 11:00 a.m.; March 12

Senate Finance Committee hearing to examine the President's proposed budget request for fiscal year 2025 for the U.S. Department of Health and Human Services; 10:00 a.m.; March 14

Recently Introduced Health Legislation

H.R.7516 — To amend the Indian Health Care Improvement Act to address liability for payment of charges or costs associated with provision of purchased/referred care services, and for other purposes. Sponsor: Johnson, Dusty [Rep.-R-SD-At Large]; Committees: House - Natural Resources; Energy and Commerce

H.R.7515 — To amend the Fair Credit Reporting Act to delay the inclusion in consumer credit reports and to establish requirements for debt collectors with respect to medical debt information of Native Americans due to inappropriate or delayed billing payments or reimbursements from the Indian Health Service, and for other purposes. Sponsor: Johnson, Dusty [Rep.-R-SD-At Large]; Committees: House - Financial Services

H.R.7513 — To prohibit the Secretary of Health and Human Services from finalizing a proposed rule regarding minimum staffing for nursing facilities, and to establish an advisory panel on the skilled nursing facility workforce. Sponsor: Fischbach, Michelle [Rep.-R-MN-7]; Committees: House - Ways and Means; Energy and Commerce

H.R.7512 — To amend title XVIII of the Social Security Act to ensure implementation of real-time benefit tools under part D of the Medicare program. Sponsor: Arrington, Jodey C. [Rep.-R-TX-19]; Committees: House - Energy and Commerce; Ways and Means

H.Res.1050 — Supporting the designation of March 2024 as National Colorectal Cancer Awareness Month. Sponsor: Payne, Donald M. [Rep.-D-NJ-10]; Committees: House - Oversight and Accountability

H.Res.1049 — Expressing the need for enhanced public awareness of traumatic brain injury and support for the designation of a National Brain Injury Awareness Month. Sponsor: Pascrell, Bill [Rep.-D-NJ-9]; Committees: House - Energy and Commerce

H.Res.1047 — Recognizing the need of Congress to prevent, address, and treat obesity as a disease in the United States on this World Obesity Day, March 4, 2024. Sponsor: Cherfilus-McCormick, Sheila [Rep.-D-FL-20]; Committees: House - Energy and Commerce

S.3860 – A bill to amend title XVIII of the Social Security Act to provide for patient protection by limiting the number of mandatory overtime hours a nurse may be required to work in certain providers of services to which payments are made under the Medicare Program; Sponsor: Merkley, Jeff [Sen.-D-OR]; Committees: Senate – Finance

S.3864 — A bill to amend the Public Health Service Act to provide for congenital Cytomegalovirus screening of newborns; Sponsor: Blumenthal, Richard [Sen.-D-CT]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.7520 — To prohibit data brokers from transferring sensitive data of United States individuals to foreign adversaries, and for other purposes; Sponsor: Pallone, Frank [Rep.-D-NJ-6]; Committees: House - Energy and Commerce

- H.R.7535 To require the Comptroller General of the United States to conduct a study and submit a report on price-related compensation and payment structures in the prescription drug supply chain; Sponsor: Caraveo, Yadira [Rep.-D-CO-8]; Committees: House Energy and Commerce; Ways and Means
- H.R.7538 To direct the Secretary of Health and Human Services, for the purpose of addressing public health crises, to require the manufacturers of covered products to develop, maintain, and update a plan to mitigate the effects of such products on public health, and for other purposes; Sponsor: DeSaulnier, Mark [Rep.-D-CA-10]; Committees: House Energy and Commerce
- H.R.7539 To require the Secretary of the Treasury to guarantee BioBonds in order to provide funding for loans to eligible biomedical companies and universities to carry out clinical trials approved by the Food and Drug Administration, and for other purposes; Sponsor: Fitzpatrick, Brian K. [Rep.-R-PA-1]; Committees: House Energy and Commerce
- H.R.7542 To amend the Public Health Service Act to provide for congenital Cytomegalovirus screening of newborns; Sponsor: Lawler, Michael [Rep.-R-NY-17]; Committees: House Energy and Commerce
- H.R.7545 To amend title XIX of the Social Security Act to include certified community behavioral health clinic services as a State plan option under the Medicaid program, and for other purposes; Sponsor: Matsui, Doris O. [Rep.-D-CA-7]; Committees: House Energy and Commerce
- H.R.7546 To amend title XVIII of the Social Security Act to provide for patient protection by limiting the number of mandatory overtime hours a nurse may be required to work in certain providers of services to which payments are made under the Medicare Program; Sponsor: Matsui, Doris O. [Rep.-D-CA-7]; Committees: House Energy and Commerce; Ways and Means
- H.R.7551 To prohibit any Federal law from making the manufacturer of a COVID-19 vaccine immune from suit or liability, or limiting the liability of such a manufacturer, with respect to claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a COVID-19 vaccine, and for other purposes; Sponsor: Roy, Chip [Rep.-R-TX-21]; Committees: House Judiciary
- S.Res.574 A resolution expressing support for starting and growing a family through in vitro fertilization; Sponsor: Scott, Rick [Sen.-R-FL]; Committees: Senate Health, Education, Labor, and Pensions
- S.Res.575 A resolution declaring racism a public health crisis; Sponsor: Brown, Sherrod [Sen.-D-OH]; Committees: Senate Health, Education, Labor, and Pensions
- S.3882 A bill to amend title XIX of the Social Security Act to provide States with resources to support efforts to integrate or coordinate Medicare and Medicaid benefits for individuals that are eligible for both programs; Sponsor: Casey, Robert P., Jr. [Sen.-D-PA]; Committees: Senate Finance
- S.3885 A bill to expand medical, employment, and other benefits for individuals serving as family caregivers for certain veterans, and for other purposes; Sponsor: Sinema, Kyrsten [Sen.-I-AZ]; Committees: Senate Veterans' Affairs
- H.Res.1060 Expressing support for starting and growing families through in vitro fertilization; Sponsor: Cammack, Kat [Rep.-R-FL-3]; Committees: House Energy and Commerce
- H.Res.1062 Declaring racism a public health crisis; Sponsor: Hayes, Jahana [Rep.-D-CT-5]; Committees: House Energy and Commerce; Judiciary

H.R.7563 — To strengthen compliance with the FDA Food Traceability Rule, to enhance the FDA foodborne illness outbreak investigation process, and for other purposes; Sponsor: Franklin, C. Scott [Rep.-R-FL-18]; Committees: House - Energy and Commerce

H.R.7573 — To amend title XIX of the Social Security Act to repeal the requirement that States establish a Medicaid Estate Recovery Program and to limit the circumstances in which a State may place a lien on a Medicaid beneficiary's property; Sponsor: Schakowsky, Janice D. [Rep.-D-IL-9]; Committees: House - Energy and Commerce

S.3892 — A bill to amend titles XVIII and XIX of the Social Security Act to increase access to community health workers under the Medicare and Medicaid programs; Sponsor: Casey, Robert P., Jr. [Sen.-D-PA]; Committees: Senate – Finance