# HHS

## Hart Health Strategies Inc.



# Policy Briefi

February 19, 2024

### Senate Passes Supplemental Appropriations Measure

The Senate passed a \$95 billion bipartisan national security supplemental appropriations package last week including \$60 billion in aid for Ukraine, \$14 billion in aid for Israel, and \$10 billion in humanitarian assistance to the Gaza Strip and Ukraine. The package also includes the *FEND Off Fentanyl Act*, which would provide \$1.2 billion to curb fentanyl trafficking and allow for the sanctioning of fentanyl cartels. House Speaker Mike Johnson (R-La.) has stated that he will not bring the bill for consideration before the House of Representatives.

### Lawmakers Consider Potential of Short and Long-Term Physician Fee Schedule Reform

Lawmakers are going on the record regarding the chances of a Medicare physician reimbursement fix this year. A 3.37% reduction to Medicare physician payments went into effect on January 1, 2024. Reps. Ami Bera (D-Calif.) and Robin Kelly (D-Ill.) told an American Medical Association conference last week that their current priority is at least partial reversal of the cut that took place at the beginning of this year. At the same event, Rep. Larry Bucshon (R-Ind.) stated that a doctor pay fix could be included in a government funding package next month. While there is bipartisan agreement that broader reforms to the Medicare Physician Fee Schedule (MPFS) are necessary, such work is not likely until 2025 given the slow-down in legislative activity during presidential election years. This effort will also be complicated by the retirement from Congress of several physician lawmakers and other champions of Medicare physician payment reform. In related news, Sens. Catherine Cortez Masto (D-Nev.), Marsha Blackburn (R-Tenn.), John Thune (R-S.D.), John Barrasso (R-Wyo.), Debbie Stabenow (D-Mich.), and Mark Warner (D-Va.) recently

announced the formation of a working group to investigate and propose long-term reforms to the MPFS and make necessary updates to the *Medicare Access and CHIP Reauthorization Act*. The working group plans to reach out to stakeholders in the coming weeks to seek feedback and to begin developing policies that will address Medicare physician payment in the long-term.

### Inside

Durbin, Braun Call on FDA to Address Rx Dru PromotiononSocialMedia	1 <u>8</u>
E&C Leaders Ask GAO to Assess Risks of Sellin Excess Laboratory Equipment	1 <u>8</u>
Sanders Urges Strong Warning Labels to Comba Diabetes Epidemicand Obesity	a1
Lawmakers Express Concerns About Private Equity i Health Care	ir .2
HHS, FTC Issue RFI on Generic Drug Shortages	.3
HHSOIGReleases Telehealth ReportFDA Approves First Cell Therapy for Solid Tumors	.3
Congressional Retirements and Resignations	.4
Recently Introduced Health Legislation	.5

### Durbin, Braun Call on FDA to Address Rx Drug Promotion on Social Media

Sens. Dick Durbin (D-Ill.) and Mike Braun (R-Ind.) have sent a letter the Food and Drug Administration (FDA) calling on Commissioner Robert Califf to take action to address the "alarming proliferation of dangerous and misleading content promoting prescription drugs." The lawmakers specifically request that the FDA modernize its draft guidance on prescription drug promotion, which has not been updated since 2014, to clarify that platforms like Instagram, Snapchat, X, and TikTok are subject to FDA regulation and requirements. They highlight the social media promotion of prescription drugs by telehealth companies as a perceived gap in the FDA's jurisdiction. Durbin and Braun also argue that prescription drug promotion by social media influencers warrants particular attention. "The threats to children from misleading and unsubstantiated advertisements necessitate action," the letter argues. "You have called health misinformation and disinformation a leading cause of death in the United States—and it is time the FDA addresses this challenge."

### E&C Leaders Ask GAO to Assess Risks of Selling Excess Laboratory Equipment

Robertment of Health and Human Services (HHS) and the Department of Agriculture manage the resale of laboratory equipment and protective gear. "The availability of both biological laboratory equipment and protective clothing on the commercial market provides access to materials needed to conduct legitimate scientific research, but also increases the chances this equipment could be used for malicious purposes, such as biological terrorism or warfare," Committee Chair Cathy McMorris Rodgers (R-Wash.), Health Subcommittee Chair Brett Guthrie (R-Ky.), and Oversight Subcommittee Chair Morgan Griffith (R-Va.) write. The lawmakers request that the Government Accountability Office (GAO) examine the extent to which these items are resold or exported and the controls in place to limit the risk they are used to create biological weapons both within and outside the U.S.

### Sanders Urges Strong Warning Labels to Combat Diabetes Epidemic and Obesity

Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Bernie Sanders (I-Vt.) has sent a letter to the FDA urging Commissioner Califf to require the food and beverage industry to place strong warning labels on products high in sugar, salt, and saturated fats. Sanders points out the direct relationship between the nation's diabetes epidemic and obesity crisis, and argues that the FDA "can and must do more to ensure that Americans, especially children, teens, and their parents understand the health risks associated with the consumption of these unhealthy and ultraprocessed foods." Sanders' letter notes his plans for the HELP Committee to hold a hearing in the near future to consider what the FDA can do to ensure that the food and beverages Americans consume are not harming them.

### Lawmakers Express Concerns About Private Equity in Health Care

The Massachusetts congressional delegation has <u>written</u> to Ceberus Capital Management expressing concerns about the private equity firm's role in the finances of Steward Health Care-owned hospitals across the state. "We have long been concerned about the nefarious role of private equity in our economy. Ownership by private equity investors increases health care costs and reduces quality of care, and private equity firms have played a role in the collapse of hospitals around the country, hurting communities and the health care workers and other staff that serve them," the letter argues. "The dire threat of Steward's collapse appears to be a textbook example of the grave risks posed by a private equity takeover of the health care system."

### HHS, FTC Issue RFI on Generic Drug Shortages

HS and the Federal Trade Commission (FTC) have issued a <u>request for information (RFI)</u> on generic drug shortages and the impact of group purchasing organizations (GPOs) and drug wholesalers on access to generic pharmaceuticals. The agencies are requesting public input on:

- Whether and to what extent manufacturers, GPOs, and drug wholesalers are complying with their legal obligations under Section 3 of the *Clayton Act* and the *Robinson-Patman Act*.
- Whether and to what extent the available protections for GPOs under the Federal Anti-Kickback Statute affect market concentration and contracting practices by GPOs, as well as drug shortages.
- Whether and to what extent market concentration among GPOs and drug wholesalers has impacted smaller health care providers and rural hospitals.
- Whether and to what extent concentration among GPOs and drug wholesalers has disincentivized suppliers from competing in generic drug markets.
- The impact of the prevailing GPO compensation model, which may rely on rebates, chargebacks, and administrative
  fees from manufacturers and suppliers in exchange for favorable treatment, on generic manufacturers and other
  suppliers.

The RFI is a part of the administration's effort to promote competition in pharmaceutical markets and ensure access to high-quality, affordable care. This latest announcement notes another forthcoming joint RFI from the FTC, HHS, and Department of Justice seeking input on how private equity and other corporations' control of health care is impacting Americans.

### HHS OIG Releases Telehealth Report

The HHS Office of the Inspector General (OIG) released a <u>report</u> last week finding that health care providers largely complied with Medicare requirements when billing for evaluation and management (E/M) services provided via telehealth during the first nine months of the COVID-19 pandemic. The agency found that for 105 of the 110 sampled E/M services provided via telehealth, providers complied with Medicare requirements; the Medicare program paid \$446 for the five sampled E/M services for which providers did not document or insufficiently documented the services. Investigators determined that unallowable payments identified resulted primarily from clerical errors or the inability to access records.

### FDA Approves First Cell Therapy for Solid Tumors

The FDA has approved Iovance Biotherapeutics' Amtagvi to treat advanced melanoma that either cannot be removed from the body or has spread throughout the body and was previously treated with other therapies. It is the first cell therapy to be approved for the treatment of solid tumors. Iovance is currently working to complete a confirmatory trial to ensure Amtagvi has a clinical benefit to cancer patients.

### Congressional Retirements and Resignations

**R**ep. Matt Rosendale (R-Mt.) has dropped his bid to unseat Sen. Jon Tester (D-Mont.) less than a week after launching his campaign for the Senate. Rosendale has not yet decided whether he will run for reelection to the House of Representatives. The filing deadline for Montana is March 11.

Rep. Mark Green (R-Tenn.) has announced his decision to retire at the end of the year. Green was first elected to Congress in 2018. He currently serves as the chair of the House Homeland Security Committee.

Former Rep. Tom Suozzi (D) defeated Republican candidate Mazi Pilip to succeed ousted Rep. George Santos (R-N.Y.) in the House of Representatives. His victory flips the state's third congressional district back to Democrats and further narrows the GOP's majority in the House.

Rep. James Clyburn (D-S.C.) has stepped down from his role as assistant Democratic leader, a position he has held for just over a year. He previously served as the House Majority Whip. His decision follows similar moves by former House Speaker Nancy Pelosi (D-Calif.) and former Majority Leader Steny Hoyer (D-Md.) to step down from their respective leadership roles after the 2022 election. Rep. Joe Neguse (D-Colo.), chair of the Democratic Policy and Communications Committee, plans to run for assistant leader, according to two Democratic leadership aides.

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			
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 (R), TX		
Blunt Rochester (D), DE	Wenstrup (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 (R), GA		
Sarbanes (D), MD	Curtis (R), UT		
Blumenauer (D), OR	Luetkemeyer (R), MO		
Kilmer (D), WA	Lamborn (R), CO		
Spanberger (D), VA	Bucshon (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)	Green (R), TN		
Nickel (D), NC			
Ruppersberger (D), MD			
Sablan (D), MP			

# Hart Health Strategies Inc. Recently Introduced Health Legislation

H.R.7317 — To amend the Public Health Service Act to authorize the Secretary of Health and Human Services to award grants to nursing homes, assisted living facilities, and other long-term care facilities to improve their preparedness for power outages. Sponsor: Wilson, Frederica S. [Rep.-D-FL-24]; Committees: House - Energy and Commerce

H.R.7312 — To provide for requirements for electronic-prescribing for controlled substances under group health plans and group and individual health insurance coverage. Sponsor: Kuster, Ann M. [Rep.-D-NH-2]; Committees: House - Energy and Commerce; Education and the Workforce; Ways and Means; Judiciary

H.R.7307 — To amend the Public Health Service Act to establish a grant program to expand the number of allied health professionals in underserved communities and rural areas, and for other purposes. Sponsor: Molinaro, Marcus J. [Rep.-R-NY-19]; Committees: House - Energy and Commerce

S.3797 — A bill 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: Rounds, Mike [Sen.-R-SD]; Committees: Senate - Indian Affairs

S.3799 — A bill to require the Secretary of Health and Human Services to evaluate how the frequency of summary notices provided to patients can be increased, and for other purposes; Sponsor: Rubio, Marco [Sen.-R-FL]; Committees: Senate – Finance

S.3800 — A bill to increase the penalties for health care fraud, and for other purposes; Sponsor: Rubio, Marco [Sen.-R-FL]; Committees: Senate – Judiciary

S.Res.560 — A resolution designating February 2024 as "American Heart Month"; Sponsor: Durbin, Richard J. [Sen.-D-IL]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

H.R.7327 — To amend title XIX of the Social Security Act to ensure adequate consideration of payment rates for multimission hospitals under the Medicaid program, and for other purposes; Sponsor: DeGette, Diana [Rep.-D-CO-1]; Committees: House - Energy and Commerce

H.R.7346 — To amend the Public Health Service Act to provide for the continued implementation of the Climate and Health program by the Centers for Disease Control and Prevention; Sponsor: Underwood, Lauren [Rep.-D-IL-14]; Committees: House - Energy and Commerce

H.R.7347 — To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to report on whether the Secretary will include certain psychedelic drugs in the formulary of the Department of Veterans Affairs; Sponsor: Van Orden, Derrick [Rep.-R-WI-3]; Committees: House - Veterans' Affairs

H.R.7354 — To establish an Interagency Task Force to examine the conditions and experiences of Black women and girls in education, economic development, healthcare, labor and employment, housing, justice and civil rights, to promote community-based methods for mitigating and addressing harm and ensuring accountability, and to study societal effects on Black women and girls, and for other purposes; Sponsor: Kelly, Robin L. [Rep.-D-IL-2]; Committees: House - Judiciary; Education and the Workforce; Energy and Commerce; Financial Services

H.R.7368 — To amend title XVIII of the Social Security Act to provide for the application of Medicare secondary payer rules to certain workers' compensation settlement agreements and qualified Medicare set-aside provisions; Sponsor: Carey, Mike [Rep.-R-OH-15]; Committees: House - Ways and Means; Energy and Commerce

H.R.7373 — To direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to include alpha-gal syndrome on the list of nationally notifiable diseases; Sponsor: Garbarino, Andrew R. [Rep.-R-NY-2]; Committees: House - Energy and Commerce

H.R.7379 — To amend title XXX of the Public Health Service Act to establish standards and protocols to improve patient matching; Sponsor: Kelly, Mike [Rep.-R-PA-16]; Committees: House - Energy and Commerce; Ways and Means

H.R.7381 — To direct the Director of the National Institutes of Health to establish a grant program to facilitate research regarding the use of generative artificial intelligence in health care, and for other purposes; Sponsor: Lieu, Ted [Rep.-D-CA-36]; Committees: House - Energy and Commerce

H.R.7383 — To amend the Federal Food, Drug, and Cosmetic Act to set forth limitations on exclusive approval or licensure of drugs designated for rare diseases or conditions; Sponsor: Matsui, Doris O. [Rep.-D-CA-7]; Committees: House - Energy and Commerce

H.R.7384 — To amend the Federal Food, Drug, and Cosmetic Act to extend the authority of the Secretary of Health and Human Services to issue priority review vouchers to encourage treatments for rare pediatric diseases; Sponsor: McCaul, Michael T. [Rep.-R-TX-10]; Committees: House - Energy and Commerce

H.R.7397 — To amend title XVIII of the Social Security Act to establish a definition of essential health system in statute; Sponsor: Trahan, Lori [Rep.-D-MA-3]; Committees: House - Ways and Means; Energy and Commerce