# **HHS** Hart Health Strategies Inc.



# Policy Briefi ealth

October 14, 2024

## Policymakers Spotlight GLP-1 Counterfeits, Costs

A bipartisan group of House Energy and Commerce Committee members have sent a <u>letter</u> to the Food and Drug Administration (FDA) requesting a briefing from the agency about the presence of counterfeit Ozempic and other similar products in the nation's medical supply chain. The lawmakers express concerns about potential gaps in supply chain security infrastructure, citing reports of the availability of counterfeit Ozempic injection products in both the legitimate supply chain and also via illegal channels. The letter requests a committee staff briefing from the agency by October 22.

In related news, the Congressional Budget Office (CBO) estimates that Medicare coverage of anti-obesity drugs would cost the program \$35 billion over the next nine years. Were Medicare to expand coverage to include weight-loss treatments, CBO found that more than 12.5 million beneficiaries would be eligible for the drugs. The agency also stated its expectation that semaglutide would be selected for government price negotiations in 2025 because of its high cost to the Medicare Part D program. The *Inflation Reduction Act* required drugs be approved by the FDA for at least seven years prior to inclusion in the drug price negotiation program, and Ozempic, the first approved semaglutide product, will have been on the market for seven years by January 2025. Currently, Medicare is statutorily prohibited from paying for weight-loss drugs, though the program covers GLP-1s for other conditions.

### Prior Authorization Bills Secure Bipartisan Majority Support

The *Improving Seniors' Timely Access to Care Act* (H.R. 8702) has surpassed 218 cosponsors in the House of Representatives. This critical milestone means that the bill has secured support from a bipartisan majority of the chamber. The Senate bill (S. 4532) previously achieved bipartisan majority support with the endorsement of 55 senators. The bill, which would streamline and standardize the use of prior authorization by Medicare Advantage plans, was unanimously passed by the House of Representatives in the 117th Congress

but has not yet passed in the House or Senate in the 118th Congress.

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### Warren Raises Concerns About Novo Nordisk Merger

Sen. Elizabeth Warren (D-Mass.) is <u>urging</u> the Federal Trade Commission to closely scrutinize Novo Nordisk's proposed merger with health contract development and manufacturing organization Catalent. Warren expresses concerns that the merger could reduce competition and result in higher prices for patients. "I am concerned that Novo Nordisk's merger with Catalent will give Novo Nordisk unprecedented visibility into and control over its competitor's production capacity, costs, and business practices, and the ability to preference its own products and obstruct its competitors' use of Catalent to produce GLP-1 drugs," Warren writes. She goes on to cite examples of Novo Nordisk's prior efforts to restrict competition and maximize profits on these drugs.

### Wyden Asks DOJ to Investigate Residential Treatment Centers

Senate Finance Committee Chairman Ron Wyden (D-Ore.) has <u>asked</u> the Department of Justice (DOJ) to investigate whether youth residential treatment facilities (RTFs) are providing adequate care to Medicaid beneficiaries. Wyden cites evidence of potential Medicaid fraud and civil rights violations uncovered by a two-year Finance Committee investigation into four RTF operators. The investigation found that children suffer "routine harms inside RTFs, including sexual, physical, and emotional abuse, unsafe and unsanitary conditions, inadequate provision of behavioral health treatment, and substandard educational activities." Wyden asserts that this risk of harm to children in RTFs "is endemic to the operating model: to maximize per diem margins, RTF providers often offer minimal therapeutic treatment in deficient physical settings, understaffing and failing to train staff," and that despite advertising short to medium-term duration stays, that children sometimes remain in facilities for many years. He refers the findings to the DOJ for consideration by the agency.

### CMS Releases RFI on \$2 Drug List Model

The Centers for Medicare and Medicaid Services (CMS) has released a <u>request for information</u> and a sample <u>list</u> of prescription drugs that the agency preliminarily intends to include under the proposed Medicare \$2 Drug List Model. The model stems from President Biden's Executive Order 14087, "Lowering Prescription Drug Costs for Americans" and will allow Part D beneficiaries to access certain generic drugs for a fixed copayment of no more than \$2 for a month's supply per drug. Participation in the model would be voluntary for Part D sponsors and could start as early as January 2027. The deadline to respond to the RFI is December 9, 2024.

# Congressional Retirements and Resignations

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 (effective Aug. 20, 2024)					
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	Burgess, MD (R), TX				
Trone (D), MD	Wenstrup, DPM (R), OH				
Blunt Rochester (D), DE	McHenry (R), NC				
Napolitano (D), CA	Ferguson, IV, DMD, PC (R), GA				
Wexton (D), VA	Curtis (R), UT				
Kim, Andy (D), NJ	Luetkemeyer (R), MO				
Jackson, Jeff (D), NC	Lamborn (R), CO				
Sarbanes (D), MD	Bucshon, MD (R), IN				
Blumenauer (D), OR	Pence (R), IN				
Kilmer (D), WA	Duncan (R), SC				
Spanberger (D), VA	Armstrong (R), ND				
Kildee (D), MI	McMorris Rodgers (R), WA				
Phillips (D), MN	Gallagher (R), WI (effective April 19, 2024)				
Cardenas (D), CA	Rosendale (R), MT				
Eshoo (D), CA	Carl (R), AL				
Manning (D), NC	LaTurner (R), KS				
Nickel (D), NC	Posey (R), FL				
Sablan (D), MP	González-Colón (R), PR				
Ruppersberger (D), MD	Graves (R), LA				
Kuster (D), NH	Good (R), VA				
Bowman (D), NY					
Bush (D), MO					
Payne (D), NJ (died April 24, 2024)					
Jackson Lee (D), TX (died July 19, 2024)					
Pascrell (D), NJ (died Aug. 21, 2024)					

# Hart Health Strategies Inc. Recently Introduced Health Legislation

H.Res.1531 — Expressing support for designation of the week of October 6, 2024, through October 12, 2024, as "Latex Allergy Awareness Week"; Sponsor: Dingell, Debbie [Rep.-D-MI-6]; Committees: House - Oversight and Accountability

H.R.9916 — To direct the Comptroller General of the United States to conduct a study relating to 1-800-MEDICARE; Sponsor: De La Cruz, Monica [Rep.-R-TX-15]; Committees: House - Ways and Means; Energy and Commerce

H.R.9924 — To amend title 38, United States Code, to establish standard practices for a grant or pilot program administered by the Secretary of Veterans Affairs through the Veterans Health Administration, and for other purposes; Sponsor: Landsman, Greg [Rep.-D-OH-1]; Committees: House - Veterans' Affairs

H.R.9929 — To provide funding to the Bureau of Prisons, States, and localities to carry out mental health screenings and provide referrals to mental healthcare providers for certain corrections officers; Sponsor: Miller-Meeks, Mariannette [Rep.-R-IA-1]; Committees: House – Judiciary

H.R.9938 — To amend the Federal Food, Drug, and Cosmetic Act to establish a time-limited conditional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes; Sponsor: Westerman, Bruce [Rep.-R-AR-4]; Committees: House - Energy and Commerce

H.R.9939 —To direct the Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation, to conduct a study on existing efforts of hospitals with respect to electronic automated referrals for purposes of organ donation, and for other purposes; Sponsor: Wittman, Robert J. [Rep.-R-VA-1]; Committees: House - Energy and Commerce

H.Res.1539 — Recognizing the roles and the contributions of United States certified nurse-midwives and certified midwives in providing high-quality, evidence-based, and cost-effective health care services to women and childbearing families; Sponsor: Watson Coleman, Bonnie [Rep.-D-NJ-12]; Committees: House - Energy and Commerce

H.R.9942 — To support the development, licensing, and initial manufacturing of a human vaccine for valley fever; Sponsor: Duarte, John S. [Rep.-R-CA-13]; Committees: House - Energy and Commerce