HHS | Hart Health Strategies Inc.

Health Policy Briefing

August 26, 2024

DNC Approves 2024 Party Platform During Chicago Convention

The Democratic National Committee (DNC) finalized its platform during the Democratic convention in Chicago last week. The 2024 platform reiterates the party's commitment to protecting Medicare, Medicaid, and the Affordable Care Act (ACA). Under the platform, Democrats would permanently extend enhanced ACA premium subsidies; create dental, vision, and hearing benefits under the Medicare program; and ban surprise billing for ground ambulance services. Democrats would add "at least" 50 drugs annually to the Medicare drug price negotiation program, and would create a model to limit Medicare cost sharing for some generic drugs to $2. The DNC also promises to increase transparency around the pharmacy benefit manager industry. The platform supports expansion of the Medicaid program, including through increasing postpartum coverage to a full year, but would require Medicaid managed care organizations to return excess funding to states. The platform promises to "keep using antitrust laws to stop hospital, insurance, and Big Pharma mergers that undermine competition and increase health care prices for consumers." The DNC proposes to exclude all medical debt from credit reporting, and calls for strengthening the nation's mental and behavioral health care system. Democrats would also repeal the Hyde amendment and codify access to abortion and in vitro fertilization services. While Kamala Harris did not spend much time discussing health care issues during her speech accepting the Democratic presidential nomination, she did pledge to protect Medicare and the ACA, and to address rising health care costs. Harris also warned about the potential impact of a second Trump presidential term on reproductive rights and access to birth control and abortion.

Inside

Bipartisan Lawmakers Write FDA on China-Linked Clinical Trials

A bipartisan group of lawmakers are asking the Food and Drug Administration (FDA) for details about U.S. pharmaceutical companies conducting clinical trials with medical centers affiliated with the Chinese military. The letter outlines the national security risks and ethical concerns associated with trials that have taken place in Xinjiang as well as hospitals affiliated with the People's Liberation Army (PLA). The lawmakers cite data indicating that over the last ten years, major U.S. biopharmaceutical companies have conducted hundreds of clinical trials in China that included at least one entity with PLA in the name as a research trial partner. "The United States needs the FDA to take on a greater role in protecting U.S. national security interests. With this data, it is clear that the FDA should play a greater role in analyzing U.S. biopharma entities clinical trial operations in the People's Republic of China," the lawmakers argue. The letter was led by Chairman and Ranking Member of the House Select Committee on the Chinese Communist Party John Mollenaar (R-Mich.) and Raja Krishnamoorthi (D-Ill.), and signed by Energy and Commerce Health Subcommittee Ranking Member Anna Eshoo (D-Calif.) and Rep. Neal Dunn (R-Fla.).

CBO Updates ACA Subsidy Cost Estimate

The Congressional Budget Office (CBO) estimates that spending on ACA premium tax credits have doubled since it was first calculated in 2020 because of high enrollment. CBO originally estimated a cost of $600 billion between 2021 and 2040; the agency's updated projection stands at $1.3 trillion between 2025 and 2034. According to CBO, the change is primarily a result of legislation in 2021 and 2022 expanding the premium tax credit through 2025. The update comes in response to a question for the record from Senate Budget Committee Ranking Member Chuck Grassley (R-Iowa) about CBO's report ***An Update to the Budget and Economic Outlook: 2024 to 2034***.

GAO Examines FDA's Medical Device Postmarket Surveillance System

The Government Accountability Office (GAO) has released a new report reviewing the FDA's work to establish an active postmarket surveillance system for medical devices. GAO's review details the two key challenges faced by the agency is establishing this system – the limited use of unique device identifiers in electronic health records and billing claims, and funding considerations to support active surveillance. A 2018 study of FDA data found that more than 1.7 million injuries and 83,000 deaths over a ten-year period were potentially linked to medical devices.

Second Lawsuit Filed Against FDA LDT Rule

The Association for Molecular Pathology (AMP) filed a lawsuit on Monday against the FDA's laboratory developed test (LDT) final rule. AMP's suit cites the ***Loper Bright Enterprises v. Raimondo*** Supreme Court ruling, which overturned the Chevron doctrine, in arguing against the LDT final rule. The American Clinical Laboratory Association (ACLA) filed a lawsuit against the final rule in May, before ***Chevron*** was overturned. Among other complaints, AMP and ACLA both assert that FDA exceeded their statutory authority in promulgating the LDT final rule and have asked the courts to prohibit FDA from regulating LDTs as medical devices.

Judge Blocks FTC's Ban on Noncompete Agreements

Last week, a federal judge blocked the Federal Trade Commission's (FTC) nationwide ban on employee noncompete agreements. The judge from the U.S. District Court for the Northern District of Texas argued that the FTC lacked legal authority to prohibit restrictive employment contracts and that the ban was "the product of an unconstitutional exercise of power." The decision cited the Supreme Court's ***Loper Bright Enters. v. Raimondo*** decision – which overturned the Chevron deference – multiple times. According to an agency spokesperson, the FTC is "seriously" considering an appeal. The FTC rule had been set to take effect on September 4.

Fourteen Term Democrat Pascrell Dies at 87

Rep. Bill Pascrell (D-N.J.) passed away last Wednesday following a July hospitalization for a respiratory infection. Pascrell, 87, was one of the oldest members of the House of Representatives. He was first elected to Congress in 1996 and served on the Ways and Means Committee. Party officials from New Jersey's 9th congressional district will select a new candidate for the November election; the deadline to replace Pascrell on the ballot is August 29. There are now 220 Republicans, 211 Democrats, and four vacancies in the House.

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)	

Upcoming Congressional Hearings and Markups

Senate HELP Committee hearing "Why Is Novo Nordisk Charging Americans with Diabetes and Obesity Outrageously High Prices for Ozempic and Wegovy?" 10:00 a.m.; September 24

H.R.9365 — To amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of pharmacist services; Sponsor: Davis, Donald G. [Rep.-D-NC-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.9367 — To amend the Federal Food, Drug, and Cosmetic Act to require a recall of electronic nicotine delivery systems that have not been subject to premarket review, and for other purposes; Sponsor: DeSaulnier, Mark [Rep.-D-CA-10]; Committees: House - Energy and Commerce

H.R.9382 — To amend the Federal Food, Drug, and Cosmetic Act to add alpha-gal to the definition of "major food allergen;" Sponsor: Van Drew, Jefferson [Rep.-R-NJ-2]; Committees: House - Energy and Commerce

H.R.9383 — To amend the Older Americans Act of 1965 to include screening for loneliness and coordination of supportive services and health care to address the negative health effects of loneliness, to require a report on loneliness, and for other purposes; Sponsor: Banks, Jim [Rep.-R-IN-3]; Committees: House - Education and the Workforce

H.R.9384 — To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to provide an explanation of benefits not later than 30 days after an item or service is furnished under the Medicare program; Sponsor: Bean, Aaron [Rep.-R-FL-4]; Committees: House - Ways and Means; Energy and Commerce