



Health Policy Briefing

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Democrats Hold Senate as House Balance of Power Remains TBD

Midterm elections almost always see the party out of power pick up seats in Congress. In this cycle, Republicans needed a net gain of just five seats in the House of Representatives, and only one seat in the evenly divided Senate to retake the majority. As of Sunday, the midterm elections resulted in the Democrats retaining majority control of the Senate after Democrat incumbent Sen. Catherine Cortez Masto secured her reelection in Nevada. The outcome of the Georgia Senate run-off election on Dec. 6 will determine whether the Senate remains a 50/50 split or if Democrats have a decisive majority with 51 seats. Control of the House is yet to be determined. Hart Health Strategies Inc. continues to update our Special Post Election Newsletter as races are called. The latest document can be found [here](#).

Four Corners to Meet on Inclusion of FDA Reforms in Year-End Package

It appears increasingly possible that proposals to overhaul the Food and Drug Administration’s regulation of diagnostics, cosmetics, and dietary supplements may be included in year-end government funding legislation, according to POLITICO. The measures were dropped from the medical product user fee reauthorization agreement reached in September. Bipartisan leaders of the Senate Health, Education, Labor, and Pensions (HELP) Committee and the House Energy and Commerce Committee plan to return to the negotiating table ahead of the December 16 deadline to fund the federal government to discuss the inclusion of these provisions, along with other previously considered measures to reform the accelerated approval pathway and strengthen clinical trial diversity in the end-of-year package.

Inside

- Lawmakers Considering Extension of Telehealth Flexibilities.....2
- Finance Committee Releases Mental Health Care Integration Discussion Draft.....2
- McCarthy Announces GOP Transition Teams for 118th Congress.....2
- CMMI Releases New Strategy on Value-Based Specialty Care.....2
- HHS Argues *No Surprises Act* Rule Should Stand.....3
- FDA Grants EUA to Rheumatoid Arthritis Drug for Treatment of Severe COVID.....3
- Upcoming Congressional Hearings and Markups.....3
- Recently Introduced Health Legislation.....3

Lawmakers Considering Extension of Telehealth Flexibilities

Congress is also expected to include an additional extension of COVID-era telehealth flexibilities in the year-end appropriations package. According to POLITICO, the Senate Finance Committee is considering a one-year extension of telehealth waivers. GOP leadership on key congressional committees with health care jurisdiction are also nearing agreement on a telehealth strategy should Republicans retake the majority in the House of Representatives, according to GOP staff. They hope to use the must-pass year end funding legislation as a vehicle for a two-year extension of the Medicare telehealth flexibilities instituted in response to the pandemic, and then to pass permanent telehealth reforms in the 118th Congress. House Republicans have previously been divided on whether to support a temporary or permanent telehealth extension because of the cost and concerns about fraud and abuse, but policymakers on the Ways and Means Committee and the Energy and Commerce Committee are now encouraging the Senate to take up the House-passed *Advancing Telehealth Beyond COVID-19 Act* (H.R. 4040) with the intention of tackling a permanent policy next year. H.R. 4040 would extend pandemic telehealth waivers through 2024, including those related to geographic and originating site restrictions, the types of providers eligible to provide telehealth, in-person requirements for behavior health services, provision of audio-only telehealth, and face-to-face requirements for hospice care. Maintaining access to telehealth is generally a bipartisan issue, though it remains unclear where Senate Republicans stand on the new Ways and Means/Energy and Commerce approach.

Finance Committee Releases Mental Health Care Integration Discussion Draft

The Senate Finance Committee [released](#) a new mental health discussion draft last week, the fourth in the panel's series of bipartisan proposals to strengthen the nation's mental health care system. The latest bill includes provisions to increase payment rates to incentivize the integration of mental health services with primary care (and require the Centers for Medicare and Medicaid Services to create best practices for doing so), standardize Medicare reimbursement for mobile crisis response services, and create bundled Medicare payments for crisis-stabilization services, such as observation care and suicide risk screening. According to the committee's press release, additional mental health discussion drafts may be released in the future.

McCarthy Announces GOP Transition Teams for 118th Congress

House Minority Leader Kevin McCarthy (R-Calif.) [announced](#) the Republican transition teams for the 118th Congress last week. The transition teams aim to address three core priorities for the GOP next congress should Republicans hold the majority in the House: (1) Commitment to America Implementation, led by Republican Whip Steve Scalise (R-La.); (2) Oversight and Accountability, led by Committee on Oversight and Government Reform Ranking Member James Comer (R-Ky.) and Judiciary Committee Ranking Member Jim Jordan (R-Ohio); and (3) Restoring the People's House, led by Rep. Bryan Steil (R-Wis.). "Our committees will be prepared to immediately start holding this administration accountable for its incompetence and abuses of power," McCarthy stated. "Unlike the Democrat majority over the past two years, our Republican majority will restore the people's voice inside the People's House."

CMMI Releases New Strategy on Value-Based Specialty Care

The Center for Medicare and Medicaid Innovation has released a new [strategy](#) to advance person-centered, value-based specialty care. To achieve the agency's goal of having 100% of original Medicare beneficiaries and most Medicaid beneficiaries in accountable care relationships by 2030, the Innovation Center states that testing models and tools to improve access to high-quality, value-based specialty care will be an area of critical focus going forward. The Innovation Center provides a description of the new strategy and the timeframe for its implementation. Their plan is comprised of four elements: enhancing specialty care performance data transparency, maintaining momentum on acute episode payment models and condition-based models, creating financial incentives within primary care for specialist engagement, and creating financial incentives for specialists to affiliate with population-based models and move to value-based care.

HHS Argues *No Surprises Act* Rule Should Stand

The Biden administration argued last week before a federal court in Texas that its interim final rule to implement the *No Surprises Act* should stand because the independent dispute resolution (IDR) process established by regulation aligns with congressional intent. The original final rule, issued by the U.S. Department of Health and Human Services (HHS) and later invalidated in court, instructed the arbitrators settling payment disputes between providers and insurers to choose the offer closest to the median in-network rate, or qualifying payment amount (QPA). The latest version of the regulation instructs arbitrators to consider the QPA first, followed by “all additional permissible information submitted by each party to determine which offer best reflects the appropriate out-of-network rate.” A lawsuit filed by the Texas Medical Association is arguing that the latest rule has the same effect as HHS’ original rule – to “unfairly skew IDR results in insurers’ favor, granting them a windfall they were unable to obtain in the legislative process.” HHS argued that the court should grant its motion for summary judgement.

FDA Grants EUA to Rheumatoid Arthritis Drug for Treatment of Severe COVID

The Food and Drug Administration (FDA) has [granted](#) emergency use authorization (EUA) to Kineret, an injectable drug to treat rheumatoid arthritis and certain pediatric inflammatory diseases, for the treatment of hospitalized adults with severe COVID-19. Kineret can be used to treat COVID-19 patients who are receiving supplemental oxygen and have other indicators of elevated immune activity and whose health is at risk of declining. Side effects include elevated liver enzymes, low counts of certain white blood cells, and rashes or irritation at the injection site.

Upcoming Congressional Hearings and Markups

House Oversight and Reform Subcommittee on Civil Rights and Civil Liberties hearing “Developments in State Cannabis Laws and Bipartisan Cannabis Reforms at the Federal Level;” 10:00 a.m.; November 15

Senate Veterans’ Affairs Committee hearing to examine the Department of Veterans Affairs implementation of the SFC Heath Robinson Honoring our PACT Act; 10:00 a.m.; November 16

Recently Introduced Health Legislation

H.R.9271 — To amend title XVIII of the Social Security Act to preserve access to rehabilitation innovation centers under the Medicare program. Sponsor: Schakowsky, Janice D. [Rep.-D-IL-9]; Committees: House - Ways and Means; Energy and Commerce

H.R.9284 — To clarify that the Federal Trade Commission Act prohibits excessive and unjustified price increases in the sale of certain products and services when an emergency or disaster results in abnormal disruptions of the market, and for other purposes; Sponsor: Cleaver, Emanuel [Rep.-D-MO-5]; Committees: House - Energy and Commerce

H.R.9285 — To provide payment for patient navigator services under title XIX of the Social Security Act, and for other purposes – Sponsor: DeSaulnier, Mark [Rep.-D-CA-11]; Committees: House - Energy and Commerce