Health Policy and Legislation

Akin Gump

Congressional Health Policy Outlook for 2023

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The House and Senate convened this week to kick off the 118th Congress. Republicans control the House after four years of a Democratic majority. House Republicans have a very slim majority, with only 222 seats to the Democrats' 212, and it is likely that various groups of House Republicans will attempt to leverage their votes to influence the agenda. The House is expected to return to pre-pandemic operations as House Republicans have made clear that they will reopen the House buildings to the public, eliminate proxy voting and pursue a robust work schedule as laid out in the 2023 House calendar.

Democrats control the Senate, 51 to 49, after two years at a 50 to 50 split, which means as a practical matter that Vice President Kamala Harris will no longer be needed to cast tie-breaking votes for Democrats' party-line issues as was required over the past two years. Senate Democrats currently have three caucus members who are independents, with the recent addition of Sen. Kyrsten Sinema (I-AZ), but these members are still expected to caucus with Senate Democrats. Democrats are expected to be in a position to move legislation and nominations more quickly through the Senate given these dynamics. According to the 2023 Senate calendar, January 23, 2023, will be the first day senators may introduce legislation in the chamber, as the Senate is not scheduled to be in session following the beginning of the 118th Congress on January 3. In preparation for the 118th Congress, last month the Senate Sargent at Arms circulated a notice that the Senate Office Buildings will be open to the public beginning Tuesday, January 3, 2023, and no staff escorts or pre-registration with the Sargent at Arms will be necessary for access to the buildings.

Leaders and committee chairs in both chambers appear to be poised to pursue their respective agendas; although, in an era of divided government two years ahead of a presidential election, it remains unclear whether they will be able to fully advance these various agendas in the absence of bipartisan, bicameral collaboration. The 118th Congress is convening on the heels of enactment of the Consolidated Appropriations Act, 2023, which included numerous health care provisions that in many ways cleared the policymaking decks from the last Congress. The health care provisions were far reaching and spanned reforms related to mental health and substance use disorder (SUD), changes to our nation's medical and public health preparedness and response framework, Food and Drug Administration (FDA) reforms spanning human medical products, food, and cosmetics, and extensions for a host of

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Medicare and Medicaid coverage and reimbursement policies through 2024 or beyond.

This alert provides a high-level outlook on some of the health care issues the 118th Congress may take up, with a particular focus on House Republicans' priorities given the change in House leadership and that the Democrats advanced numerous legislative priorities over the past two years.

House GOP Healthy Future Task Force

The House Republicans' legislative and oversight agenda, known as the Commitment to America, reflects the work of numerous task forces. The Healthy Future Task Force and its Subcommittees have mapped out the House Republican health care priorities. The policy ideas outlined by each of the five Subcommittees—Affordability, Doctor/Patient Relationship, Modernization, Security and Treatments—provide a roadmap to the topics House Republicans will look to focus on in the days and months ahead.

In particular, House Republicans are expected to focus on policies that advance innovative technologies and cures and patient access to these innovations. As part of these efforts, House Republicans are expected to focus on the Centers for Medicare & Medicaid Services (CMS) and facilitating timely Medicare coverage for drugs and devices that are cleared, licensed or approved by the FDA. For example, Republicans will continue to support establishing a pathway for expedited Medicare coverage of breakthrough devices.

COVID-19 Public Health Emergency

When and how the COVID-19 public health emergency (PHE) declaration winds down continues to be an issue of significant interest by many stakeholders and members of Congress. The Biden-Harris administration did not release a 60-day notice that would have signaled the administration intends to wind down the COVID-19 PHE on January 11, 2023. Therefore, the Department of Health and Human Services (HHS) Secretary Xavier Becerra is expected to renew the declaration for another 90 days through April 11, 2023.

House Energy & Commerce Committee Leader Cathy McMorris Rodgers (R-WA) has repeatedly called on the administration to outline a plan to end the PHE and "provide full accounting of how it spent trillions of dollars that fueled inflation." Scrutiny of the administration's handling of the PHE is expected to increase as the House Republicans implement their health care oversight agenda.

PAHPA Reauthorization

The Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization is expected to be one of the first issues the House Energy & Commerce Committee tackles as many of PAHPA's provisions are set to expire at the end of the fiscal year (September 30, 2023). Rep. Richard Hudson (R-NC) and Rep. Anna Eshoo (D-CA) are expected to lead the effort to reauthorize PAHPA in the House. With the retirement of Sen. Richard Burr (R-NC) at the end of last Congress, Sen. Bob Casey (D-PA) is expected to partner with Sen. Bill Cassidy (R-LA) on the Senate's PAHPA reauthorization bill. Rep. Guthrie, who is in line to Chair the Energy & Commerce

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Committee Health Subcommittee, has indicated that the Committee should review the FDA's emergency use authorization process as part of the PAHPA reauthorization. Stakeholders will be closely watching to see how bipartisan legislation looks to build on the preparedness reforms enacted at the end of last Congress against the backdrop of the ongoing focus on COVID-19 related issues.

Two FDA User Fee Program Reauthorizations

Both the Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA) are up for reauthorization as these programs are set to expire at the end of the current fiscal year (September 30, 2023). While the reauthorizations of these programs focuses on animal drugs, this will create an FDA legislative vehicle that members may seek to leverage to advance policies not directly related to the review of animal drugs.

Medicare Solvency

In its 2022 report, the Medicare Trustees projected that assets in the Part A trust fund will be depleted in 2028 absent action from Congress. Republicans will be eager to advance policies that could protect the Medicare program in the House. The Healthy Future Task Force Affordability Subcommittee, for example, calls for site neutral payments in physician offices and hospitals and addressing consolidation that increases costs. The Medicare Payment Advisory Commission (MedPAC) continues to deliberate on recommendations to extend site neutral policies across ambulatory settings. Policymakers have expressed an interest on a bipartisan basis in making permanent changes to Medicare physician fee schedule payments to avoid the need for Congress to regularly mitigate payment cuts. The omnibus appropriations legislation enacted in December provided payment relief through 2024.

The Congressional Budget Office (CBO) issued its Budget Options report in December, which outlines options to reduce Medicare and Medicaid spending. CBO highlighted the following policy changes that would reduce the federal budget deficit by more than \$300 billion over 10 years: increasing Medicare Part B premiums and reducing Medicare Advantage benchmarks. CBO also notes the following Medicare changes would result in savings of \$10 billion or more: changing the cost-sharing rules for Medicare and restrict Medigap insurance; reducing Medicare's coverage of bad debt; and consolidating and reducing federal payments for Graduate Medical Education (GME) at teaching hospitals. It remains to be seen where bipartisan consensus could be found on any of these policies such that that it would culminate in them advancing in both the House and Senate this Congress.

Medicaid Access to Care

In 2022, House Energy & Commerce Committee Leader Cathy McMorris Rodgers (R-WA) issued a report and request for information (RFI) on disability policies, which included a focus on ensuring access to Medicaid long-term services and supports. The Medicaid program's institutional bias limits access to home- and community-based services (HCBS), which can be provided at a lower cost. The Committee may consider Medicaid issues more broadly, including access to innovative therapies and care coordination for beneficiaries who are eligible for both Medicare and Medicaid. The Committee's Medicaid work may be guided by CBO's Budget Options report, which

included policy changes that would generate significant savings: establishing caps on federal spending for Medicaid; limiting state taxes on health care providers; and reducing federal Medicaid matching rates.

Addressing the Fentanyl Crisis

The Centers for Disease Control and Prevention (CDC) released provisional drug overdose death data in November, which estimated 107,582 overdose deaths in the 12-month period ending in June 2022. CDC noted that the majority of overdose deaths are the result of illicit synthetic drugs such as fentanyl. Policymakers could elect to address the flow of illicit fentanyl into the United States through a multi-prong approach, such as through measures seeking to deter individuals from using drugs, improve interdicting drugs, and curb the manufacturing and distribution of fentanyl and its pre-cursor chemicals.

HIPAA Privacy

With the failed effort to advance broad privacy legislation and a final Health Insurance Portability and Accountability Act (HIPAA) regulation pending at HHS/Office for Civil Rights (OCR), House Republicans may pursue hearings to examine health care privacy laws and whether revisions are warranted.

Oversight

House Republicans have already made clear they intend to conduct intensive oversight of the executive branch, including on health care issues.

House Republicans may conduct oversight regarding the implementation of the drug pricing provisions in the Inflation Reduction Act (IRA). Additionally, Republicans may also focus on the October 22 Executive Order giving the CMS Center for Medicare & Medicaid Innovation (CMMI) 90 days to report on any drug pricing models it has selected for testing, as well as the timing for such models. Policymakers are likely to examine other aspects of drug pricing, such as pharmacy benefit managers (PBMs) and the 340B Drug Pricing Program.

COVID-19 will also be a significant focus for House Republicans. It is likely that they will probe the virus' origins. Republicans will likely also investigate the Biden-Harris administration's response to the pandemic, with a focus on the repeated extension of the PHE declaration.

Looking Ahead

Once again, there are no shortage of health care issues on the congressional agenda and the potential for health care issues to come up as Congress seeks to tackle other issues, such as addressing the \$31.4 trillion debt limit and the potential for cuts to health care programs as part of the negotiations to address related must pass legislation. This Congress will also be a defining moment for House Republicans as they take the Majority in the House and have the opportunity to advance their agenda through both legislation and robust oversight. While divided government and partisanship is expected to define much of the next two years ahead of the 2024 elections, there are opportunities for bipartisanship through the reauthorization of programs that have a track record of long-standing bipartisan support. How the House

and Senate approach the first few months of this year and some of these reauthorizations will be a strong indicator for what might be in the realm of the possible when it comes to legislation this Congress.

Expiring Health Care Policies

Program/Provision	Expiration Date
Pandemic and All-Hazards Preparedness Act	September 30, 2023
FDA User Fee Programs (Animal Drug, Animal Generic Drug)	September 30, 2023
Funding for Quality Measure Endorsement, Input, and Selection	September 30, 2023
Funding Outreach and Assistance for Low-Income Programs	September 30, 2023
Community Mental Health Services Demonstration Program	September 30, 2023
Medicaid Disproportionate Share Hospital (DHS) reimbursement cuts begin through FY 2027	October 1, 2023 (effective date)
Extension of the Medicare Work Geographic Index Floor	December 31, 2023
Independence at Home Medical Practice Demonstration Program	December 31, 2023
Moratorium on Medicare Physician Fee Schedule Payment for the Add On Code for Inherently Complex Evaluation and Management Services (HCPCS code G2211)	December 31, 2023
Home Health 1% Medicare Add-On Payment	December 31, 2023
Blended Medicare Payment Rates for DMEPOS in Certain Non-Competitive Bidding Areas	December 31, 2023

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