



## H&K Health Dose: January 24, 2023

A weekly dose of healthcare policy news

### LEGISLATIVE UPDATES

#### Congress Back in Session, Organizing Efforts Continue

The House and Senate are both in session this week. The House majority and minority reached an agreement this weekend regarding ratios for the remaining standing committees for the 118th Congress. The ratios for non-exclusive committees are as follows:

- 28 majority seats and 24 minority seats on the House Committee on Agriculture
- 21 majority seats and 16 minority seats on the House Committee on the Budget
- 25 majority seats and 20 minority seats on the House Committee on Education and Labor
- 27 majority seats and 24 minority seats on the House Committee on Foreign Affairs
- 18 majority seats and 15 minority seats on the House Committee on Homeland Security
- 25 majority seats and 19 minority seats on the House Committee on the Judiciary
- 25 majority seats and 20 minority seats on the House Committee on Natural Resources
- 26 majority seats and 21 minority seats on the House Committee on Oversight and Accountability

The Democratic Steering Committee will be convening this week to determine committee assignments. The committee will begin with exclusive committees before moving on to non-exclusive committees. Assignments will first be given to returning members, followed by new members. It is expected that no returning member of the Democratic Party will have to give up their pre-existing committee assignment, except for the House Committee on Ways and Means. Democratic committee assignments will likely be announced at the end of the week or earlier next week.

On the administration side, it was announced this weekend that Jeff Zients will replace Ron Klain as White House chief of staff next month. Zients has worked in both the Obama and Biden Administrations and has significant business and private sector experience.

#### Debt Limit Discussions Ramp Up

The U.S. reached its statutory debt limit of \$31.381 trillion on Jan. 19, 2023. As a result, U.S. Secretary of the Treasury Janet Yellen announced to Congressional leadership that the Treasury Department began taking "extraordinary measures" to delay a default on the national debt. The announcement created a new urgency in Congress to raise the debt limit. Yellen has warned that these measures will be exhausted by early June, at which point the United States will default unless the debt limit is raised. House conservatives have vowed to oppose raising the debt limit unless significant spending cuts are made. Democratic leaders are scheduled to meet with President Joe Biden this week regarding the nation's borrowing cap.

Sen. Joe Manchin (D-W.Va.) indicated that he would be open to working across the aisle to find a bipartisan compromise on the debt limit. Specifically, he has mentioned that he supports a proposal by Sen. Mitt Romney (R-Utah) to create fiscal commissions tasked with recommending policy solutions that address the solvency of the Medicare and Social Security trust funds.



## Senate Hopefuls Announce Campaign for Upper Chamber

Rep. Jim Banks (R-Ind.) has set his eyes on the Senate and recently announced he is seeking the seat currently held by Sen. Mike Braun (R-Ind.) in 2024. Braun is vacating the seat to run for governor of Indiana instead. Banks is the first to launch his campaign in what is anticipated to be a competitive primary. Banks is serving his fourth term in the House and recently served as the Republican Study Committee chair.

Additionally, Rep. Ruben Gallego (D-Ariz.) announced that he would be throwing his hat in the Arizona Senate race, potentially setting up a face-off against incumbent Sen. Krysten Sinema (I-Ariz.). Sinema has yet to say whether she plans to seek reelection. In December 2022, Sinema announced that she was switching her party affiliation from Democrat to Independent. Gallego's announcement comes after Sinema has faced criticism from Democrats for not supporting President Joe Biden's agenda fully.

## House Oversight Committee to Hold First Hearing on COVID-19 Relief Programs

With Republicans taking control of the House during the 118th Congress, congressional investigations in the House will shift focus. The House Committee on Oversight and Accountability will hold its first hearing of the 118th Congress on Feb. 1, 2023. The [hearing will focus](#) on using taxpayer dollars in COVID-19 relief programs, specifically investigating fraud issues in the pandemic unemployment insurance program.

## Energy and Commerce Democrats Put Pressure on NIH, FDA to Report on Clinical Trials

House Energy and Commerce Ranking Member Frank Pallone (D-N.J.) [sent a letter](#) last week to the U.S. Food and Drug Administration (FDA) and National Institutes of Health (NIH) inquiring about the agencies' requirement to publicly report clinical trial results. Trials that are subject to FDA oversight and NIH funding are required to register their studies within 21 days of their first subject enrollment and post their results within a year of the trial's completion. While the FDA released guidance on penalties for non-compliance with these standards in 2020, only four non-compliance notices have been posted – and none required the subjects to pay a civil money penalty. Pallone cites a study indicating that 31 percent of registered trials failed to report any results, while another 30 percent of trial sponsors failed to do so on time. He requests a response from the agencies by Feb. 17, 2023, regarding clinical trial sponsor compliance with applicable requirements and appropriate agency enforcement.

## REGULATORY UPDATES

### CMS Announces Accountable Care Update

The Centers for Medicare & Medicaid Services (CMS) on Jan. 17, 2023, [announced the growth](#) of three accountable care initiatives in 2023, aimed at providing higher-quality care to more than 13.2 million Medicare beneficiaries. CMS noted that this growth will advance its goal of having all traditional Medicare beneficiaries in an accountable care relationship with their healthcare provider by 2030.

The announcement from CMS included the following programs:

- **The Medicare Shared Savings Program (MSSP).** Currently, there are 456 accountable care organizations (ACOs) serving 10.9 million beneficiaries in the MSSP, the most popular option available to providers. CMS noted that while the MSSP experienced a decrease in the number of ACOs and assigned beneficiaries for 2023, the policies finalized in the calendar year (CY) 2023 Medicare physician fee schedule final rule are expected to increase program participation for 2024 and beyond, when many of the new policies are set to go into effect.



- The ACO Realizing Equity, Access, and Community Health (REACH) Model, which has 132 ACOs with 131,772 healthcare providers and organizations providing care to an estimated 2.1 million beneficiaries in 2023. It will also have 824 federally qualified health centers, rural health centers and critical access hospitals participating in 2023, which is more than double the 2022 number and extends the reach of ACOs in underserved communities.
- The Kidney Care Choices (KCC) Model, which focuses on Medicare beneficiaries with chronic kidney disease stages 4 and 5 and end-stage renal disease. The KCC Model includes 130 KCC entities with almost 8,400 participating healthcare providers and organizations and almost 250,000 beneficiaries in 2023.

## **Innovation Center Drug Pricing Report**

President Joe Biden signed Executive Order (EO) 14087, "Lowering Prescription Drug Costs for Americans," on Oct. 14, 2022. The EO calls for additional actions to "complement the IRA" in lowering drug costs and directs the Center for Medicare & Medicaid Innovation (CMMI) within CMS to submit a report to the White House on potential payment and delivery models that would lower drug costs and promote access to innovative drugs within 90 days. The EO specifically requests CMMI to consider "models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care." The White House is now reviewing the report. CMS will also meet with drug makers today in a second meeting to discuss implementation of the drug-pricing provisions in the IRA, specifically recent inflation rebate guidance in relation to the 340B drug discount program.