Holland & Knight

H&K Health Dose: December 13, 2022

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

Congress This Week: Federal Funding Cliff Fast Approaching; Another Short-Term CR Looks Increasingly Likely

With the current continuing resolution (CR) set to expire on Dec. 16, 2022, negotiations over a fiscal year (FY) 2023 are moving along. Congress will need to enact another CR before Friday to keep the federal government funded or risk a partial government shutdown. The attached draft CR language extends funding until Dec. 23, 2022, providing Congress with another week to reach an agreement on topline spending figures. Democrats and Republicans remain about $25 billion apart on nondefense issues. House Minority Leader Kevin McCarthy (R-Calif.) has called for passage of a CR that would extend the deadline into 2023 when House Republicans will have more leverage as the incoming majority. However, Senate Republicans do not appear to be on board. Meanwhile, Democrats have threatened to bring draft bills, including a full-year CR, to a vote if the current stalemate cannot be overcome but have held off citing some progress with Republicans over the weekend.

Several items need to be addressed in the healthcare space, including addressing Medicaid funding in the territories; Medicare PAYGO 4 percent cut; Medicare Low-Volume Payment Adjustment; Medicare-Dependent Hospital Program; and Maternal, Infant and Early Childhood Home Visiting Program. Congress may also address several other priorities in a year-end package, including mental health, telehealth and Medicare physician payment cuts. Additionally, it is likely the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021 will be included in the year-end package.

Congressional Lawmakers Try to Drum Up Support to Stop Medicare Physician Cuts

Two new letters to congressional leadership regarding forthcoming Medicare physician reimbursement cuts are circulating in the House. The first, from Reps. Susan Wild (D-Pa.) and Mariannette Miller-Meeks (R-Iowa), request that a 4 percent PAYGO cut and a 4.47 percent cut to the Medicare conversion factor both be prevented in addition to the 2 percent Medicare sequestration cut, which resumed on July 1. Regarding spending offsets, the letter explicitly states opposition "to paying for preventing these cuts with additional provider cuts." As of Dec. 13, there are 95 signatories on the letter.

Another letter from the GOP Doctors Caucus requests support for policies to address impending Medicare payment cuts. Sen. John Kennedy (R-La.) introduced the Protecting Medicare Patients and Physicians Act (S. 5194) last week. The bill would hold providers harmless against the cut to the Medicare conversion factor and suspend the 4 percent PAYGO cut for one year. Unspent COVID-19 provider relief funds would be transferred to the Medicare Part B Trust Fund to offset costs. The difference in approach comes as some members are increasingly concerned with how to pay for the reimbursement adjustments, particularly as they continue to wait for topline spending numbers from leadership.

Democratic Leadership Elections, Sinema Party Switch

Senate Democrats held leadership elections last week. Senate Majority Leader Chuck Schumer's (D-N.Y.) leadership team had only one change, the addition of Sen. Brian Schatz (D-Hawaii). House Democrats previously approved a wave of leadership changes, passing off control to a younger generation of lawmakers, including selecting Hakeem Jeffries (D-N.Y.) to succeed Nancy Pelosi as House Minority Leader.

Meanwhile, on Dec. 9, Sen. Kyrsten Sinema (I-Ariz.) announced that she will be changing her party affiliation from Democrat to Independent. Her decision will not have a practical impact on Democrats' control of the chamber, given her stated intent not to caucus with her Republican colleagues. Senate Majority Leader Schumer also said that Sinema would maintain her committee positions. However, it will likely make an already challenging potential reelection campaign in 2024 even more of an uphill battle.

REGULATORY UPDATES

CMS Issues Proposed Rule on Prior Authorization

The Centers for Medicare & Medicaid Services (CMS) released the Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule, intended to streamline and speed up prior authorization processes and improve data access and exchange for certain payers. The rule would apply to Medicare Advantage organizations, state Medicaid and Children's Health Insurance Program (CHIP) agencies and managed care entities, Medicaid managed care plans and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs).

Specifically, the rule would:

- require payers to implement electronic prior authorization and leverage application programming interfaces (APIs)
- require payers to respond to prior authorization requests within seven calendar days for standard requests and within 72 hours for expedited requests
- improve transparency by requiring payers to report metrics on prior authorization requests publicly and explain their reasoning for rejecting requests
- improve data access and exchange by advancing patient and provider access to data through APIs and requiring payer-to-payer data exchange with patient permission.

Most of these policies would take effect Jan. 1, 2026, with metric reporting beginning in March 2026. The proposed rule also includes several requests for information. Comments are due March 13, 2023, and a CMS fact sheet on the rule is available.

In addition to the direct regulatory implications, the proposed rule may have additional consequences for the Improving Seniors' Timely Access to Care Act (H.R. 3173), which would standardize prior authorization procedures in Medicare Advantage plans, among other changes. The bill was passed by the House in September, and a companion measure in the Senate has 49 bipartisan cosponsors. A previous economic score of $16 billion had held up passage but as a result of this rule, the expected cost of the bill likely will be lowered, thereby improving the bill's chances of passing next year.

Proposed FDA Rule Would Align Annual Safety Reporting with International Standards

Sponsors of investigational drugs would need to comply with an internationally adopted standard for annual reporting under a new rule proposed by the U.S. Food and Drug Administration (FDA) on Dec. 8. Currently, the FDA allows companies studying experimental drugs to submit development safety update reports (DSURs) on the status of clinical studies, any adverse event reports and other details in their own desired format. The new standards, supported by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), would specify consistent formatting and content standards.

ARPA-H Director Predicts Programs to Start Rolling Out in Q3 2023

Advanced Research Projects Agency for Health (ARPA-H) Director Renee Wegrzyn recently stated that she expects the agency will install program managers during the first quarter of 2023 and will start to roll out programs in the second quarter. The new agency was established in legislation passed earlier this year and is intended to bring together academics, industry and government leaders to drive innovation in healthcare as well as bring about cures to common and rare diseases. ARPA-H has only $1 billion in funding so far, but many are hoping that additional funding will be approved in the 2023 budget package. The ARPA-H website was just launched a few weeks ago.

QUICK SHOTS

- Rep. Greg Murphy, M.D. (R-N.C.) will serve as co-chair of the GOP Doctors Caucus. Rep. Andy Harris, M.D. (R-Md.) will complete his 4-year term at the end of the 117th Congress. Rep. Brad Wenstrup, D.P.M. (R-Ohio), and Rep. Michael Burgess, M.D. (R-Texas) will remain as co-chairs in the 118th Congress.

- The Medicare Payment Advisory Commission (MedPAC) held a two-day public meeting focusing on annual payment recommendations for hospital inpatient and outpatient services, physician services, home health services and inpatient rehabilitation services.

- The Medicaid and CHIP Payment and Access Commission (MACPAC) also held a two-day public meeting during which it held sessions on Medicaid coverage drug coverage, Section 1115 demonstration waivers, Medicaid race and ethnicity data collection and reporting and Disproportionate Share Hospital (DSH) Allotments.

- The U.S. Patent and Trademark Office announced the implementation of the Cancer Moonshot Expedited Examination Pilot Program to replace the Cancer Immunotherapy Pilot Program.

- Centers for Disease Control (CDC) Director Rochelle Walensky said that if Congress wants to see a more effective and modernized CDC, it needs to give the agency more authority.

- The U.S. Department of Health and Human Services (HHS) issued updated guidance on good faith estimate requirements under the No Surprises Act.

- The Centers for Medicare & Medicaid Services (CMS) released an infographic providing a general overview of Emergency Medical Treatment and Labor Act (EMTALA) requirements and information on filing a complaint against a provider or supplier if an individual believes that EMTALA has been violated.