Holland & Knight

H&K Health Dose: October 17, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: Upcoming Hearings and Markups

In the U.S. House of Representatives, the Committee on Energy and Commerce's Subcommittee on Health will review 23 pieces of legislation on Oct. 19, 2023, aiming to improve Medicare payment and strengthen the program, with witnesses from the Centers for Medicare & Medicaid Services (CMS), U.S. Government Accountability Office (GAO) and Medicare Payment Advisory Commission (MedPAC). This week's additional House health hearings will focus on artificial intelligence (AI), data use, rural healthcare access and investigating pandemic fraud.

In the U.S. Senate, the Committee on Health, Education, Labor, and Pensions (HELP) will consider President Joe Biden's pick to lead the National Institutes of Health (NIH) on Oct. 18, 2023. The hearing for Dr. Monica Bertagnolli, who heads the National Cancer Institute, has been on hold since May 2023 after Chair Bernie Sanders (I-Vt.) demanded the White House act to more aggressively slash drug costs. The HELP Committee also has a hearing planned on hospital understaffing in New Jersey, where 1,700 Robert Wood Johnson University Hospital nurses have been on strike. However, Ranking Member Bill Cassidy (R-La.) has objected to the hearing, raising concerns that Sanders is using committee resources to support unions during a labor dispute, which Cassidy said in a letter on Oct. 13, 2023, is a violation of Senate rules.

Additionally, the Senate Committee on Finance will hold a hearing, "Medicare Advantage Annual Enrollment: Cracking Down on Deceptive Practices and Improving Senior Experiences," on Oct. 18, 2023. The hearing comes as community health plans press CMS to regulate the total compensation third-party Medicare Advantage (MA) brokers are paid in its upcoming 2025 MA rule and as hospitals express concern that some MA plans might not comply with certain existing agency guardrails.

House Speaker Vote

The House held a vote to choose a new speaker on Oct. 17, 2023, at 1:00 p.m.. Rep. Jim Jordan (R-Ohio) won the Republican nomination to lead the House on Oct. 13, 2023. Still, he fell short of the 217 votes he needed to seize the speaker's gavel in the first ballot vote on Oct. 13, 2023. House Republicans currently control the chamber by 221-212 – a slim, nine-member majority – and Rep. Jordan did not secure the votes of 20 of his Republican colleagues. Most Republican "defector" votes were cast for House Majority Leader Steve Scalise (R-La.), who withdrew his name from candidacy on Oct. 12, 2023, and former Speaker Kevin McCarthy (R-Calif.). Majority Leader Scalise received seven votes, and former Speaker McCarthy received six. Other Republican votes cast went to Rep. Lee Zeldin (R-N.Y.), Rep. Tom Cole (R-Okla.), Rep. Tom Emmer (R-Minn), Rep. Mike Garcia (R-Calif.), and Rep. Thomas Massie (R-Ky.). All 212 House Democrats voted for Minority Leader Hakeem Jeffries (D-N.Y.).

Any nominee will need to receive 217 votes to win the speakership on the floor. A group of centrist House Democrats sent a letter to House Speaker Pro Tempore Patrick McHenry (R-N.C.) stating that they would back the temporary expansion of McHenry's authority to allow the chamber to take up urgent legislative matters, including government funding and foreign aid. They suggest the expansion of the speaker pro tempore's authorities in 15-day increments until the election of a new speaker. Four bipartisan Problem Solvers Caucus leaders signed the letter.

Without a resolution, the government runs out of funding on Nov. 17, 2023, and funding for some key healthcare programs – such as community health centers – also expires. Additionally, several healthcare items that expired on Sept. 30, 2023, still need a path forward. The longer the speaker race drags out, the longer expired programs are without funding and the less time Congress has to develop an end-of-the-year legislative healthcare package.

HELP Democrats Release Staff Report on Nonprofit Charity Care

HELP Committee Chair Bernie Sanders (I-Vt.) has released a majority staff report asserting that major nonprofit hospitals prioritize profits over spending on charity care. The Affordable Care Act requires nonprofit hospitals to establish financial assistance policies to care for patients who cannot afford treatment. According to the report, nonprofit hospitals increased their average operating profits between 2012 and 2019 by 36 percent. They nearly doubled their cash reserves, while their average spending on charity care decreased from $6.7 million to $6.4 million over the same period. Of the 16 largest nonprofit hospitals, 12 dedicated less than 2 percent of their total revenue to charity care, and half dedicated less than 1 percent. The report recommends mandating that tax-exempt hospitals provide a minimum level of charity care and suggests reforms to increase transparency around reporting community benefit data to the IRS. Notably, the HELP Committee does not have jurisdiction over the IRS. The American Hospital Association (AHA) quickly responded with its report noting that tax-exempt hospitals provided more than $130 billion in benefits to their communities in 2020 alone.

House GOP Doctors Caucus Releases Draft Legislation

The House GOP Doctors Caucus announced a proposal to provide more flexibility around how much CMS can spend. A budget neutrality requirement currently restrains the agency. The draft legislation would update the $20 million budget neutrality threshold under the Physician Fee Schedule (PFS) to $53 million in 2025. The $53 million threshold would be updated by Medical Education Institute (MEI) every fifth year starting in 2030. The legislation also would require CMS, starting in 2025, to implement budget neutrality corrections by comparing estimated utilization to actual utilization for each relative value unit adjustment made in the previous year and adjust estimated PFS expenditures for services the following year to reconcile any miscalculations in utilization. The legislation would require CMS to update the prices and rates for each of the direct cost inputs every five years and, beginning in 2025, limit any increase or decrease in the conversion factor to 2.5 percent.

REGULATORY UPDATES

340B-Related Increases Impact 2024 Medicare Parts A & B Premiums and Deductibles; Part D IRMAAs Announced

CMS published its annual update on Oct. 12, 2023, announcing Medicare Parts A and B average monthly premiums, deductibles and coinsurance amounts for Calendar Year (CY) 2024, as well as the CY 2024 Medicare Income-Related Monthly Adjustment Amounts (IRMAA). In CY 2024, the standard monthly premium for Medicare Part B enrollees will be $174.70 – an increase of $9.80 from $164.90 in CY 2023 – and the deductible for all Part B beneficiaries will be $240 – an increase of $14 from $226 in CY 2023.

Typically, Part B premiums and deductibles are based on estimated program expenditures; greater increases indicate greater expected program spending. According to CMS, the CY 2024 increases are in part due to "the remedy for the 340B-acquired drug payment policy for the 2018-2022 period under the Hospital Outpatient Prospective Payment System (OPPS)." In 2017, CMS altered Medicare reimbursement rates for Part B-covered outpatient drugs from the average sales price (ASP) of a product plus 6 percent to the ASP minus 22.5 percent. This modified rate was in effect until the U.S. Supreme Court's 2022 ruling in *American Hospital Association v. Becerra*.

For Part A, the inpatient hospital deductible will be $1,632 – an increase of $32 from $1,600 in CY 2023. For Part D, where higher-income beneficiaries' monthly premiums are adjusted based on income, CMS set the CY 2024 minimum income threshold for IRMAA at $103,000 for individual beneficiaries and $206,000 for dual-income beneficiaries. Individual beneficiaries and dual-income beneficiaries with incomes great than $103,000 and $206,000, respectively, will see an incremental IRMAA of up to $81 per month for those with modified gross adjusted annual incomes greater than or equal to $500,000.

FDA Forms Digital Health Advisory Committee

In a news release published last week, FDA announced it established a Digital Health Advisory Committee to inform and advise agency officials on issues related to digital health technologies (DHTs) such as potential applications of augmented reality and virtual reality (AR/VR), AI and machine learning (AI/ML), wearable devices, remote patient monitoring and mobile health platforms.

DHTs have seen rapid advancement and utilization in recent years, along with increased attention from industry, legislators and regulators. In Fall 2020, the U.S. Food & Drug Administration (FDA) established a Digital Health Center of Excellence (CoE) within its Center for Devices and Radiological Health (CDRH). The formation of a new advisory committee, which is expected to be operational in 2024, signals the FDA's continued focus on DHTs and associated challenges and opportunities.

ARPA-H Awards $26 Million to Address Transplant Shortages

The U.S. Department of Health and Human Services (HHS), through the Advanced Research Projects Agency for Health (ARPA-H), announced on Oct. 17, 2023, as part of its Open Broad Agency Announcement (Open BAA), up to $26 million for a newly funded project that aims to lay the groundwork for the development of 3D printed, fully functional human organs.

Paxlovid to Enter Commercial Market Under New HHS-Pfizer Agreement

The HHS and Pfizer announced on Oct. 13, 2023, a new agreement that will allow Paxlovid to enter the commercial market starting in 2024. Since Paxlovid was first granted Emergency Use Authorization (EUA), the U.S. has purchased nearly 24 million treatment courses of the antiviral at an average price of $530 per course. HHS-procured Paxlovid was made available to patients at no cost. While Pfizer has not made any public statements regarding Paxlovid's list price on the private market, it is expected to increase.

Under the new agreement, HHS may continue to order Paxlovid until Dec. 15, 2023. At the end of 2023, the U.S. will return nearly 8 million EUA-labeled treatment courses to Pfizer. In exchange, Pfizer will supply HHS with 1 million treatment courses of New Drug Approval (NDA)-labeled Paxlovid to replenish the Strategic National Stockpile (SNS). Additionally, Pfizer will administer a Patient Assistance Program (PAP) to continue to provide HHS-procured Paxlovid – at no cost – to Medicaid and Medicare beneficiaries through 2024 and to uninsured and underinsured individuals through 2028. Pfizer has also announced it will offer a copay assistance to individuals with commercial insurance through 2028.

CMS Lifts National Coverage Determination Limiting Coverage of Amyloid PET Scans for Alzheimer's Disease

CMS issued a decision memo on Oct. 13, 2023, removing its 2013 National Coverage Determination (NCD) on amyloid Positron Emission Tomography (PET) scans. The 2013 NCD provided for coverage of amyloid PET scans under coverage with evidence development (CED) restrictions, limiting coverage to only one scan per patient, and only for individuals participating in clinical trials. Under CMS' new policy, Medicare Administrative Contractors (MACs) will have the authority to make coverage determinations for amyloid PET scans.

Final Rule on Civil Money Penalties for Failure to Meet Medicare Secondary Payer Reporting Obligations

CMS has issued its final rule detailing how and when it will calculate and impose Civil Money Penalties (CMPs) for failure to meet Medicare Secondary Payer (MSP) reporting obligations under Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007. Under the final rule, CMS will impose CMPs on non-group health plans (NGHPs) responsible reporting entities (RREs) for "untimely reporting" – defined in the final rule as the submission of required information "more than 1 year after the date of settlement, judgment, award, or other payment" – and use a time-based "tiered approach" to calculate CMP amounts.