



H&K Health Dose: November 7, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: FY 2024 Appropriations

The government will run out of funding on Nov. 17, 2023 – in 10 days. The U.S. House of Representatives will continue to work to advance annual appropriations bills this week. However, a continuing resolution (CR) will be needed to fund the government, and it appears that House Republicans' goal is to extend government funding through the CR until at least Jan. 15, 2024. The House has passed seven of the 12 annual appropriations measures (Military Construction-Veterans Affairs (VA), Defense, Homeland Security, State-Foreign Operations, Energy-Water, Legislative Branch and Interior-Environment). In contrast, the U.S. Senate passed the chamber's first minibus package containing appropriations for Agriculture-Food and Drug Administration, Military Construction-VA, and Transportation-Housing and Urban Development in a bipartisan 82-15 vote last week.

Republican appropriators in the House released a revised [version](#) of their fiscal year (FY) 2024 Labor, Health and Human Services, and Education legislation last week. The revised U.S. Health and Human Services (HHS) appropriations measure includes a number of controversial policy riders. Notably, Speaker Mike Johnson (R-La.) plans to bypass a full committee markup and instead bring the bill to the floor for a vote the week of Nov. 13, 2023.

Senate Committee on Finance Markup

The Senate Committee on Finance leadership released a bipartisan discussion [draft](#) of legislation containing measures related to pharmacy benefit managers (PBMs), mental healthcare, and Medicare and Medicaid healthcare extenders. The package would expand eligibility for workforce shortage incentive programs for mental health and substance use disorder clinicians, support the use of licensed clinical social workers in the Medicare program and require Medicare Advantage (MA) plans to have up-to-date and accurate provider directories. The package also mitigates the impending Medicare physician fee schedule cut by extending the relief from last year at the 2.5 percent level rather than letting it drop to 1.25 percent. The panel plans to mark up the package on Nov. 8, 2023.

Dr. Monica Bertagnolli Confirmed as NIH Director

The Senate confirmed Dr. Monica Bertagnolli's nomination on Nov. 7, 2023, to serve as director of the National Institutes of Health (NIH) in a 62-36 vote. The position has been vacant since the departure of Dr. Francis Collins in December 2021, with Lawrence Tabak filling in as acting director in the interim. Bertagnolli's nomination was submitted to Congress by President Joe Biden in May 2023, but it hit a months-long roadblock in the Senate Committee on Health, Education, Labor and Pensions (HELP). Up until October 2023, Senate Committee on HELP Chair Bernie Sanders (I-Vt.) had blocked hearings on Bertagnolli's nomination over a disagreement with the Biden Administration on drug pricing reform. During an Oct. 25, 2023, markup, several HELP Republicans – including Ranking Member Bill Cassidy (R-La.) – joined Democrats on the panel to advance the nomination to the full Senate in a 15-6 vote.



REGULATORY UPDATES

CMS Releases PFS Final Rule

The Centers for Medicare & Medicaid Services (CMS) issued the [final calendar year \(CY\) 2024 Physician Fee Schedule \(PFS\)](#) on Nov. 2, 2023. The final rule sets the 2024 Medicare payment rates for physician services. For 2024, CMS finalized a conversion factor of \$32.7442 and \$20.4349 for Anesthesia (a decrease of 3.4 percent and 3.3 percent, respectively, over final 2023 rates).

Other policies of note:

- Implements evaluation and management (E/M) add-on code G2211 and defines the "substantive portion" of a split (or shared) E/M visit to mean more than half of the total time spent by the physician or nonphysician practitioner or a substantive part of the medical decision-making
- Reimburses telehealth services furnished to patients in their homes at the non-facility PFS rate
- Allows direct supervision by a supervising practitioner through real-time audio and video interaction telecommunications through 2024
- Continues coverage and payment of telehealth services included on the Medicare Telehealth Services List through 2024
- Pauses implementation and rescinds the Appropriate Use Criteria program regulations
- Maintains the performance threshold of 75 points for all three Merit-Based Incentive Payment System (MIPS) reporting options
- Ends the 3.5 percent alternative payment method (APM) Incentive Payment after the 2023 performance year/2025 payment year and transitions to a Qualifying APM Conversion Factor in the 2024 performance year/2026 payment year
- Expands behavioral health services and prioritizes "whole-person" health. It will allow marriage and family therapists and mental health counselors who meet qualification requirements to enroll in Medicare for the first time and start billing for services starting Jan. 1, 2024. It also increases payment for crisis care, substance use disorder treatment and psychotherapy.

This rule will be effective on Jan. 1, 2024. A more detailed summary is forthcoming.

CMS Releases OPSS Final Rule

CMS issued the final calendar year (CY) 2024 [Outpatient Prospective Payment System \(OPSS\)](#) rule on Nov. 2, 2023. For 2024, CMS is finalizing an Outpatient Prospective Payment System (OPSS) payment rates for hospitals and ambulatory surgery centers (ASCs) that meet applicable quality reporting requirements by 3.1 percent.

Other policies of note:

- Continuing to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPSS hospitals using the most recently submitted or settled cost report data
- Advanced several changes regarding price transparency, including a requirement that hospitals make cost data publicly available in a more standardized manner, which CMS said will make it easier for third-party developers to use and simpler for patients to parse through
- Finalizes provisions from the Consolidated Appropriations Act of 2023, which will create a new benefit category for intensive outpatient services provided to behavioral health patients



- Finalizing the proposal to continue to apply the default rate, generally average sales price (ASP) plus 6 percent, to 340B acquired drugs and biologicals. Therefore, drugs and biologicals acquired under the 340B program would be paid at the same payment rate as those drugs and biologicals not acquired under the 340B program.

This rule will be effective on Jan. 1, 2024. A more detailed summary is forthcoming.

CMS Releases 340B Remedy Final Rule

The [rule](#) is responsive to the U.S. Supreme Court's June 2022 decision in *American Hospital Association (AHA) v. Becerra*, which held that CMS' 2018 payment cuts exceeded the agency's statutory authority to set Medicare payments to hospitals for outpatient drugs. CMS is finalizing its policy to make an additional payment to affected providers for 340B-acquired drugs as a one-time lump sum payment. Providers will not be able to bill beneficiaries for any cost sharing. CMS is also maintaining its budget-neutral policy and implementing a \$7.8 billion offset by adjusting the OPPS conversion factor by -0.5 percent starting in CY 2026 (a change from the proposed rule that had the offset starting in 2025). CMS will make this adjustment until the \$7.8 billion is recouped, which CMS estimates will take 16 years.

CMS Proposes 2025 Policy Changes for the MA and Medicare Part D Programs

CMS released a sweeping [proposed rule](#) on Nov. 6, 2023, updating Medicare Advantage (MA) and Medicare Part D policies relating to behavioral health, biosimilars, prior authorization, broker compensation and deceptive MA plan marketing practices. Among other changes, the proposed rule would establish a new "Outpatient Behavioral Health" facility-specialty type subject to CMS' MA plan network adequacy standards, as well as expand flexibilities for Part D plans to substitute certain reference biologics with biosimilars without CMS' pre-approval. CMS has issued a [fact sheet](#) summarizing the major provisions of the proposal.

AI Executive Order

As shared last week, President Joe Biden's [executive order](#) (EO) on artificial intelligence (AI) is broad-reaching, crossing many different sectors, and includes certain directives that impact healthcare stakeholders. The EO requires the establishment of an HHS AI Task Force to develop a strategic plan for responsible deployment and use of AI and AI-enabled technologies in the health and human services sector. To learn more about the healthcare implications, see Holland & Knight's previous alert, "[New Artificial Intelligence Executive Order Contains Numerous Healthcare Implications](#)," Nov. 6, 2023.