Holland & Knight

H&K Health Dose: October 31, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: The New House Speaker and His Health Policy Record

Rep. Mike Johnson (R-La.), who came to Congress in 2017, became Speaker of the House on Oct. 25, 2023, with a final vote on the first ballot of 220-209. The U.S. House of Representatives is now able to resume working on legislative priorities, the most pressing of which is funding the government ahead of the Nov. 17, 2023, expiration of the current continuing resolution (CR). Johnson circulated a letter to his colleagues last week outlining his intent for a floor vote on the Labor, Health and Human Services, Education and Agriculture, Rural Development, Food and Drug Administration appropriations bills for the week of Nov. 13, 2023, and a stopgap CR that would fund the government through Jan. 15, 2024, including implementation of the 1 percent cut from the debt limit deal.

Regarding Johnson's healthcare background, he has supported efforts to repeal the Affordable Care Act (ACA). When he served as chair of the Republican Study Committee, the group introduced "The RSC Health Care Plan: A Framework for Personalized, Affordable Care," which chiefly sought to repeal the ACA. Johnson also voted in favor of the American Health Care Act of 2017, which would have repealed the ACA, but the bill died in the U.S. Senate. Johnson, a constitutional attorney, also served as counsel for a conservative Christian advocacy group classified as a hate group by the Southern Poverty Law Center that helped overturn *Roe v. Wade* and is pushing to end access to abortion medications. He also introduced a bill last year that would prohibit discussion of sexual orientation and gender identity at any institution that receives federal funds. In addition, he introduced legislation this year to permanently place fentanyl-related substances as Schedule I under the Controlled Substances Act (CSA), but the legislation has not yet been taken up in committee.

Senate Special Committee on Aging Examines Rare Diseases

The Senate Special Committee on Aging held a hearing to hear from patients who are impacted by rare, serious and progressive diseases and to discuss solutions to speed the U.S. Food and Drug Administration (FDA) approval process for new drugs and treatments without disrupting safety and ethics. Ranking Member Mike Braun (R-Ind.) introduced the Promising Pathway Act, supported by many members and witnesses, which aims to speed the drug and treatment approval processes for patients with rare, serious and progressive diseases. Witnesses noted inconsistencies with the U.S. Food and Drug Administration (FDA) approval process for new drugs and treatments and shared concerns that patients with progressive and fatal diseases do not have time to wait for long approval processes.

Finance Healthcare Markup on Nov. 8

The Senate Committee on Finance plans to vote Nov. 8, 2023, on legislation that includes substance misuse, mental health policies, reforms to Pharmacy Benefit Manager (PBM) practices and healthcare extenders like a remedy to the forthcoming Disproportionate Share Hospital (DSH) cuts and the State Health Insurance Assistance Program. The package intends to be offset with the goal to be attached to a CR or omnibus legislation.

REGULATORY UPDATES

Biden Uses Executive Order To Push For AI Healthcare Standards

President Joe Biden issued an executive order (EO) on Oct. 30, 2023, to guide federal agencies on the development and use of artificial intelligence (AI). The Biden Administration laid out eight principles to guide federal agencies in advancing, using and overseeing AI. To ensure safe and responsible use of AI in the healthcare industry, the EO directs the U.S. Department of Health and Human Services (HHS) to establish an HHS AI Task Force within one year. This task force shall develop a strategic plan that includes policies – and possibly regulatory action – on responsible deployment of AI and AI-enabled technologies in the healthcare sector, including research and discovery, drug and device safety, healthcare delivery and financing, and public health. The EO also directs HHS to consider appropriate actions to advance compliance and understanding of federal nondiscrimination laws by health providers that receive federal financial assistance and its relationship to AI. Further, the EO directs HHS to develop a strategy for regulating the use of AI or AI-enabled tools in drug development processes, and the EO directs HHS, in consultation with the Secretaries of Defense and Veterans Affairs, to establish an AI safety program that establishes a common framework for approaches to identifying and capturing clinical errors resulting from AI deployed in healthcare settings.

NIH Nominee Advances

The Senate Committee on Health, Education, Labor, and Pensions (HELP) advanced Monica Bertagnolli's nomination to lead the National Institutes of Health (NIH) with a vote of 15-6, with Chair Bernie Sanders (I-Vt.) voting against her. She, however, advanced with bipartisan support and now moves to consideration by the full Senate. Currently, Bertagnolli is serving as the director of the National Cancer Institute (NCI), the NIH's largest research institute. She is the first woman to lead NCI, and since she took over the role in October 2022 she has focused on making cancer studies less expensive and complicated. Bertagnolli also developed the new National Cancer Plan, which aims to reduce cancer death rates, as well as other goals from President Joe Biden's cancer "moonshot" efforts.

HRSA Issues Notice on 340B Off-site, Outpatient Facility Registration Requirements

The Health Resources and Services Administration (HRSA) rescinded guidance in May 2023 that waived certain reporting and registration requirements for 340B hospital offsite outpatient facilities (child sites). The waiver, which was announced during the COVID-19 public health emergency, lifted a requirement that child sites already be listed on a hospital's Medicare Cost Report before becoming eligible to participate in the 340B program. A notice published Oct. 27, 2023, formally ended the waiver, clarifying that child sites must be listed as reimbursable on a hospital's most recent Medicare Cost Report and be registered on the Office of Pharmacy Affairs Information System (OPAIS) to participate in 340B. The notice outlines HRSA's planned approach to registration enforcement, including a 90-day "transition period" for 340B hospitals to come into compliance.

No Surprises Act Federal IDR Proposed Rule

The HHS, U.S. Department of Labor and the U.S. Department of the Treasury (collectively, the Departments) released a Notice of Proposed Rulemaking (NPRM) on Oct. 27, 2023, intended to improve and streamline the No Surprises Act Federal Independent Dispute Resolution (IDR) process used to resolve out-of-network billing disputes between plans and providers. The Centers for Medicare & Medicaid Services (CMS) has published a fact sheet on the NPRM. The proposed rules will be open for public comment for 60 days.

To "reduce the number of ineligible disputes that are submitted to the Federal IDR process," under the proposed rules, payers would be required to disclose certain information – including identifying information such as the legal business name of the plan and plan sponsor, if applicable – when issuing an initial payment or a notice of

denial of payment. Payers would also be required to include specific claim adjustment reason codes and remittance advice remark codes with the initial payment or notice of denial of payment.

Additionally, the proposed rules would codify the definition of Bundled Payment Arrangements established in the August 2022 Federal IDR Process Technical Assistance for Certified IDR Entities. Under the proposed rules, items and services furnished in a single patient encounter or billed under the same service code, as well as certain anesthesiology, radiology and laboratory items and services billed under service codes in the same CPT category, would be qualified to be batched (included as separate payment determinations within a single dispute). The proposed rules would also restructure the administrative fee collection process and set new timelines for fee payments, as well as other changes intended to promote "meaningful engagement" in open negotiation.

FDA Publishes Draft Guidance on Remote Evaluations of Drug Manufacturing and Other Facilities

The FDA issued draft guidance on Oct. 25, 2023, for remote inspections of drug manufacturing facilities, facilities under FDA's Bioresearch Monitoring (BIMO) program and certain other facilities. The agency also expanded its use of remote evaluation tools in response to the COVID-19 public health emergency. Once this guidance is finalized, the FDA plans to withdraw its pandemic-era remote evaluation rules. Under the new guidance, the FDA "may request to conduct a remote interactive evaluation whenever a program office determines it is appropriate based on mission needs and any travel limitations." Participation in remote evaluations will be voluntary, though declining a remote evaluation may hinder the FDA's ability to "make timely regulatory decision[s]."