



H&K Health Dose: December 6, 2023

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: FY 2024 Appropriations Watch

The U.S. House of Representatives has passed seven of 12 annual appropriations bills for Fiscal Year (FY) 2024. The U.S. Senate has passed three. The first round of funding authorized by last month's "laddered" Continuing Resolution (CR) – passed by Congress at the eleventh hour to temporarily prevent a government shutdown – expires on Jan. 19, 2024, for federal agencies and programs in the Agriculture-FDA, Energy and Water, Military Construction-VA and Transportation-HUD spending bills. Only 16 scheduled legislative days are left before this first deadline arrives, and legislators have not yet reached an agreement on topline funding levels.

Further complicating the regular appropriations process, Senate leaders are currently at odds with House Republicans over a supplemental funding package that would potentially provide aid to Ukraine and Israel. The package is stalled due to intense disagreements over border security and immigration policies. Additionally, negotiations surrounding the must-pass National Defense Authorization Act (NDAA) are still ongoing, as are discussions about the looming Dec. 31, 2023, expiration of Federal Aviation Administration (FAA) authorities. Efforts to advance bipartisan legislation to fully extend and reauthorize the FAA have been unsuccessful thus far, despite an apparent bicameral consensus on the importance of sustained long-term funding. A short-term stopgap measure introduced last week by House Committee on Transportation and Infrastructure Chair Sam Graves (R-Mo.) has potential to move before the end of the year.

These items (among others) will undoubtedly take up a significant amount of members' time and attention during the few legislative days of 2023. A January 2024 appropriations scramble is a near-certainty, and it is increasingly unlikely that Congress will be able to pass all 12 regular appropriations acts by either of the deadlines established by the laddered CR. Speaker Mike Johnson (R-La.) has stated that if an agreement is not reached by Feb. 2, 2024, House Republicans will pursue a full-year CR – a plan that has been criticized as a "nonstarter" by members on the opposite side of the aisle, including Senate Committee on Appropriations Chair Patty Murray (D-Wash.), who pushed back on this plan during a Dec. 5, 2023, press conference: "I understand the Speaker has proposed an unprecedented, date-change, full-year CR. I want to be very clear that is a nonstarter. ... It is deeply dangerous; it would lock in outdated spending plans and devastating across-the-board cuts with no rhyme or reason."

The use of short-term stopgap measures past April 30, 2024, would trigger a provision of this year's debt limit deal that would automatically implement a 1 percent cut across all federal departments – reducing discretionary defense spending to \$849.8 billion and the nondefense discretionary to about \$736.5 billion for FY 2024. As such, a January 2024 CR would probably push the deadline back no later than this date.

House Committee on Energy and Commerce to Mark Up 44 Bills

In a two-day markup held on Dec. 5 and 6, 2023, the House Committee on Energy and Commerce considered a total of 44 pieces of legislation. Of the measures noticed for the markup, about half pertain to healthcare. The healthcare provisions that the committee discussed on Dec. 5 included measures addressing Medicare provider payments, drug pricing, biosimilar access, Pharmacy Benefit Manager (PBM) transparency and reporting requirements, several proposals to alter U.S. Food and Drug Administration (FDA) coverage determination processes and several other bills. Related to a partial reprieve of Medicare provider payment, Reps. Mariannette Miller-Meeks, MD (R-Iowa), Ami Bera, MD (D-Calif.), Larry Bucshon, MD (R-Ind.) and Kim



Schrier, MD (D-Wash.) are seeking signatories on a letter to House and Senate leadership, urging them to take action before a 3.4 percent Medicare cut takes effect on Jan. 1, 2024. The letter has garnered more than 100 signatures to date.

Senate Hearing on Drug Shortages; House Panel Discusses AI/ML in Healthcare

The Senate Committee on Finance held a hearing on Nov. 5, 2023, "Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective." Senate Finance Committee Chair Ron Wyden (D-Ore.) convened the hearing to inform of his plan to put together bipartisan legislation to address the issue, with a particular focus on the role of pharmaceutical consolidation in contributing to the crisis. During the hearing, Sen. Wyden specifically expressed interest in advancing measures to improve oversight of group purchasing organizations (GPOs) – three of which control 90 percent of the current pharmaceutical market. Other discussion topics included potential financial incentives to encourage generic drug purchasers to prioritize quality and reliability, the impact of shortages on patients and providers, and bolstering the domestic supply chain.

On Nov. 29, 2023, the House Committee on Energy and Commerce Subcommittee on Health convened to examine the implications of recent advances in artificial intelligence (AI) and machine learning (ML) in the healthcare sector. This is the fourth AI-related hearing that the committee has held this year. Discussion topics included the importance of establishing national data privacy standards, the potential of AI to reduce administrative burdens for physicians and a need for better data inputs for algorithms and solutions to limit bias in AI – gaps the FDA included on website updates days before the hearing.

Next Week: Floor Vote on the Lower Costs, More Transparency Act

The Lower Costs, More Transparency Act – a legislative package crafted jointly by the House Committees on Energy and Commerce, Ways and Means, and Education and Labor – was unveiled this fall. The sweeping legislation, which builds upon policies included in the bipartisan Patient Act, contains a number of provisions addressing health transparency, site-neutral payment and health extenders, among other provisions.

Initially set to be taken up under the suspension of the rules on Sept. 18, 2023 – where floor debate is limited prior to a House vote, all floor amendments are prohibited, points of order against the bill are waived and final passage requires a two-thirds majority vote – it was ultimately pulled from the schedule without a vote. The Lower Costs, More Transparency Act was again set up for a vote on Dec. 5, 2023, under the suspension of the rules next week.

Next Week: Senate HELP Committee to Mark Up Legislation Reauthorizing Expired SUPPORT Act Provisions

This week, the Senate Committee on Health, Education, Labor and Pensions (HELP) announced it had finally reached an agreement to reauthorize provisions of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act funding opioid treatment and prevention programs that expired on Sept. 30, 2023. The committee plans to hold a markup Dec. 12, 2023, to consider the legislation. The bipartisan proposal would double the Substance Use Disorder Treatment and Recovery Loan Repayment Program and expand access to fentanyl and xylazine test strips.



Senate HELP Committee Ranking Member Bill Cassidy Seeks Stakeholder Input on Gene Therapy

Sen. Bill Cassidy (R-La.), the top Republican on the Senate Committee on Health, Education, Labor and Pensions (HELP), circulated a lengthy [Request For Information \(RFI\)](#) on Dec. 5, 2023, seeking input from stakeholders "to inform future legislation to modernize and improve the market structure for gene therapies to ensure that the U.S. commercial health insurance market supports Americans with ultra-rare diseases, while ensuring the continued development of innovative gene therapies," per a press release from Sen. Cassidy's office.

The 59 questions in the RFI request information on topics, including specific treatments that should be covered under such legislation, the status of access to treatments for patients with rare and ultra-rare conditions, how health plans and third-party payors manage financial risk under the current landscape, manufacturer pricing and contract design, and supply chain issues, among other topics. Sen. Cassidy has requested that interested parties submit responses by Jan. 22, 2024.

House Retirement Announcements Continue to Roll In

Rep. Patrick McHenry (R-N.C.) on Dec. 5, 2023, announced his retirement from Congress. While his three weeks in the role of House Speaker Pro Tempore brought him significant national attention, Rep. McHenry is no stranger to the gavel. He is currently the chair of the House Committee on Financial Services – which he has served on since he entered Congress in 2005 – and was the ranking Republican on the panel from 2019 to 2022. Further, former House speaker Rep. Kevin McCarthy (R-Calif.) announced that he will not seek reelection to his congressional seat and will retire at the end of the month.

REGULATORY UPDATES

New FAQs on No Surprises Act Federal IDR Process Released

Last week, the U.S. Department of Health and Human Services (HHS), U.S. Department of Labor (DOL) and U.S. Department of the Treasury (collectively, the Departments) released two FAQ documents clarifying certain information about the No Surprises Act (NSA) Federal Independent Dispute Resolution (IDR) process in light of two court orders issued in August 2023 by the U.S. District Court for the Eastern District of Texas. In these two rulings, the district court vacated portions of Centers for Medicare and Medicaid Services (CMS) regulations implementing the NSA. To comply with the district court's rulings, CMS "temporarily suspended all Federal IDR process operations."

Subsequent CMS guidance has allowed certified IDR entities to resume making eligibility and payment determinations for single and bundled disputes – with the exception of disputes involving air ambulance services initiated prior to Aug. 3, 2023. Additional guidance reopened the IDR portal for all single and bundled disputes, again with the exception of new disputes involving air ambulance services. The Federal IDR portal remains closed for disputing parties to submit new batched disputes and single disputes involving air ambulance services. However, in the FAQs released last week, the Departments indicate their intent "to reopen the Federal IDR portal to these disputes as soon as possible."

The [FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation, Part 63](#), in conjunction with the [Federal IDR Process Batching and Air Ambulance FAQs](#) indicate that until the Departments' [Federal IDR Operations Rule](#) is finalized, certified IDR entities have full discretion to determine whether items and services may be batched in accordance with the statute and the remaining regulations. The FAQs also "provide information regarding the extension of existing IDR deadlines once the Federal IDR portal reopens to all batched disputes and single disputes involving air ambulance services."



Dr. Namandjé N. Bumpus Announced as FDA Principal Deputy Commissioner

FDA Chief Scientist Dr. Namandjé N. Bumpus has been announced as the FDA's principal deputy commissioner. The position – held by the second-most senior official within the FDA – is currently held by Dr. Janet Woodcock, who previously announced she will retire in early 2024, after more than 30 years with the agency.

Prior to joining the FDA in 2022, Dr. Bumpus was a professor and chair of the Department of Pharmacology and Molecular Sciences (DPMS) at the Johns Hopkins University School of Medicine. Dr. Bumpus, who spent much of her career in academia, was inducted into the prestigious National Academy of Medicine in 2022 for her work on HIV research. Dr. Bumpus will be the first Black woman to serve as principal deputy commissioner at the FDA.