



H&K Health Dose: May 14, 2024

A weekly dose of healthcare policy news

The U.S. Senate and U.S. House of Representatives are in session, with healthcare activity expected at the committee level, including a Senate Committee on Finance hearing on rural health and an anticipated House Committee on Energy and Commerce (E&C) markup that includes telehealth legislation.

LEGISLATIVE UPDATES

House Speaker Johnson Survives Motion to Vacate

The majority of Democrats in the House joined with Republicans to block an attempt to oust House Speaker Mike Johnson (R-La.). The chamber ultimately voted 359-43 to block consideration of a motion that was filed by Rep. Marjorie Taylor Greene (R-Ga.) to vacate the chair, with 11 Republicans seeking to remove Johnson as speaker. Democrats' support followed Speaker Johnson's efforts to secure \$61 billion in aid for Ukraine.

FY 2025 Appropriations

Government funding for the current fiscal year (FY) expires on Sept. 30, 2024. The last major item on Congress' to-do list will be passing FY 2025 spending bills through the normal appropriations process by that deadline, and to hopefully avoid a protracted series of stopgap funding measures that continued for months in FY 2024. House Republicans have indicated they will announce topline spending levels for FY 2025 appropriations bills as soon as next week, and appropriators are currently in the process of working on spending bills – although legislators acknowledge the specifics of these bills will likely need to be renegotiated further down the line.

FAA Reauthorization

The House is expected to vote on the five-year reauthorization of the Federal Aviation Administration (FAA), which passed in the Senate last week. The FAA reauthorization package, as well as more than a dozen unrelated measures, are currently scheduled for debate in the House on May 14, 2024, under suspension of the rules – a voting procedure that requires a two-thirds majority for passage.

Senate HELP Committee Ranking Member Cassidy Releases White Paper on NIH Transparency and Modernization

Senate Committee on Health, Education, Labor and Pensions (HELP) Ranking Member Bill Cassidy (R-La.) released a white paper, "[NIH in the 21st Century: Ensuring Transparency and American Biomedical Leadership](#)," on May 9, 2024. It was informed by responses from stakeholders to a September 2023 request for information (RFI) seeking feedback on current National Institutes of Health (NIH) activities and the agency's statutory framework. The white paper lays out several concerns with NIH's research priorities and grant management practices, potential improvements to help sustain the United States' strategic advantages in science and biomedical research, and emphasizes the "need for NIH to enhance transparency."

MA Prior Authorization Bill

During a Senate Committee on the Budget hearing on reducing administrative burdens in the healthcare industry last week, Sen. Roger Marshall, M.D. (R-Kan.) discussed plans for the reintroduction of the bipartisan, bicameral Improving Seniors' Timely Access to Care Act next month. The bill would establish requirements to streamline and standardize the use of prior authorization in the Medicare Advantage (MA) program. Sen.



Marshall noted that he and his colleagues have worked to address the Congressional Budget Office's (CBO) cost estimate of the bill and that the score of the legislation has been revised to \$0 as a result of the Centers for Medicare & Medicaid Services (CMS) finalizing the Interoperability and Prior Authorization Final Rule (CMS-0057-F) earlier this year.

GOP House E&C Committee Leaders Call Out ASPR Over Issues with National Stockpile

House E&C Committee Chair Cathy McMorris Rodgers (R-Wash.), House E&C Committee Subcommittee on Health Chair Brett Guthrie (R-Ky.) and House E&C Committee Oversight and Investigations Subcommittee Chair Morgan Griffith (R-Va.) [sent a letter](#) on May 9, 2024, to the Assistant Secretary for Preparedness and Response (ASPR) Dawn O'Connell to express concerns over the agency's management of the Strategic National Stockpile (SNS). The legislators indicate they are "alarmed by a pattern of fiscal mismanagement and a series of failed acquisitions that have left the SNS dangerously under-resourced and likely underprepared to respond to future public health emergencies." The letter lays out a series of questions related to ASPR spending, procurement and contracting practices, requesting a written response by May 23, 2024.

House W&M Committee Marks Up Telehealth Extension, PBM Reform, Rural Health Bills

The House Committee on Ways & Means (W&M) convened for a markup of legislation on May 8, 2024, that would extend several pandemic-era telehealth flexibilities through 2026, as well as legislation to extend certain other Medicare hospital bonuses into 2025. Proposed "pay fors" include pharmacy benefit manager (PBM) reforms and phased-in decreases to payments under the Medicare Clinical Laboratory Fee Schedule, among other proposals.

The committee also approved, on a partisan basis, several bills related to rural health, including legislation that would alter the designation criteria for rural hospitals. [A full list of legislation](#) considered and approved by the committee, as well as an archived webcast of the hearing, is available.

House E&C Committee to Mark Up Telehealth Legislation

The House E&C Committee is expected to hold its own markup of telehealth legislation next week. Of particular interest, we will see how the House E&C Committee legislation differs from the bill advanced by the House W&M Committee, including whether they use the same or different offsets to pay for the bill.

REGULATORY UPDATES

CMS Proposes New Mandatory Organ Transplant Model for ESRD

CMS [proposed](#) a mandatory Medicare payment model on May 8, 2024, to test whether performance-based incentive payments to kidney transplant hospitals increase access to kidney transplants for patients with end-stage renal disease (ESRD). The model, the Increasing Organ Transplant Access (IOTA) Model, is designed to enhance kidney transplant accessibility and quality of care for individuals with ESRD. The mandatory model aims to decrease disparities in transplant access and improve transplant hospital efficiency. CMS would measure hospitals within the model on increases in the number of kidney transplants, increased organ acceptance rates and post-transplant outcomes. Eligible hospitals are to include non-pediatric facilities that conduct a minimum of 11 kidney transplants during a three-year baseline period. Ninety out of an estimated 257 transplant hospitals (35 percent) in the country would be required to participate in the six-year model, which begins Jan. 1, 2025.

Transplant hospitals selected for participation would receive upside risk payments from CMS, fall into a neutral zone or owe downside risk payments to CMS, based on a final performance score that would be calculated on



a set of metrics in three proposed domains (number of kidney transplants with health equity performance adjustment, organ offer acceptance ratio and quality scores). The maximum positive payment per Medicare fee-for-service (FFS) transplant under the model (the upside risk payment) would be \$8,000. The maximum negative payment per Medicare FFS transplant under the model (the downside risk payment) would be \$2,000.

As a mandatory model, CMS is required to accept comments on the plan. Comments on the proposed rule are due on July 16, 2024.

DOJ To Combat Healthcare Market Consolidation with New Healthcare Task Force

The U.S. Department of Justice (DOJ) announced on May 9, 2024, the formation of the [Antitrust Division's Task Force on Health Care Monopolies and Collusion \(HCMC\)](#). Assistant Attorney General Jonathan Kanter of the DOJ's Antitrust Division said in the announcement, "Every year, Americans spend trillions of dollars on health care, money that is increasingly being gobbled up by a small number of payers, providers and dominant intermediaries that have consolidated their way to power in communities across the country. Led by Katrina Rouse, the task force will identify and root out monopolies and collusive practices that increase costs, decrease quality and create single points of failure in the health care industry."

The DOJ aims to address "widespread competition concerns shared by patients, health care professionals, businesses and entrepreneurs, including issues regarding payer-provider consolidation, serial acquisitions, labor and quality of care, medical billing, health care IT services, access to and misuse of health care data and more." Additionally, the release states that the task force will utilize civil and criminal prosecutors, economists, healthcare industry experts, technologists, data scientists, investigators and policy advisors from across the division's Civil, Criminal, Litigation and Policy Programs, as well as the Expert Analysis Group, to identify and address pressing antitrust problems in healthcare markets.

Upcoming FDA Annual Meeting on User Fee Programs

The U.S. Food and Drug Administration (FDA) will hold its [annual meeting](#) on June 6, 2024, to assess the financial status and efficiency of the three primary medicine user-fee programs. The meeting, "Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments," will discuss the financial transparency and efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act and Generic Drug User Fee Amendments. To submit electronic comments, due 11:59 p.m. June 6, 2024, go to [Regulations.gov](#) and follow the instructions for submitting comments.

New Cyberattack of Private Health System Bolsters Concerns of Healthcare Security

Following the ripples of the Change Cyberattack earlier this year, one of the largest private healthcare systems in the U.S. was attacked on May 9, 2024. Systems impacted included its electronic health records system, phone systems and ability to order certain tests and procedures. In response to the attack, the healthcare system has postponed or canceled some elective procedures and forwarded emergency care to other nearby hospitals. The U.S. Department of Health and Human Services (HHS) has addressed the attack and said they are working with the system's leadership to "understand and assess their efforts to minimize any disruptions to patient care."

CMS Extends State Unwinding Flexibilities Through June 2025

CMS has announced it will extend flexibilities through June 30, 2025, in order to assist states with the magnitude of Medicaid eligibility renewals. In some recent public meetings and conferences, Medicaid directors have requested this extension, noting concerns that their states' redetermination processes may hit a wall after the post-pandemic renewal period ends.