



H&K Health Dose: July 23, 2024

A weekly dose of healthcare policy news

The U.S. Senate and U.S. House of Representatives are in session with votes scheduled and health-related activity at the committee level.

Since the last Health Dose, a number of rules have been released, including the Physician Fee Schedule, the Hospital Outpatient Prospective Payment System, and Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2).

Election Updates

With just over 100 days until the election, President Joe Biden announced over the weekend that he will not seek a second term. Shortly thereafter, Vice President Kamala Harris declared her candidacy for president and received endorsements from President Biden and many others. All focus now is on her choice of running mate. The frontrunners appear to be North Carolina Gov. Roy Cooper and Pennsylvania Gov. Josh Shapiro.

The remainder of the election cycle will be a preview of how healthcare is platformed. From her time in the Senate, Vice President Harris has focused on maternal health, reproductive rights, expanding drug price negotiations and limiting drug price increases. She views the Inflation Reduction Act (IRA) drug negotiation as a significant achievement and has advocated for "march-in rights" under the Bayh-Dole Act to seize patents of certain high-priced medicines.

Also of note, Republican presidential candidate Donald Trump recently selected Sen. J.D. Vance (R-Ohio) as his running mate. Sen. Vance, who was first elected to the Senate in 2022, does not currently serve on any committees with healthcare jurisdiction. However, his legislative record on health issues includes introducing legislation to prohibit minors from receiving access to gender-affirming medical care (S. 2357) and to add childbirth as a protected reason for not returning to work under the amended Family and Medical Leave Act (S. 3048). He is also a cosponsor of the Affordable Insulin Now Act (S. 954), which aims to cap commercial insulin costs at \$35. Additionally, Sen. Vance has introduced legislation to exclude Deferred Action for Childhood Arrivals (DACA) recipients from accessing health insurance under the Affordable Care Act. He supports allowing Medicare to negotiate prescription drug prices and has called for the importation of drugs from overseas.

LEGISLATIVE UPDATES

Hearings This Week

The House Committee on Veterans' Affairs [held a hearing](#) on July 22, 2024, assessing the modernization of electronic health records.

The House Committee on Oversight and Accountability [held a hearing](#) on July 23, 2024, on "The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part III: Transparency and Accountability."

The House Committee on Energy and Commerce's Subcommittee on Health [held a hearing](#) on July 23, 2024, on restoring public trust in the Centers for Disease Control and Prevention (CDC).

Additionally, the Senate Committee on Health, Education, Labor and Pensions (HELP) [will hold a markup](#) with potential for drug pricing legislation on July 25, 2024.



Also of note, the House Committee on Administration [held a hearing](#) on July 23, 2024, "Congress in a Post-Chevron World," that discussed the *Loper Bright* decision's impact on the congressional process, with its witnesses offering ideas for congressional oversight of agencies and how to bolster congressional authority logistically.

House Oversight Committee Releases PBM Report

The pharmacy benefit managers (PBMs) [report](#), which is just over 50 pages, concludes that "patients are seeing significantly higher costs with fewer choices and worse care." The article argues that PBMs inflate prescription drug costs and interfere with patient care for their own financial benefit. This comes as multiple committees in both the House and Senate have held hearings and produced legislation, some of which has gone through some phases of the legislative process. With the limited number of working days left for Congress, legislators would have to move expeditiously to pass any such legislation by the end of the year.

Senators Form Working Group to Assess Post-Chevron Legislative Landscape

A group of senators, led by Sen. Eric Schmidt (R-Mo.), has launched a working group to evaluate the current policy environment and discuss how the Senate can most effectively legislate following the U.S. Supreme Court's *Loper Bright* decision to overturn the *Chevron* deference. The group plans to send letters to 101 federal agencies, including the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA), concerning more than 50 regulations finalized since 2000. The working group will request information from regulators about how ongoing rulemaking, civil enforcement actions and adjudications are affected by the recent Supreme Court decision.

REGULATORY UPDATES

FDA Launches Joint Rare Disease Innovation Hub

The FDA has launched a new [Rare Disease Innovation Hub](#) that aims to bring various invested parties of the rare disease community together to inform system improvements. The Hub will be co-led by the Directors of the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) and in close collaboration with FDA's Center for Devices and Radiological Health, Oncology Center of Excellence, Office of Orphan Products Development and Office of Combination Products. The Hub will work in conjunction with activities of the CDER Accelerating Rare Disease Cures program and CBER Rare Disease Program and will build on lessons learned from various pilot programs across the agency such as the Rare Disease Endpoint Advancement (RDEA) Pilot Program and the Support for Clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program.

FTC Releases PBM Report

The Federal Trade Commission's [interim PBM report](#) is a part of an ongoing study of PBMs and their impact on access to and affordability of medicines. According to the report, PBMs paid their own pharmacies significantly more than other pharmacies. The FTC asserted in the report that "PBM business practices and their effects remain extraordinarily opaque." The report suggests that vertical integration is a perpetuating factor of unfair practices, alongside consolidation and rising opacity in pricing practices. The report also found that the six largest PBMs account for 95 percent of prescriptions. Responses to the report have been mixed, with critics of the PBM industry stating that the report alone will not catalyze the changes necessary.



Former HHS Officials Propose AI Framework

Former ONC National Coordinator David Blumenthal and former FDA Digital Health Chief Bakul Patel released [an article](#) in the *New England Journal of Medicine* outlining a new regulatory framework to clinical utilization of generative artificial intelligence (AI). The study "reviews approaches in the United States to regulating pregenerative clinical AI and examines a novel possible approach to GAI regulation."

Microsoft Outage Impacts Hospitals

The Microsoft outage that occurred last week didn't just impact flights; Various health systems across the country experienced significant technological system outages with tools such as electronic health records and online portals. This forced certain hospitals to delay non-emergent procedures and surgeries. Some problems persist, including lingering issues with clinical applications and work systems.