



# H&K Health Dose: June 11, 2024

## A weekly dose of healthcare policy news

The U.S. Senate and U.S. House of Representatives are in session this week, with floor and committee-level activity in both the House and Senate expected. The House is set to consider the National Defense Authorization Act (NDAA), which may include the BIOSECURE Act, at the House Committee on Rules meeting on June 11, 2024, with a vote expected later in the week. Pending the Congressional Budget Office (CBO) scoring feedback by June 12, 2024, the House Committee on Energy and Commerce (E&C) will hold a [full committee markup](#) of 13 pieces of legislation, including pharmacy benefit manager (PBM) reform and the Accelerating Kids' Access to Care Act. The committee will not mark up legislation unanimously approved by the House E&C Committee's Subcommittee on Health from May 2024 (41-0) that would extend telehealth flexibilities for two years.

Additionally, the House E&C Committee postponed the markup of the American Privacy Rights Act, which was scheduled for this week.

Last week, House Committee on Appropriations Chair Tom Cole (R-Okla.) updated the markup schedule for Fiscal Year (FY) 2025 appropriations bills. A previously announced markup schedule included a subcommittee markup for the FY 2025 Commerce, Justice, Science and Related Agencies Bill on June 12, 2024. Due to scheduling conflicts with the Congressional Baseball Game, that bill will be marked up in subcommittee on June 26, 2024. The Agriculture-FDA funding bill text has been released, and the subcommittee markup occurred on June 11, 2024.

## Hearings

The Centers for Medicare & Medicaid Services (CMS) Office of Minority Health will co-host with the Centers for Disease Control and Prevention (CDC) Office of Health Equity a virtual forum on the healthcare workforce and incorporating health equity on June 12, 2024, at 11 a.m. The House E&C Committee's Subcommittee on Health will hold a hearing, "Checking-In on CMMI: Assessing the Transition to Value-Based Care," on June 13, 2024. Additionally, the House Budget Committee will hold a hearing, "[Medicare and Social Security: Examining Solvency and Impacts to the Federal Budget.](#)" The U.S. Food and Drug Administration's (FDA) Oncology Center of Excellence will [hold a webinar](#) on June 14, 2024, in its Conversations on Cancer series as part of the Annual National Black Family Cancer Awareness Week initiative, focused on reducing disparities in preventative health and clinical trial participation.

## LEGISLATIVE UPDATE

### Sen. Wyden Calls for Stricter Cybersecurity Measures

Senate Committee on Finance Chair Ron Wyden (D-Ore.) is calling on the U.S. Department of Health and Human Services (HHS) to enforce stricter cybersecurity measures for large healthcare companies. Wyden attributes the February 2024 cyberattack on Change Healthcare, deemed the worst in U.S. health sector history, to HHS' inadequate regulation of cybersecurity practices among major providers like UnitedHealth Group (UHG). He proposes that HHS 1) enforce mandatory minimum technical cybersecurity standards for systemically important entities (SIEs), 2) impose resiliency requirements on SIEs, 3) perform regular cybersecurity audits on covered entities and business associates under Section 13411 of the HITECH Act and 4) offer technical cybersecurity assistance to healthcare providers.

### Sen. Warren Sends Letter to HHS, DOJ, FTC

Last week, Sen. Elizabeth Warren (D-Mass.) sent a letter to HHS, U.S. Department of Justice (DOJ) and Federal Trade Commission (FTC), thanking them for their efforts to "address the corporatization of health care, including DOJ's reported antitrust investigation into UnitedHealth, FTC's suit against U.S. Anesthesia Partners and its private equity parent company over alleged anticompetitive practices and its recently finalized rule banning noncompete provisions in contracts, and HHS's appointment of a Chief Competition Officer and rules reining in abusive prior authorization and marketing practices in Medicare Advantage (MA) and requiring greater ownership transparency for long-term care facilities." She urged the agencies to "continue to closely scrutinize, promulgate regulations regarding, and take appropriate enforcement actions against vertically integrated insurers, private equity firms, and pharmaceutical companies that are driving health care consolidation."



## Multi-Stakeholder Coalition Puts Pressure on Senate Finance Committee to Hold Hearing

The coalition – which consists of almost 50 organizations, including healthcare workers, businesses, unions and advocates – wants the Senate Finance Committee to host a hearing on several policies that they say contribute to rising healthcare costs and decreased patient access. They call for permanence of the enhanced Advanced Premium Tax Credits (APTCs), previously extended through December 2025, and site-neutral payments for drug administration, which require that off-campus hospitals' outpatient departments use separate provider identifiers when billing Medicare or private issuer. They also ask the committee to consider making permanent the enhanced Affordable Care Act (ACA) tax credits. CBO most recently estimated that making the ACA credits permanent would cost \$383 billion, but supporters of this action say it will save the healthcare system over time and will minimize premium increases.

## REGULATORY UPDATES

### FDA'S CDER Launches EDSTP

The Center for Drug Evaluation and Research (CDER) announced on June 10, 2024, the establishment of the [Emerging Drug Safety Technology Program \(EDSTP\)](#), a new center focused on the use of artificial intelligence (AI) and other emerging technologies in pharmacovigilance (PV). EDSTP is part of the CDER's multifaceted approach to enhance mutual learning of where and how specific innovations, such as AI, can be best used across the drug product lifecycle. Program [details published](#) in the *Federal Register* on June 11, 2024, state that meeting requests to discuss the use of AI between drug regulators and academia, contract research organizations, vendors and software developers are open as of June 11, 2024.

### Medicare DSH Calculations to Receive SCOTUS Review

The current HHS Disproportionate Share Hospital (DSH) Program payment calculation practice of counting patients who receive Supplemental Security Income (SSI) benefits will be considered by the U.S. Supreme Court. This case follows a prior case from 2022 in which the primary question regarded the distinction between beneficiaries who are entitled versus eligible to receive Medicare benefits. That case upheld that HHS can exclude patients who have exhausted their Medicare Part A benefits from a hospital's DSH payments. However, some hospitals are arguing that the current payment calculation goes against that ruling.

### Drug Shortages: FDA Report and Potential Regulatory Route

Last week, the FDA released its [annual report](#) on drug shortages for Calendar Year (CY) 2023. In the report, the FDA highlighted the legislative proposals it put forth in the FY 2025 proposed budget that would include "authorities intended to promote the Agency's response efforts, such as requirements for manufacturers both to notify FDA of an increase in demand that the manufacturer likely will be unable to meet without meaningful shortfall or delay and to provide manufacturing volume and supplier information."

Additionally, various industry stakeholders have suggested the upcoming Healthcare System Resiliency and Modernization (HSRM) rule as an avenue to address drug shortage concerns without requiring legislative action through adjustments to the Medicare conditions of participation. These conversations have increased as plausibility of a legislative pathway shrinks.