



H&K Health Dose: June 18, 2024

A weekly dose of healthcare policy news

The U.S. Senate will be in session this week (with the exception of June 19, 2024) and will be in recess from June 24-July 5, 2024. When the Senate returns, members are expected to begin marking up fiscal year (FY) 2025 appropriations bills.

The U.S. House of Representatives is not in session this week.

LEGISLATIVE UPDATES

MA Electronic Prior Authorization Legislation Reintroduced

Sen. Roger Marshall (R-Kan.) reintroduced the [Improving Seniors' Timely Access to Care Act \(S. 4532\)](#) legislation on June 12, 2024, that would require Medicare Advantage (MA) plans to implement an electronic prior authorization program and impose a number of prior authorization transparency and reporting requirements.

A previous iteration of this measure, passed unanimously by the House last Congress, was stalled due to a \$16 billion Congressional Budget Office (CBO) cost estimate. Centers for Medicare & Medicaid Services (CMS) regulations on prior authorization issued in January 2024 reduced the cost estimate, but the measure was still expected to score. Specifically, CBO pointed to two provisions of the legislation – a "real-time" decision requirement and expedited determination requirements – that were removed and replaced with cost-neutral alternatives in the 2024 reintroduced bill. As introduced, the new measure has a \$0 CBO cost estimate.

BIOSECURE Act NDAA Amendment

The House Committee on Oversight and Accountability advanced the [BIOSECURE Act \(H.R. 8333\)](#) in May 2024 with bipartisan support. The legislation would prohibit Chinese biotechnology companies of concern from receiving federal contracts, grants or loans and is aimed at blocking foreign governments from accessing Americans' health and genomic data. The [Senate version of the bill \(S. 3558\)](#) was approved by the Committee on Homeland Security & Governmental Affairs earlier this year. An amendment containing this legislation was dropped from the House Committee on Rules' list of FY 2025 National Defense Authorization Act (NDAA) amendments to be considered on the House floor.

NIH Reform Proposals

Republicans on the House Committee on Energy and Commerce (E&C) released a [proposed framework](#) on June 14, 2024, for National Institutes of Health (NIH) reform that would "streamlining the currently existing 27 NIH Institutes and Centers (ICs) into 15 revised Ics." This framework mirrors a [white paper](#) released by the Senate Committee on Health, Education, Labor, and Pensions (HELP) in May 2024. The House proposal includes an expanded prohibition on NIH-conducted or supported "gain of function" research in countries designated as foreign adversaries. Gain of function research continues to be the focus of a series of committee hearings; On June 18, 2024, the Senate Homeland Security Committee convened for a hearing, "[Origins of COVID-19: An Examination of the Available Evidence.](#)"

Senators Send Letter on Change Healthcare Data Breach Notifications

Sens. Maggie Hassan (D-N.H.) and Marsha Blackburn (R-Tenn.) sent a letter on June 7, 2024, urging the CEO of the payor impacted in the Change Healthcare cyberattack to "quickly assume responsibility for informing patients, providers, and federal and state regulators about the patient data that was exposed in the February ransomware attack on Change Healthcare" and alleging that the company "continues to be in violation of the Health Information Portability and Accountability Act (HIPAA), which requires covered entities to notify individuals of a known or suspected data breach within 60 days of discovering the breach." The letter calls on the payer to send out all data breach notifications no later than June 21, 2024.



House E&C Committee Marks Up Medicaid, Telehealth, Public Health Legislation

The House E&C Committee held a [full committee markup](#) on June 12, 2024, of 13 pieces of legislation. The panel voted to approve each of the measures under consideration, including the Honor Our Living Donors Act (H.R. 6020), which would prevent an organ recipient's income from being considered when providing reimbursement for qualifying expenses incurred by a living organ donor during the donation process, and an amended version of the Accelerating Kids' Access to Care Act (H.R. 4758), which would implement a ban on spread pricing by pharmacy benefit managers (PBMs) in Medicaid as a pay-for. The spread pricing ban is similar to the ban included in the House-passed Lower Costs, More Transparency Act, as well as in the Modernizing and Ensuring PBM Accountability Act (MEPA), which passed the Senate Finance Committee 26-1 in July 2023. A full list of [legislation considered at the hearing](#) is available on the committee's website.

House E&C Committee Hearing on CMMI Activities

On June 13, 2024, the House E&C Committee's Subcommittee on Health [conducted a hearing](#) to investigate the impact of Center for Medicare and Medicaid Innovation (CMMI) activities on the federal budget. Specifically, the subcommittee examined the disparity between initial projected savings and the September 2023 U.S. Government Accountability Office (GAO) estimate, which indicated CMMI activities resulted in a net increase of \$5.4 billion in direct spending. CMMI's failure to generate expected cost-savings led some members to scrutinize the design, testing and implementation of pilot programs, while others suggested CMMI achieved success in measures outside net-budget calculations.

Diabetes and Weight Loss Drug Manufacturer to Testify at Senate HELP Hearing

Senate HELP Committee Chair Bernie Sanders (I-Vt.) announced last week a vote to compel the manufacturer of type-2 diabetes and obesity drugs to appear before the committee at an expected July 2024 hearing. Following this announcement, the company's North America president agreed to testify at a solo panel. The hearing is now expected to take place in September 2024.

Senate Finance Committee Hearing on Social Security Disability Programs

The Senate Committee on Finance convened on June 18, 2024, for a hearing, "[Work and Social Security Disability Benefits: Addressing Challenges and Creating Opportunities](#)," – legislation to update "woefully out-of-date" Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI) eligibility rules and to "simplify the administration of Social Security disability programs."

Retirements

Rep. Garret Graves (R-La.) announced on June 14, 2024, that he will not seek re-election, following congressional redistricting in Louisiana that impacted his district.

REGULATORY UPDATES

CMS Releases 2023-2032 National Health Expenditure Projections

CMS released the 2023-2032 National Health Expenditures (NHE) and health insurance enrollment projections on June 12, 2024. According to the report, average annual growth in NHE will outpace average annual growth in gross domestic product (GDP) by 1.3 percent. The average annual growth in healthcare spending is estimated to be at 5.6 percent, lower than in 2023 when NHE growth was projected to have been 7.5 percent. According to CMS, the surpassing of GDP over NHE reflects "broad increases in the use of care associated with an insured share of the population of 93.1 percent (an unprecedented high)." The report evaluates impacts of the Inflation Reduction Act (IRA) including drug pricing negotiations, Medicare Part D redesign and enrollment trends relative to the IRA's temporary extension of additional subsidies for plans. The [press release](#), a [full report](#) and [accompanying journal article](#) can be found online.



Coalition Responds to FTC, HHS, DOJ Joint RFI on Healthcare Consolidation

A coalition of nearly 100 organizations – including physician groups, trade unions and disability advocacy groups – [recently wrote](#) to Federal Trade Commission (FTC) Chair Lina Kahn, Secretary of the U.S. Department of Health and Human Services (HHS) Xavier Becerra and Assistant Attorney General for the U.S. Department of Justice (DOJ) Jonathan Kanter in response to the three agencies' recent [RFI on Consolidation in Healthcare Markets](#). The letter urges the Biden Administration to increase regulatory oversight and enforcement of private equity firms in the healthcare system, calls for increased transparency and increased alignment of MA payments and quality measurement.

CMS MA Star Rating Recalculation and Resubmission Ability

Following litigation wins for insurers on the issue, CMS announced last week that they will recalculate 2024 MA star ratings and let plans with increased scores resubmit their 2025 contract bids by June 18, 2024. The action has received expected praise as a "win for beneficiaries" from leaders in the private insurance marketplace.

CMS Updates Coverage to Care (C2C) Resources

The CMS Office of Minority Health (CMS OMH) and Division of Tribal Affairs (DTA) released a newly updated Coverage to Care (C2C) [Roadmap to Better Care: Tribal Version](#), aimed to better address the specific health needs of Native Americans and Alaska Natives. Additions to this resource include:

- a new introduction that details the unique health protections in place for Native Americans and Alaska Natives
- an updated glossary of terms
- important links and contact information for Native Americans and Alaska Natives
- updated imagery to enhance connection and inclusivity

NOFO Application Period Announced for IBH Model

CMS announced on June 17, 2024, the release of the [Notice of Funding Opportunity \(NOFO\) application](#) for the Innovation in Behavioral Health (IBH) Model. The model seeks to integrate behavioral and physical healthcare by incentivizing specialty behavioral health practices and aligning payment for Medicare and Medicaid under the leadership of state Medicaid agencies (SMAs). Up to eight SMAs will be selected for participation with funding specified for health information technology (HIT), electronic health records (EHRs), practice transformation and staffing necessary to implement the model. This model reflects the recent call from CMMI model participants for advanced model infrastructure incentives. The IBH [model general fact sheet](#) is available online, as well as a [fact sheet tailored to SMAs](#).

DEA Telehealth Developments

The U.S. Drug Enforcement Administration's (DEA) proposed rules on the prescribing of controlled substances have reached the U.S. Office of Management and Budget (OMB), igniting conversation around the future of telehealth prescribing for certain substances currently permitted under COVID-era telehealth flexibilities that are set to expire at the end of 2024. The flexibilities temporarily lifted restrictions on the virtual prescribing of controlled substances without requiring an in-person visit.

This process update comes as two telehealth company executives were indicted last week on charges of a "distribution and health care fraud scheme" that drew criticism of the industry. Industry leaders were quick to communicate that the alleged behavior was not reflective of the telemedicine industry as a whole.

The U.S. Food and Drug Administration's (FDA) [legislative proposals](#) for FY 2025 center around increased authority requests that the agency says would help address medical product shortages and build supply chain resiliency. The proposals include increased oversight of dietary supplements, updates to tobacco user fee assessments and increased information sharing across states. Pillars of the proposals include competition, innovation, data, information, post-market safety and medical product shortages.