Impact Health Policy Weekly

Framing the Week

The House is on recess until September 9, calling it quits a week earlier than planned after it became clear that they could not pass any additional appropriations bills. They managed to move five of the 12 annual spending bills, but with a slim majority and several Republican hold outs, Speaker Mike Johnson (R-LA) pulled the remaining bills and recessed for the summer. The Senate Appropriations Committee is expected to finish marking up the last of their fiscal year 2025 bills this week, but floor action is not going to happen anytime soon. When Congress returns, they will need to pass a Continuing Resolution (CR) to fund the government past September 30, the end of the fiscal year. It is expected the CR will run through the elections, but it is unclear if Speaker Johnson will push for a December date, or for the CR to go into next year.

For the last days of session before summer recess, this week the Senate will consider a package of online safety bills that include the Kids Online Safety Act (KOSA) and the Children's Online Privacy Protection Act (COPPA) that are meant to hold Big Tech companies accountable for the harms their platforms can inflict on minors.

Hearings and Markups

- **Senate Banking Committee:** On Tuesday the Senate Banking, Housing, and Urban Affairs Subcommittee on Economic Policy will hold a hearing to examine banning noncompete agreements, focusing on benefits for workers, businesses, and the economy.

- **Senate HELP Committee:** On Wednesday the Senate Health, Education, Labor, and Pensions Committee will hold a markup to consider S.4776, to amend the Older Americans Act of 1965 to authorize appropriations for FY 2025 through 2029, S.4762, to amend the Public Health Service Act to reauthorize programs and research relating to autism, and S.4755, to reauthorize traumatic brain injury programs.

- **Senate Commerce, Science and Transportation Committee:** On Wednesday the Senate Commerce Committee will hold a markup of more than 30 bills including eight measures on artificial intelligence (AI)-related issues such as the CREATE AI Act to establish a national research hub, the TEST AI Act, and the AI Research, Innovation and Accountability Act.

- **Senate Appropriations Committee:** On Thursday the Senate Appropriations Committee will hold a markup of the Energy and Water Development and Related Agencies Appropriations Act, the Defense Appropriations Act, the Departments of Labor, Health and Human Services, and

Education, and Related Agencies Appropriations Act, the Department of Homeland Security Appropriations Act, and the Financial Services and General Government Appropriations Act.

New Data and Health Technology Administration

Last week the Department of Health and Human Services (HHS) announced that the technology and data policy and strategy role of the Assistant Secretary for Administration will be moved to the Office of the National Coordinator for Health Information Technology (ONC). HHS intends for the reorganization to better align technology, cybersecurity, data, and artificial intelligence (AI) strategy and policy. ONC will now have dual names as the Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology (ASTP/ONC). ASTP/ONC will include the Office of Policy, Office of Standards, Certification, and Analysis, Office of the Chief Operating Officer, and Office of the Chief Technology Officer. The Office of the Chief Technology Officer will include the Office of the Chief AI Officer, Office of the Chief Data Officer, and a new Office of Digital Services. Finally, the 405(d) public-private partnership on cybersecurity will move to the Assistant Secretary for Preparedness and Response (ASPR).

Regulatory Update

The Office of Management and Budget (OMB) completed reviewing several final rules for Medicare FY 2025 payment updates to skilled nursing facilities, inpatient rehabilitation facilities, hospice providers, and psychiatric facilities

OMB is reviewing the following rules:

Medicare
- **Fiscal Year (FY) Payment Updates** – The FY 2025 final rules for hospitals and long-term care hospitals (August 2024).

Medicaid
- **Drug Rebate Program** – The final rule would establishes requirements related to manufacturers' misclassification of covered outpatient drug products under the Medicaid Drug Rebate Program (MDRP). In addition, it finalizes beneficiary protections, as well as MDRP program integrity and administration changes (June 2024).

Private Insurance
- **ACA Marketplace** – The proposed rule would set payment parameters and provisions related to the risk adjustment programs; cost-sharing parameters; and user fees for issuers offering plans on Federally-facilitated Exchanges and State-based Exchanges using the Federal platform. It would also provide additional standards for several other ACA programs (September 2024).

Other Topics:

- **Healthcare System Resiliency and Modernization** – The proposed rule would revise and update national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers (was set for December 2023).
- **Tobacco Control** – The final rule would prohibit the sale of tobacco products to persons younger than 21 years of age (was set for April 2024).
- **Retail Pharmacy Standards** – The final rule would require pharmacies and vendors to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version 10 (was set for February 2024).

This Week in Health Policy

Mon. (7/29)

- **10:00am – Paragon Discussion: Medicare Site-Neutral Payments –** The Paragon Health Institute holds a discussion with former Department of Health and Human Services (HHS) Secretaries Alex Azar and Kathleen Sebelius on reasons for site neutral payments in Medicare, focusing on reducing health care costs for patients and taxpayers. Details.

Tue. (7/30)

- **11:00am – HITAC Meeting: HTI-2 Proposed Rule Task Force –** The Health Information Technology Advisory Committee (HITAC) holds a meeting of the HTI-2 Proposed Rule Task Force to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. This meeting of Group 1 will be focusing on: Existing public health certification criteria. Details.
- **2:30pm – Hearing: Noncompete Agreements –** The Senate Banking, Housing, and Urban Affairs Subcommittee on Economic Policy holds a hearing to examine banning noncompete agreements, focusing on benefits for workers, businesses, and the economy. Details.

Wed. (7/31)

- **10:00am – Markup: Older American Support, Autism Research, and Traumatic Brain Injury Programs –** The Senate Health, Education, Labor, and Pensions Committee holds a markup to consider S.4776, to amend the Older Americans Act of 1965 to authorize appropriations for FY 2025 through 2029, S.4762, to amend the Public Health Service Act to reauthorize programs and research relating to autism, and S.4755, to reauthorize traumatic brain injury programs. Details.
- **10:00am – Markup: AI –** The Senate Commerce, Science and Transportation Committee holds a markup of more than 30 bills including eight measures on artificial intelligence (AI)-related issues such as the CREATE AI Act to establish a national research hub, the TEST AI Act, and the AI Research, Innovation and Accountability Act. Details.

- **10:00am – CSIS Discussion: U.S. Vision for AI Safety** – The Center for Strategic and International Studies (CSIS) holds a discussion with Elizabeth Kelly, Director of the National Institute of Standards and Technology's (NIST) AI Safety Institute on the Institute's strategic vision and its activities under President Biden's AI Executive Order. Details.
- **11:00am – HITAC Meeting: HTI-2 Proposed Rule Task Force** – HITAC holds a meeting of the HTI-2 Proposed Rule Task Force to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. This meeting of Group 2 will be focusing on: Modular API capabilities certification. Details.
- **1:00pm – R Street Discussion: Federal Cyber Regulatory Harmonization** – The R Street Institute holds a discussion on the goal of cybersecurity regulatory harmonization, including how baselines might be developed, and how to move forward with the number of federal agencies and independent regulators involved. Sen. Gary Peters (D-MI) will be participating. Details.
- **2:00pm – Hearing: Birth Behind Bars** – The Senate Judiciary Subcommittee on Human Rights and the Law holds a hearing to examine birth behind bars. Details.

Thurs. (8/1)
- **9:00am – CSIS Discussion: Naloxone Over-the-Counter Access** – CSIS holds a discussion with Rahul Gupta, Director of the White House Office of National Drug Control Policy, and Rep. Ann McLane Kuster (D-NH), on the lessons and gains of the past year since the Biden Administration approved over-the-counter (OTC) sale of naloxone, the drug that reverses life-threatening opioid overdoses. Details.
- **9:30am – Markup: Senate Appropriations** – The Senate Appropriations Committee holds a markup of the Energy and Water Development and Related Agencies Appropriations Act, the Defense Appropriations Act, the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, the Department of Homeland Security Appropriations Act, and the Financial Services and General Government Appropriations Act. Details.
- **11:00am – HITAC Meeting: HTI-2 Proposed Rule Task Force** – HITAC holds a meeting of the HTI-2 Proposed Rule Task Force to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. This meeting of Group 3 will be focusing on: Information Blocking Enhancements. Details.
- **3:30pm – CMS Meeting: CMS Strategic Plan** – The Centers for Medicare and Medicaid Services (CMS) holds its third CMS Leadership National Call Update in 2024 to provide an update on how cross-cutting initiatives are advancing the CMS Strategic Plan and how stakeholders can partner with CMS to implement the plans and key initiatives. Details.

Additional Multi-Day Events
- **Aug 1-Aug 2 – HRSA Meeting: Medicine/Dentistry Diversity/Equity/Inclusion** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry for upskilling clinicians to serve in underserved areas; diversity, equity, and inclusion; integrated medical and dental training models; and

matters pertaining to policy, program development, and other matters of significance concerning medicine and dentistry activities. Details.

Featured Analysis

- ***NEW* Impact Regulatory Outlook: Spring 2024 Unified Agenda** – In the Policy Hub Insight Bank here.
- **Making Sense of the New Landscape for Health Policy After Recent Supreme Court Decisions** – In the Policy Hub Insight Bank here.
- **Impact Mental Health Legislative Update** – In the Policy Hub Insight Bank here.
- **Impact Roundup of Behavioral Health Administrative Actions** – In the Policy Hub Insight Bank here.
- **Impact Chart of Key Provisions of Legislative Proposals on Health Care Price Transparency Requirements** – In the Policy Hub Insight Bank here.

Congressional Lookback

Weds. (7/24)
- **Sens. Durbin (D-IL) and DeLauro (D-CT)** introduced the Federal Food Administration Act of 2024 to create a separate agency responsible for oversight of food safety and foodborne illness. Details.

Tues. (7/23)
- **The House Committee on Oversight and Accountability** convened its third hearing on the role of PBMs in prescription drugs markets. Details.
- **The Committee on House Administration** convened a hearing to examine the implications of the recent Supreme Court decision in *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce* which overturned the Chevron Deference doctrine. Details.

Regulatory Lookback

Fri. (7/26)
- **The GAO** released a report evaluating actions taken by selected jurisdictions for COVID-19 isolation and quarantine, federal support provided, and the CDC's evaluation processes. Details.

Thurs. (7/25)
- **SAMHSA** announced $45.1 million to programs aimed at further improving behavioral health. Details.

Weds. (7/24)

- **CMMI** held a webinar to review the financial methodology and describe changes in version 2.0 of the Medicare FFS hospital global budgets (HGBs) for the AHEAD Model. Details.
- **ONC** released the US Core Data for Interoperability Version 5 (USCDI v5) with new data classes and data elements. Details.

Tues. (7/23)

- **The Biden Administration** distributes new information for youth online safety and Medicaid and CHIP services for incarcerated youth. Details.

Comment & Application Deadlines

- **July 29:** CMS released a proposed rule to mitigate the impact of significant, anomalous, and highly suspect billing activity involving intermittent urinary catheters on financial calculations in CY 2023 for ACOs participating in the MSSP. Details.
- **July 31:** AHRQ issued an RFI on new strategies to advance interoperable, shareable, and reusable clinical decision support resources. Details.
- **July 31:** ONC announced a new data initiative to support maternal health. Details.
- **August 12:** The CFPB issued a proposed rule aimed at eliminating medical bills from most credit reports. Details.
- **August 15:** CMS is seeking nominations to the Advisory Committee on Immunization Practices. Details.
- **August 17:** CMS released a notice of funding opportunity for the Expanding Access to Women's Health Grant. Details.
- **August 20:** SAMHSA is seeking applications for the Women's Behavioral Health Technical Assistance Center (Women's BH TAC) program for fiscal year 2024. Details
- **August 26:** CMS issued the CY 2025 home health prospective payment and rate update proposed rule. Details.
- **August 26:** CMS released its CY 2025 end-stage renal disease (ESRD) prospective payment system (PPS) proposed rule. Details.
- **September 2:** CMS released an ICR for the Negotiation Data Elements and Drug Price Negotiations Process for IPAY 2027 of the Medicare Drug Price Negotiation Program. Details.
- **September 7:** The FDA released draft Q&As to address misinformation about medical devices and prescription drugs. Details.
- **September 9:** CMS released the CY 2025 MPFS proposed rule. Details.
- **September 9:** CMS released the CY 2025 OPPS/ASC proposed rule. Details.

- **September 20:** CMS released a notice of funding opportunity (NOFO) for the Transforming Maternal Health (TMaH) Model. Details.
- **September 26:** The FDA issued draft guidance entitled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies." Details.
- **September 30:** The CDC is seeking nominations for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). Details.
- **February 25:** CMMI released an RFA for the Cell and Gene Therapy Access Model. Details.