# Impact Health Policy Weekly

## Framing the Week

With a mere 14 weeks to go before the presidential election, this morning we find ourselves without an official Democratic candidate!  President Joe Biden withdrew from the race yesterday afternoon and has endorsed his vice president Kamala Harris to be the Democratic nominee.  In the next two weeks the Democratic party is expected to take a virtual roll call vote of the 3900 delegates to decide a new nominee.  Notable party leaders, potential running mates, state party delegations and Congressional Democrats have all endorsed Harris, and as the only candidate that can tap into the campaign war chest that the Biden-Harris campaign has built it will be a steep hill for any challenger to climb.  But, if Harris does not secure the majority of the 3900 delegate votes, the upcoming Democratic convention will be an open convention where delegates decide who to nominate.  An unprecedented time in modern American politics, the next several days and weeks will be important in shaping both the Democratic party and the election.

The House comes back into session today and the Senate returns tomorrow for the final two weeks before the August recess.  Israeli Prime Minister Benjamin Netanyahu is scheduled to give a joint Congressional address on Wednesday afternoon and the House leadership continues to push movement on fiscal year (FY) 2025 appropriations bills.

Prime Minister Netanyahu is expected to meet with both House and Senate leaders, as well as President Biden and Vice President Harris.  A number of Democrats, most notably Sen. Bernie Sanders (I-Vt.), have stated they will not attend the speech over Netanyahu's handling of the war in Gaza following the October 7 attacks by Hamas.

Also this week, House leadership will continue to try and move appropriations bills on the House floor, including the Energy & Water, Interior, Financial Services and Agriculture bills.  The goal to move all 12 bills through the floor before the August recess hit a snag when the Legislative bill failed to pass earlier this month.  With the notoriously difficult Labor-HHS bill and the politically charged Commerce-Justice-Science bills still to go, it may prove difficult to get through all 12 bills on schedule.

The Senate Appropriations Committee is scheduled to continue marking up their FY 2025 bills this week with the Commerce-Justice-Science, State and Foreign Operations, and Transportation-HUD bills.  At the end of this week, the Committee will have marked up 6 of the 12 bills.

**Hearings and Markups**

**House Oversight and Accountability Committee:** On Tuesday the House Oversight and Accountability Committee will hold a hearing to examine Pharmacy Benefit Managers' (PBMs) role as middlemen in rising health care costs, focusing on anticompetitive policies which can potentially increase prescription drug costs, hurt independent pharmacies, and harm patient care.

**House Administration Committee:** On Tuesday the House Administration Committee will hold a hearing title "Congress in a Post-Chevron World."

**House Energy & Commerce Committee:** On Tuesday, the House Energy and Commerce Health Subcommittee will hold a hearing to examine the Centers for Disease Control and Prevention's (CDC) current priorities and hear directly from CDC officials what steps the agency is taking to regain public trust.

**Senate Homeland Security and Government Affairs Committee**: On Wednesday the Senate Homeland Security and Governmental Affairs Committee will hold a markup of several AI and cybersecurity bills, including: S. 4495, Promoting Responsible Evaluation and Procurement to Advance Readiness for Enterprise-wide Deployment (PREPARED) for Artificial Intelligence Act; S. 4630, Streamlining Federal Cybersecurity Regulations Act; S. 4697, Healthcare Cybersecurity Act of 2024; and S. 4715, Federal Cyber Workforce Training Act of 2024.

**Other Recent Announcements**

- **Medicare Data:** The Medicare Payment Advisory Commission (MedPAC) released its annual data book, "Health Care Spending and the Medicare Program." The data include information about national health care and Medicare spending, Medicare beneficiary demographics, Medicare beneficiary and other payer financial liability, dual-eligible beneficiaries, alternative payment models, acute inpatient services, ambulatory care, post-acute care, Medicare Advantage, prescription drugs, and other services.
- **ACA Marketplace Survey:** The Centers for Medicare and Medicaid Services published the Final 2024 Call Letter for the Quality Rating System (QRS) and Qualified Health Plan Enrollee Experience Survey (QHP Enrollee Survey). The document communicates CMS' finalized refinements to the QRS and QHP Enrollee Survey programs. No changes are being made at this time to CMS regulations; instead, the refinements apply to QRS and QHP Enrollee Survey program operations, to the QRS measure set, and revisions to the QHP Enrollee Survey protocol.

**Regulatory Update**

The Office of Management and Budget (OMB) is currently reviewing the following rules:

**Medicare**

- **Fiscal Year (FY) Payment Updates** – The FY 2025 final rules for hospitals and long-term care hospitals, skilled nursing facilities, inpatient rehabilitation facilities, hospice providers, psychiatric facilities (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. (7/22)**

- **12:00pm – HITAC Meeting: Annual Report Workgroup** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to discuss program updates. Details.

**Tue. (7/23)**

- **9:30am – Field Hearing: Health Impacts of Abortion Ban on Georgia Women** – The Senate Judiciary Subcommittee on Human Rights and the Law holds a field hearing to examine the health impacts on women of Georgia enacting one of the most restrictive abortion bans in the country, banning women from abortion after six weeks. Details.
- **10:00am – Hearing: Role of PBMs in Prescription Drug Markets** – The House Oversight and Accountability Committee holds a hearing to examine Pharmacy Benefit Managers' (PBMs) role as middlemen in rising health care costs, focusing on anticompetitive policies which can potentially increase prescription drug costs, hurt independent pharmacies, and harm patient care. Chief executives from CVS Caremark, Express Scripts, and OptumRx are set to testify. Details.
- **10:15am – Hearing: Congress' Regulatory Role Post Chevron** – The House Administration Committee holds a hearing title "Congress in a Post-Chevron World." Details.
- **10:30am – Hearing: CDC's Priorities Restoring Public Trust** – The House Energy and Commerce Health Subcommittee holds a hearing to examine the Centers for Disease Control and Prevention's (CDC) current priorities and hear directly from CDC officials what steps the agency is taking to regain public trust. 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 1 will be focusing on: Health IT Modules Supporting Public Health Data Exchange Overview. Details.
- **3:00pm – NIH Meeting: Sickle Cell Disease Program Updates** – The National Institutes of Health (NIH) holds a meeting of the National Heart, Lung, and Blood Institute for NHLBI Sickle Cell Disease Program updates. Details.

**Wed. (7/24)**

- **8:30am – Hill Discussion: Cost of Mental Health Disparities** – The Hill holds a discussion with a diverse group of administration officials, lawmakers, medical providers, and advocates to elevate the research and findings of the Meharry School of Global Health's 2024 study, "The Projected Costs and Economic Impact of Mental Health Inequities in the United States," to help meet the needs of America's underserved communities. Reps. Lisa McClain (R-MI) and Ritchie Torres (D-NY) will be participating. Details.
- **10:00am – Markup: AI and Cybersecurity** – The Senate Homeland Security and Governmental Affairs Committee holds a markup of several AI and cybersecurity bills, including: S. 4495, Promoting Responsible Evaluation and Procurement to Advance Readiness for Enterprise-wide Deployment (PREPARED) for Artificial Intelligence Act; S. 4630, Streamlining Federal Cybersecurity Regulations Act; S. 4697, Healthcare Cybersecurity Act of 2024; and S. 4715, Federal Cyber Workforce Training Act of 2024. Details.
- **10:15am – Hearing: OSHA Oversight** – The House Education and the Workforce Subcommittee on Workforce Protections holds a hearing titled "Safeguarding Workers and Employers from Occupational Safety and Health Administration (OSHA) Overreach and Skewed Priorities." Details.
- **11:00am – CMS Meeting: CMMI AHEAD Model Hospital Global Budget Methodology Overview** – The Centers for Medicare and Medicaid Services (CMS) Innovation Center (CMMI)

holds a webinar where CMMI staff will provide an overview of version 2.0 of the States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model's CMS-Designed Medicare FFS Hospital Global Budget Methodology. 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: Standardized API for Patient and Population Service. Details.
- **1:00pm – Brookings Discussion: Changing Landscape of Economic Opportunity** – The Brookings Institution holds a discussion on the changing landscape of economic opportunity by race and class in America and the sociological forces that are driving these trends. Details.
- **2:00pm – R Street Institute Discussion: Reforming Patents to Lower Drug Costs** – The R Street Institute holds a discussion to examine how current patent laws contribute to high drug prices and explore innovative policy solutions to lower costs without stifling innovation. Details.
- **2:30pm – AHRQ Meeting: Digital Health Care Tools** – The Agency for Healthcare Research and Quality (AHRQ) holds a webinar where an expert panel of speakers will share their research about how quality improvement approaches and digital healthcare interventions such as clinical decision support tools are reducing medication errors, improving provider effectiveness, and enhancing patient safety in a variety of clinical care settings. Details.

### Thurs. (7/25)

- **8:30am – NASEM Discussion: Digital Health and AI** – The National Academies of Sciences, Engineering, and Medicine (NASEM) holds a workshop to explore the role of digital health and artificial intelligence technologies for improving diagnosis within the U.S. health care system. Speakers will consider strategies to improve patient-clinician communication, assist in decision-making, advance health equity, and mitigate unintended consequences in the context of using these diagnostic innovations. Details.
- **9:00am – Washington Post Discussion: Long Covid** – The Washington Post holds a discussion on the causes, prevalence and long-term impacts of long covid. The Director for the Office of Long COVID Research & Practice at the Department of Health and Human Services (HHS), Ian Simon, will be participating. Details.
- **9:00am – Hearing: Harmonizing Cybersecurity Regulations** – The House Oversight and Accountability Subcommittee on Cybersecurity, Information Technology, and Government Innovation holds a hearing to examine duplicative federal cybersecurity regulations issued across multiple agencies and explore how better central coordination from the Executive Office of the President could alleviate unnecessary burdens on business and improve cybersecurity outcomes. Details.
- **9:30am – Markup: Senate Appropriations** – The Senate Appropriations Committee holds a markup of the Commerce, Justice, Science, and Related Agencies Appropriations Act, the Interior, Environment, and Related Agencies Appropriations Act, the State, Foreign Operations, and Related Programs Appropriations Act, and the Transportation, Housing and Urban Development, and Related Agencies Appropriations Act. Details.
- **10:00am – Markup: Steward Health Care Systems Subpoena** – The Senate Health, Education, Labor, and Pensions Committee holds a markup to authorize a subpoena of Dr. Ralph de la

Torre, chairman and CEO of Steward Health Care Systems LLC, for testimony relating to the Committee Investigation into the bankruptcy of Steward Health Care. 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.
- **12:00pm – KFF Discussion: Chevron's Impact on Health Policy** – The Kaiser Family Foundation (KFF) holds a discussion to explore how Congress and federal health agencies are likely to adapt to the Court's decision overturning the Chevron precedent and what that may mean for health care policymaking. Details.

**Additional Multi-Day Events**
- **July 23-July 24 – HHS Meeting: Human Research Protections** – HHS holds a meeting of the Secretary's Advisory Committee on Human Research Protections for a discussion of the draft recommendation, Ethical and Regulatory Considerations for the Inclusion of LGBTQI+ Populations in HHS Human Subjects Research, a discussion of Considerations for Uninformative Research and for an update on planned changes to the structure and operation of SACHRP's subcommittees. Details.
- **July 24-July 25 – AHP Summit: AI in Health** – The Alliance for Health Policy (AHP) holds its Signature Series Summit, focusing on the transformative power of Artificial Intelligence (AI) in both health care and health policy. Panelists will explore responsible AI practices and health AI regulation, among other topics. Administration officials from the Food and Drug Administration (FDA) and Agency for Healthcare Research and Quality (AHRQ) will be participating. Details.
- **July 25-July 26 – CMS Meeting: Clinical Diagnostics Laboratory Tests** – The Centers For Medicare and Medicaid Services (CMS) holds a meeting of the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests to provide input and recommendations to the Secretary and the Administrator of CMS on the following: The establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use "cross walking" or "gap filling" processes to determine payment for a specific new test, the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests and other aspects of the payment system under section 1834A of the Act. Details.

Featured Analysis

- **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.
- **Impact Regulatory Outlook: Fall 2023 Unified Agenda** – In the Policy Hub Insight Bank here.

- **Impact Artificial Intelligence Policy Round Up** – In the Policy Hub Insight Bank here.

## Congressional Lookback

### Weds. (7/17)
- **Sens. Rosen, Young, and King** introduced the bipartisan Healthcare Cybersecurity Act to address the growing cybersecurity threats in the healthcare and public health sectors. Details.

## Regulatory Lookback

### Fri. (7/19)
- **The GAO** released a comprehensive report that highlights challenges encountered and lessons learned during the transition from pandemic-era continuous enrollment back to standard eligibility redetermination. Details.

### Thurs. (7/18)
- **The Coalition for Health AI** published a draft framework to ensure the responsible use of AI in health care. Details.

### Weds. (7/17)
- **The USDA FNS** announced that it is awarding $14.3 million in funding for 154 Farm to School grant projects in 43 states. Details.
- **CMS** is seeking nominations to the Advisory Committee on Immunization Practices. Nominations are due August 15. Details.

### Tues. (7/16)
- **CMS** released the final part two guidance for the Medicare Prescription Payment Plan (M3P). Details.

### Mon. (7/15)
- **CMS** is seeking nominations for a TEP to refine the scoring methodology for the ESRD Quality Incentive Program. Nominations are due July 26. Details.

## Comment & Application Deadlines

- **July 22:** USPSTF requests comments on a draft recommendation statement and draft evidence review on screening for food insecurity. Details
- **July 26:** CMS is seeking nominations for a TEP to refine the scoring methodology for the ESRD Quality Incentive Program. Details.

- **July 26:** AHRQ issued a request for supplemental evidence and data submissions to inform its review on Mindfulness-Based Interventions (MBIs) for Mental Health and Wellbeing in Children and Adolescents. Details.
- **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.