Impact Health Policy Weekly

The House is in recess this week as the House Republicans hold their annual caucus policy retreat at President Trump's Doral golf club in Miami. President Trump is expected to speak to the group this evening and Vice President Vance will appear tomorrow as the caucus attempts to finalize the blueprint for their reconciliation bill. They are under a strict timeline as Speaker Johnson has said he wants to pass a budget resolution by Feb. 24.

The Senate continues to work towards confirming President Trump's cabinet nominees. Last week the Senate confirmed Senator Marco Rubio to the position of Secretary of State, Mr. Pete Hegseth to the position of Secretary of Defense, Governor Kristi Noem as Secretary of Homeland Security, and Mr. John Ratcliff to the position of CIA Director. This week the Senate is expected to vote on Mr. Scott Bessent for the position of Secretary of Treasury, followed by former Congressman Sean Duffy for Secretary of Transportation.

RFK Confirmation Hearings

The <u>Senate Finance Committee</u> and the <u>Health, Education, Labor and Pensions (HELP)</u> Committee are scheduled to hold nomination hearings for Robert Kennedy Jr. for HHS Secretary on Wednesday and Thursday respectively. While both Committees are holding hearings, only the Senate Finance Committee will vote on the nomination and potentially report the nomination to the full Senate for consideration. Several groups in opposition to RFK Jr.'s past positions questioning vaccine safety have launched advertising campaigns against the nominee and we expect the confirmation hearings to be lively and potentially contentious.

Other high profile nomination hearings this week include a Senate Judiciary Committee hearing for FBI Director nominee Kash Patel and a Senate Intelligence Committee hearing for Director of National Intelligence nominee former Congresswoman Tulsi Gabbard.

FY 2025 Budget Talks

The House and Senate Appropriations Chairs and Ranking Members met last week and have started negotiating a top line funding amount. Appropriations leaders have said they hope to come to agreement this week on a top line so they can negotiate the 12 different bills prior to the current CR expiring on March 14. The omnibus package is a potential legislative vehicle for Congress to move both a disaster aid package for the California wildfires and the debt limit increase, but it will require bipartisan agreement.

Regulatory Update

President Trump issued a memorandum directing all executive departments and agencies to implement a regulatory freeze in which no rules may be issued or proposed until the agency head appointed or designated by the President after noon on January 20, 2025, reviews and approves the rule. The memorandum also directs federal agencies to consider postponing for 60 days the effective date of any rules that have been published in the *Federal Register*, or any rules that have been issued but have not taken effect. During this 60-day period, federal agencies could consider further delaying the rule beyond the initial 60 days. This memorandum creates uncertainty about the timing and applicability of rules.

This Week in Health Policy

Tue. (1/28)

- **10:30am Hearing: VA's Community Care Program –** The Senate Veterans' Affairs Committee holds a hearing to examine the VA's Community Care Program. <u>Details</u>.
- **5:00pm R Street Discussion: Data Privacy** The R Street Institute holds its Data Privacy Day event, focusing on legislative and regulatory opportunities facing the new Congress and administration, including the prospect of enacting a comprehensive data privacy and security law. Details.

Wed. (1/29)

- 9:00am Markup: Attorney General Nomination The Senate Judiciary Committee holds a markup to consider the nomination of Pamela Bondi to be Attorney General at the Department of Justice (DOJ). Details.
- 10:00am Hearing: Health Secretary Nomination The Senate Finance Committee holds a
 hearing to examine the nomination of Robert F. Kennedy, Jr., to be Secretary of Health and Human
 Services. <u>Details</u>.
- 10:00am Hearing: Commerce Nomination The Senate Commerce, Science, and Transportation Committee holds a hearing to examine the nomination of Howard Lutnick to be Secretary of Commerce. <u>Details</u>.
- 1:30pm Urban Institute Discussion: Data/Health Equity The Urban Institute holds a
 discussion on the collection and application of demographic data to advance health equity,
 including on what state and federal policymakers can do to enhance transparency and
 accountability for addressing disparities in access to and quality of care and outcomes. Details.
 Flag for CHCF team, Katherine Haynes, a Senior Program Officer at California Health Care
 Foundation is participating
- 1:30pm ARI Discussion: AI Policy Landscape Americans for Responsible Innovation (ARI)
 holds a discussion with experts from across civil society, think tanks, and industry associations on
 the impact of Trump's repeal of the Biden Executive Order on artificial intelligence (AI), the
 President's announcement of the Stargate project, relevant appointments, and what to watch as
 the new Administration rolls out AI policy. Details.

Thurs. (1/30)

• **10:00am** – **Hearing: Health Secretary Nomination** – The Senate Health, Education, Labor, and Pensions Committee holds a hearing to examine the nomination of Robert F. Kennedy, Jr., to be Secretary of Health and Human Services. <u>Details</u>.

Additional Multi-Day Events

• Jan 28-Jan 29 – HHS Meeting: Antimicrobial Resistance – The Department of Health and Human Services (HHS) holds a meeting of the Presidential Advisory Council on Combating Antibiotic-

Resistant Bacteria (PACCARB) to discuss methods to measure global awareness of anti-microbial resistance, the Impact of AMR and food security; and AMR as a national security threat, among others. Details.

Featured Analysis

- *NEW* Impact Overview of President Trump's Day One EO In Policy Hub Insight Bank here.
- *NEW* Impact Memo on Health-Related Staff Picks for the Second Trump Administration –
 In Policy Hub Insight Bank here.
- Policy Round-Up: CBO, GAO Reports on ACA Premium Tax Credits; DACA Marketplace Eligibility – Available here.
- Impact Budget Reconciliation Primer In Policy Hub Insight Bank here.
- Impact Medicaid Outlook: Threats and Opportunities In the Policy Hub Insight Bank here.
- Insights for Impact: the 340B Drug Pricing Program In the Policy Hub Insight Bank here.

Congressional Lookback

Fri. (1/24)

 MedPAC held day two of its <u>January 2025 public meeting</u> and held sessions to vote on its recommendations for the March report, transitions from pediatric to adult care, and PACE. All Impact Health session summaries are available in Policy Hub <u>here</u>.

Thurs. (1/23)

 MACPAC convened virtually for day one of its <u>January 2025 public meeting</u> and held sessions on HCBS, medications for opioid use disorder, residential services, and managed care. All Impact session summaries are available on Policy Hub <u>here.</u>

Regulatory Lookback

Thurs. (1/23)

President Trump issued an executive order (EO) titled Removing Barriers to American Leadership
in Artificial Intelligence. Details.

Mon. (1/20)

President Trump issued sweeping Eos targeting immigration and asylum policies, declaring a
national emergency at the U.S.-Mexico border and initiating measures to combat undocumented
immigration. <u>Details</u>.

Comment & Application Deadlines

- January 27: CMS released the CY 2026 Policy and Technical Changes to the MAand Part D
 Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) proposed
 rule. Details.
- **February 2:** The FDA released <u>draft guidance</u> entitled "Notifying FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula. <u>Details</u>.
- February 10: CMS announced the <u>Advance Notice of Methodological Changes for Contract Year</u>
 (CY) 2026 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment
 <u>Policies</u> (press release, fact sheet) and the <u>Draft CY 2026 Part D Redesign Program Instructions</u>...
 <u>Details</u>.
- February 25: CMMI released an RFA for the Cell and Gene Therapy Access Model. Details.
- **February 25:** CMMI released a <u>NOFO</u> to apply for Cooperative Agreement funding to support states' participation in the Cell and Gene Therapy (CGT) Access Model. <u>Details</u>.
- March 7: HHS OCR issued a <u>proposed rule</u> to update the HIPAA Security Rule to enhance cybersecurity protections. <u>Details</u>.
- March 10: The FDA released <u>draft guidance</u> on accelerated approval and considerations for determining whether a confirmatory trial is underway. <u>Details</u>.
- March 15: The DEA issued a <u>proposed rule</u> that would establish a new special registration for the prescription of a controlled substance via telemedicine. <u>Details</u>.
- April 7: The FDA issued <u>draft guidance</u> on considerations for the use of artificial intelligence (AI) to support regulatory decision-making for drug and biological products. <u>Details</u>.
- April 7: The FDA released <u>draft guidance</u> on artificial intelligence (AI)-enabled device software functions (AI-DSFs): lifecycle management and marketing submission recommendations.
 Details.
- July 1: The CDC <u>seeking nominations</u> for membership on the Clinical Laboratory Improvement Advisory Committee (CLIAC). <u>Details</u>.