

# Impact Health Policy Weekly

Donald J. Trump was inaugurated yesterday as the  $47^{th}$  President of the United States and wasted no time issuing a plethora of Executive Orders focused on immigration, energy and government reform policies, and rescinding most of President Biden's policies and orders. Among the most high-profile actions include:

- Declaring a national emergency to deploy the military to the border and putting a pause on allowing asylum seekers into the country.
- An end to birthright citizenship for the children of noncitizens, which has already been countered by a lawsuit;
- Directing the federal government to only recognize two sexes-males and females including on all government documents, such as passports and visas.
- Reversing all of President Biden's federal DEI initiatives.
- Withdrawing from the World Health Organization (WHO).
- Ordering a hiring freeze across the federal government until the completion of a broader plan for reducing the federal work force. He also required that all federal employees return to in person work five days a week.
- Rescinding Biden Administration COVID-19 executive orders including revoking a mandate that federal employees be vaccinated against COVID.
- Rescinding an October 2023 artificial intelligence (AI) executive order deploying federal agencies to study AI's risks and benefits.
- Withdrawing from the Paris Climate accords.

It is clear that this Administration is not wasting any time, and further actions are expected in the coming days and weeks.

The House and Senate are both in session this week as both the House and Senate are expected to vote on their versions of the Born-Alive Survivors Protection Act, which requires health practitioners to exercise all medical actions necessary to save the fetus of a failed abortion or attempted abortion. The Senate will also continue to work to confirm President Trump's nominees, though we are still waiting for a hearing to be scheduled for HHS Secretary nominee RFK, Jr. Committees in the House and Senate will also continue to hold organizing meetings for the 119th Congress.

HHS Leadership: President Trump named Dorothy Fink to be the Acting Secretary of HHS until his nominee, RFK, Jr., is confirmed. Ms. Fink currently directs the HHS Office on Women's Health. It is further expected that Sara Brenner will be named acting commissioner of the FDA until Dr. Marty Makary is able to be confirmed. Last week, the Trump Administration announced a slew of appointees for the Department of Health and Human Services. Impact Health Policy will soon be putting out a comprehensive guide to the new appointees.

This Week in Health Policy

# Mon. (1/20)

Federal Holiday – Martin Luther King, Jr Day

# Tue. (1/21)

- **10:00am Hearing: VA Nomination** The Senate Veterans' Affairs Committee holds a hearing to examine the nomination of Douglas A. Collins, to be Secretary of Veterans Affairs. **Details**.
- 10:00pm HITAC Meeting: Interoperability Standards The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Interoperability Standards Workgroup to discuss program updates. Details.
- 2:00pm GovExec Discussion: Digital Technologies/Health Care The Government Executive Media Group holds a discussion on how digital technologies are reshaping patient care and operational efficiency, and actionable strategies for fostering innovation in health care organizations. Latriece Prince Wheeler, Acting deputy chief digital health officer at the Veterans Health Administration, and Andrea Fletcher, Chief digital strategy officer at the Centers for Medicare and Medicaid Services (CMS) will participate. Details.

# Wed. (1/22)

- 10:00am Hearing: Committee's Tax Jurisdiction The House Ways and Means Committee holds a hearing on "Matters Within the Committee's Tax Jurisdiction." Details.
- 10:00am Markup: Transportation Nomination The Senate Commerce, Science, and Transportation Committee holds a hearing to examine the nomination of Sean Duffy, to be Secretary of Transportation. <a href="Details">Details</a>.
- 10:00am Hearing: OMB Nomination The Senate Budget Committee holds a hearing to examine the nomination of Russell Vought, to be Director of the Office of Management and Budget (OMB). <u>Details</u>.
- 10:15am Hearing: Veterans Community Care The House Veterans' Affairs Subcommittee on Health holds a hearing titled "Restoring Focus: Putting Veterans First in Community Care."
   Details.
- 12:00pm NIH Meeting: Biomedical Imaging/Bioengineering The National Institutes of Health (NIH) holds a meeting of the National Institute of Biomedical Imaging and Bioengineering for a report from NIBIB Director Bruce Tromberg, council members and other institute staff. <u>Details</u>.
- 1:30pm HITAC Meeting: Health Equity by Design HITAC holds a meeting of the Health Equity by Design (HEBD) Task Force to discuss program updates. <u>Details</u>.

# Thurs. (1/23)

- 10:00am Markup: VA Nomination The Senate Veterans' Affairs Committee holds a hearing to examine the nomination of Douglas A. Collins, to be Secretary of Veterans Affairs. Details.
- 10:00am Hearing: Agriculture Nomination The Senate Agriculture, Nutrition, and Forestry
  Committee holds a hearing to examine the nomination of Brooke Rollins, to be Secretary of
  Agriculture. <u>Details</u>.

- 12:00pm AEI Discussion: Medicare Prescription Drug Benefit The American Enterprise Institute for Public Policy Research (AEI) holds a discussion on drug pricing challenges regarding the Medicare Prescription Drug Benefit. Nolan Ahers, Senior Policy Adviser from the Office of House Majority Whip Tom Emmer (R-MN) and Brian Miller, Commissioner from the Medicare Payment Advisory Commission (MedPAC) will be participating. Details.
- Meeting: MACPAC The Medicaid and CHIP Payment and Access Commission (MACPAC) holds a public meeting to discuss Medicaid and CHIP payment and policy issues. <u>Details</u>.

### Fri. (1/24)

• Meeting: MACPAC – MACPAC holds a public meeting to discuss Medicaid and CHIP payment and policy issues. <u>Details</u>.

## Additional Multi-Day Events

• Jan 23-Jan 24 – Families USA Discussion: Health Action Conference – Families USA holds its annual Health Action Conference 2025, convening hundreds of health advocates cutting across policy, communications, organizing, and government relations who come together annually for policy discussions, skill-building sessions, speaker panels, and presenters. Includes sessions on how to protect from potential health cuts, caps, repeals, and rollbacks; strengthening the Medicare program; drug pricing; reproductive health and gender-affirming care; and medical debt community solutions. Details.

## Featured Analysis

- 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.
- Impact 2024 Election Outlook and 2025 Congressional Preview In the Policy Hub Insight Bank here.

Congressional Lookback

#### Fri. (1/17)

MedPAC convened its <u>January 2025 meeting</u> to vote on payment adequacy updates, discuss status reports for Part D, Medicare Advantage, and ASCs, and sessions on eliminating coverage limits in IPFs and reducing beneficiary cost-sharing. All MedPAC summaries can be found <u>here</u>.

Regulatory Lookback

## Fri. (1/17)

- **CMS** announced the selection of <u>15</u> additional <u>Part D drugs</u> for the Medicare Drug Price Negotiation Program for the initial price applicability year (IPAY 2027). <u>Details</u>.
- The FTC has <u>announced</u> a proposed <u>consent order</u> with private equity (PE) firm Welsh Carson to resolve allegations of anticompetitive practices related to its role in the consolidation of the Texas anesthesiology market. <u>Details</u>.

# Thurs. (1/16)

• HHS unveiled its <u>AI Strategic Plan</u>, a comprehensive roadmap aimed at fostering innovation, ethical implementation, and equitable access to artificial intelligence (AI) technologies across various health care domains. <u>Details</u>.

# Weds. (1/15)

- The DEA and SAMHSA jointly issued a <u>final rule</u> that addresses COVID-19 telemedicine flexibilities for the prescription of controlled medications for the treatment of opioid use disorder. Details.
- The DEA issued a <u>proposed rule</u> that would establish a new special registration for the prescription of a controlled substance via telemedicine. Comments are due March 15. <u>Details</u>.
- HHS <u>released</u> a report synthesizing insights from over 2,000 public comments submitted in response to a tri-agency request for information (<u>RFI</u>) on the impacts of corporate ownership in health care. <u>Details</u>.
- The Department of Agriculture (USDA) announced a new grant opportunity for nutrition incentives and notified the public about an opportunity for feedback on reports about alcohol and health. <u>Details</u>.

## Tues. (1/14)

- The Tri-Departments <u>withdrew</u> a proposed rule intended to expand access to coverage of recommended preventive services without cost sharing in the commercial market. <u>Details</u>.
- The FTC released a <u>second interim report</u> as part of an <u>ongoing inquiry</u> launched in June 2022 into the practices of PBMs. <u>Details</u>.
- The Tri-Departments and OPM released <u>frequently asked questions (FAQs)</u> regarding the No Surprises Act (NSA) and Gag Clause Prohibition Compliance Attestation. <u>Details</u>.

# Mon. (1/13)

- CMS released the HHS Notice of Benefit and Payment Parameters for 2026 final rule. Details.
- The FTC recently <u>announced</u> updated jurisdictional thresholds and a revised filing fee schedule for reporting transactions under the Hart-Scott-Rodino (HSR) Act, effective February 10, 2025. <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. Details.
- February 10: CMS announced the <u>Advance Notice of Methodological Changes for Contract Year</u>
   (CY) 2026 for <u>Medicare Advantage</u> (MA) <u>Capitation Rates and Part C and Part D Payment Policies</u> (press release, fact sheet) and the <u>Draft CY 2026 Part D Redesign Program Instructions</u>..
   Details.
- 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 <u>Clinical Laboratory Improvement</u> Advisory Committee (CLIAC). <u>Details</u>.