

## Impact Health Policy Weekly

The House and Senate are both in session this week leading up to Inauguration Day next Monday. The Senate is set to begin nomination hearings for many of President-elect Trump's nominees. 13 of Mr. Trump's nominees will appear before the Senate Committees this week, starting with Department of Defense Secretary nominee Pete Hegseth's confirmation hearing before the Senate Armed Services Committee on Tuesday. Among the 13 nominees that will appear this week include Attorney General Nominee Pam Bondi, Secretary of State Nominee Marco Rubio, OMB Director Nominee Russell Vought, Secretary of Transportation Nominee Sean Duffy, and Secretary of Homeland Security Nominee Kristi Noem. Not included in this week's nomination hearings is Mr. Trump's nominee for HHS Secretary, RFK, Jr., who has not yet been scheduled to appear before the Senate Finance Committee.

The House Committees are also starting their work for the year, with organizing hearings scheduled for many of the Committees. The House Budget Committee is scheduled to hold their first [hearing](#) on making permanent the Trump Administration Tax Cuts. While likely to focus on tax policy, this will be the first Committee hearing on what is expected to be a big part of the Republican budget reconciliation effort.

**New Committee Membership:** House Democrats announced Committee membership last week, finalizing the Committees makeup. Democratic Representatives Brendan Boyle (D-PA); Stacey Plaskett (D-VI) and Tom Suozzi (D-NY) have been named to the Ways and Means Committee while Representatives Alexandria Ocasio-Cortez (D-NY); Jake Auchincloss (D-MA); Rep. Troy Carter (D-LA); Rob Menendez (D-NJ); Kevin Mullin (D-CA); Greg Landsman (D-OH); and Jennifer McClellan (D-VA) were all added to the Energy and Commerce Committee.

**Final Days of the Biden Administration:** In the final week of the Biden Administration there are still a few more items of business to be done. There are a few rules still pending at OMB that could be released this week, and CMS may to announce the next 15 drugs that will be subject to price negotiations. CMS has until February 1 to release the names of the drugs that will be negotiated under the Inflation Reduction Act, but could release the list this week before the presidential transition occurs

### Regulatory Update

In December, the Biden-Harris administration published its last unified agenda. The [Fall 2024 Unified Agenda](#) mostly mirrors the Spring 2024 Unified Agenda, with several new items to note. However, the incoming Trump-Vance administration will likely revamp the regulatory agenda, adjusting some items and timelines. Whether these new items are pursued by the incoming administration remains to be seen. New HHS items in the Fall 2024 Unified Agenda:

- **Medicaid:** The [proposed rule](#) would update existing regulations that govern the process for States to obtain a waiver of the statutory requirements that health care-related taxes are broad based and uniform to ensure that taxes passing the statistical test are generally redistributive (March 2025).
- **Cost Sharing:** The [proposed rule](#) would amend regulations implementing the Affordable Care Act's provisions related to preventive services and cost sharing protections. Among other actions,

this proposed rule would amend the regulations implementing the Affordable Care Act's requirement to cover recommended preventive services without cost sharing, and address the applicability of drug manufacturer support to the annual limitation on cost sharing for group and individual coverage. It would also address how these provisions would apply to a plan or coverage without an established network (November 2025).

- **ESRD ETC Model:** The [interim final rule](#) would make policy changes to the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model to account for its effects and effects from other unforeseen circumstances that impair model participant's ability to perform in the model (March 2025).

We anticipate the Biden-Harris administration will release a few more rules during its last week. The Office of Management and Budget (OMB) completed reviewing the following:

- **Notice of Benefit and Payment Parameters for 2026** – The [final rule](#) sets forth 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.
- **Tobacco Product Standard** – The [proposed rule](#) would establish a maximum nicotine level in cigarettes and certain other finished tobacco products.

OMB is also reviewing the following:

- **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).

## This Week in Health Policy

### Mon. (1/13)

- **9:00am – AEI Discussion: Parent's Rights in Children's Medical Care** – The American Enterprise Institute (AEI) holds a discussion with legal scholars, medical experts, and child welfare practitioners on the constitutional status of parents' rights and how questions of parental autonomy should be adjudicated in both pediatric and child welfare contexts. [Details.](#)

### Tue. (1/14)

- **8:30am – Politico Discussion: Trump Administration's First 100 Days** – Politico holds a discussion with leaders from the incoming Trump Administration and Congress on the new administration's policy agenda. [Details.](#)
- **9:00am – Hearing: VA Nomination** – The Senate Veterans' Affairs Committee holds a hearing to examine the expected nomination of Douglas A. Collins, to be Secretary of Veterans Affairs. [Details.](#)
- **9:30am – Hearing: Defense Nomination** – The Senate Armed Services Committee holds a hearing to examine the expected nomination of Peter B. Hegseth, to be Secretary of Defense. [Details.](#)

- **10:00am – Hearing: Interior Nomination** – The Senate Energy and Natural Resources Committee holds a hearing to examine the expected nomination of Doug Burgum, to be Secretary of the Interior. [Details.](#)
- **10:00am – Hearing: Trump Tax Cuts** – The House Ways and Means Committee holds a hearing to examine making permanent the Trump Administration tax cuts for working families. [Details.](#)  
**HE – Will likely focus on tax policy, but please lightly cover in case Medicaid (or other health-related) policy comes up.**
- **10:00am – NIH Meeting: Sickle Cell Disease Updates** – The National Institutes of Health (NIH) holds a meeting of the NIH's National Heart, Lung, and Blood Institute for NHLBI Sickle Cell Disease Program updates and long-term follow-up of participants undergoing gene therapy for sickle cell disease. [Details.](#)

### Wed. (1/15)

- **9:00am – Hearing: Homeland Security Nomination** – The Senate Homeland Security and Governmental Affairs Committee holds a hearing to examine the expected nomination of Kriti Noem, to be Secretary of Homeland Security. [Details.](#)
- **9:30am – Hearing: DOJ Nomination** – The Senate Judiciary Committee holds a hearing to examine the expected nomination of Pamela Jo Bondi, to be Attorney General, Department of Justice (DOJ). [Details.](#)
- **10:00am – Hearing: Energy Nomination** – The Senate Energy and Natural Resources Committee holds a hearing to examine the expected nomination of Chris Wright, to be Secretary of Energy. [Details.](#)
- **10:00am – Hearing: State Nomination** – The Senate Foreign Relations Committee holds a hearing to examine the expected nomination of Marco Rubio, to be Secretary of State. [Details.](#)
- **10:00am – Hearing: CIA Nomination** – The Senate Intelligence Committee holds a hearing to examine the expected nomination of John Ratcliffe, to be the Director of the Central Intelligence Agency (CIA). [Details.](#)
- **10:00am – Hearing: Transportation Nomination** – The Senate Commerce, Science, and Transportation Committee holds a hearing to examine the expected nomination of Sean Duffy, to be Secretary of Transportation. [Details.](#)
- **10:00am – ACT Media Briefing: Tax Cuts and Jobs Act/2025 Tax Reform** – The Alliance for Competitive Taxation (ACT) holds a media briefing featuring Kevin Brady, former Chairman of the House Ways and Means Committee and architect of the Tax Cuts and Jobs Act (TCJA) to discuss what to expect on tax reform from the 119<sup>th</sup> Congress. [Details.](#)
- **10:00am – Hearing: Federal Workforce Remote Work** – The House Oversight and Government Reform Committee holds a hearing to examine the Biden-Harris Administration remote work policies for the federal workforce. [Details.](#)
- **10:30am – FCC Meeting: Connect2Health Initiatives** – The Federal Communications Commission holds an Open Meeting to discuss work the teams have done over the last four years, including a presentation from the Connect2Health Chair/Office of General Counsel on the agency's work on making communications more just for more people in more places. [Details.](#)

- **1:00pm – Hearing: OMB Nomination** – The Senate Homeland Security and Governmental Affairs Committee holds a hearing to examine the expected nomination of Russell Vought, to be Director, Office of Management and Budget (OMB). [Details.](#)
- **1:30pm – HITAC Meeting: Health Equity by Design** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Health Equity by Design (HEBD) Task Force to discuss program updates. [Details.](#)
- **3:30pm – Hearing: Senior Wellness** – The Senate Aging Committee holds a hearing to examine improving wellness among seniors, focusing on “setting a standard for the American Dream.” [Details.](#)

#### **Thurs. (1/16)**

- **8:30am – Hill Discussion: Public Health Trust** – The Hill holds a discussion with leaders in government, health care, science, and patient advocacy on the importance of building public health trust and what public health leaders can do to restore trust in medical science in U.S. health agencies. Former Congressman Dr. Larry Bucshon (R-IN) will be participating. [Details.](#)
- **9:00am – Hearing: Remain in Mexico/Border Security** – The Senate Homeland Security and Governmental Affairs Committee holds a hearing to examine Remain in Mexico, a policy implemented by the first Trump Administration requiring migrants seeking asylum to remain in Mexico until their US immigration court date. The hearing will be immediately followed by a business meeting to consider an original resolution expressing the sense of the Senate that the President of the United States possesses the authority under current law to take immediate and necessary action to secure the southwest border of the United States, a motion to authorize the Chairman to issue subpoenas for records, and committee rules of procedure. [Details.](#)
- **10:00am – Hearing: HUD Nomination** – The Senate Banking, Housing, and Urban Affairs Committee holds a hearing to examine the expected nomination of Eric Scott Turner, to be Secretary of Housing and Urban Development. [Details.](#)
- **10:30am – Hearing: Treasury Nomination** – The Senate Finance Committee holds a hearing to examine the expected nomination of Scott Bessent, to be Secretary of the Treasury. [Details.](#)
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [Details.](#)

#### **Fri. (1/17)**

- **11:00am – NIH Meeting: Office of the Director Priorities/Report Review** – The National Institutes of Health (NIH) holds a meeting of the Scientific Management Review Board (SMRB) to establish priorities and review major prior recommendations and accomplishments and to review the report on Deliberating Organizational Change and Effectiveness. [Details.](#)
- **Meeting: MedPAC** – MedPAC meets to discuss Medicare issues and policy questions. [Details.](#)

#### **Additional Multi-Day Events**

- **Jan 13-Jan 14 – NIH Meeting: Child Health/Human Development** – NIH holds a meeting of the Eunice Kennedy Shriver National Institute of Child Health & Human Development for NICHD Director Diana Bianchi's report and other council business. [Details](#).
- **9:00am – AEI Discussion: Parent's Rights in Children's Medical Care** – The American Enterprise Institute (AEI) holds a discussion with legal scholars, medical experts, and child welfare practitioners on the constitutional status of parents' rights and how questions of parental autonomy should be adjudicated in both pediatric and child welfare contexts. [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

#### **Thurs. (1/9)**

- **The Senate Budget Committee** released a [bipartisan report](#) detailing the findings of its investigation into the harmful effects of private equity (PE) investment on the U.S. health care system. [Details](#).

### Regulatory Lookback

#### **Fri. (1/10)**

- **CMS** announced the [Advance Notice of Methodological Changes for Contract Year \(CY\) 2026 for Medicare Advantage \(MA\) Capitation Rates and Part C and Part D Payment Policies](#) ([press release](#), [fact sheet](#)) and the [Draft CY 2026 Part D Redesign Program Instructions](#). Comments are due February 10. [Details](#).

#### **Weds. (1/8)**

- **CMS and ASPE** [released](#) new updates and analyses on health insurance coverage ahead of the end of the Marketplace Open Enrollment Period on January 15<sup>th</sup>. [Details](#).

#### **Tues. (1/7)**

- **HHS OCR** issued a [proposed rule](#) to update the HIPAA Security Rule to enhance cybersecurity protections. Comments are due March 7. [Details](#).
- **SAMHSA** [announced](#) that 14 states and the District of Columbia have received Certified Community Behavioral Health Clinics (CCBHCs) Planning grants. [Details](#).

- **The FDA** released [draft guidance](#) on accelerated approval and considerations for determining whether a confirmatory trial is underway. Comments are due March 10. [Details](#).
- **The FDA** released [draft guidance](#) on artificial intelligence (AI)-enabled device software functions (AI-DSFs): lifecycle management and marketing submission recommendations. Comments are due April 7. [Details](#).

#### **Mon. (1/6)**

- **CMMI** [announced](#) fifteen state Medicaid agencies (SMAs) have been selected for the Transforming Maternal Health Model. [Details](#).
- **The Tri-Departments** [withdrew](#) a proposed rule intended to expand access to contraceptive coverage for individuals enrolled in group health plans or individual health insurance that do not provide such coverage due to a religious objection. [Details](#).
- **The FDA** released a [final rule](#) to update the definition of the nutrient content claim “healthy.” [Details](#).
- **The FDA** issued [draft guidance](#) on considerations for the use of artificial intelligence (AI) to support regulatory decision-making for drug and biological products. Comments are due April 7. [Details](#).
- **The FDA** issued a [final rule](#) to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). [Details](#).
- **HHS OIG** [released](#) a report after conducting an audit of Medicare’s reimbursement for Critical Access Hospitals (CAHs). [Details](#).

#### **Comment & Application Deadlines**

- **January 27:** CMS released the CY 2026 Policy and Technical Changes to the MA and Part D Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) [proposed rule](#). [Details](#).
- **February 2:** The FDA released [draft guidance](#) 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 [Advance Notice of Methodological Changes for Contract Year \(CY\) 2026 for Medicare Advantage \(MA\) Capitation Rates and Part C and Part D Payment Policies](#) ([press release](#), [fact sheet](#)) and the [Draft CY 2026 Part D Redesign Program Instructions](#). [Details](#).
- **February 25:** CMMI released an [RFA](#) for the Cell and Gene Therapy Access Model. [Details](#).
- **February 25:** CMMI released a [NOFO](#) to apply for Cooperative Agreement funding to support states’ participation in the Cell and Gene Therapy (CGT) Access Model. [Details](#).
- **March 7:** HHS OCR issued a [proposed rule](#) to update the HIPAA Security Rule to enhance cybersecurity protections. [Details](#).
- **March 10:** The FDA released [draft guidance](#) on accelerated approval and considerations for determining whether a confirmatory trial is underway. [Details](#).
- **April 7:** The FDA issued [draft guidance](#) on considerations for the use of artificial intelligence (AI) to support regulatory decision-making for drug and biological products. [Details](#).

- **April 7:** The FDA released [draft guidance](#) on artificial intelligence (AI)-enabled device software functions (AI-DSFs): lifecycle management and marketing submission recommendations. . [Details.](#)
- **July 1:** The CDC [seeking nominations](#) for membership on the Clinical Laboratory Improvement Advisory Committee (CLIAC). [Details.](#)