

# Impact Health Policy Weekly

# Framing the week

Last night, the House Budget Committee <u>reconvened its vote</u> and advanced the budget reconciliation package, by a vote of 17-16, with the Republican holdouts, Reps. Chip Roy (R-TX), Josh Brecheen (R-OK), Ralph Norman (R-SC) and Andrew Clyde (R-GA.), voting 'present' to allow the bill to proceed. Prior to the vote, it is reported that discussions were had regarding moving up the implementation of work requirements from 2029 to 2027, with more Conservative members still pushing for changes to the Federal Medical Assistance Percentage (FMAP). During the reconvening, the Committee <u>rejected</u> the following motions:

- Rep. Balint's motion to amend the bill by striking all provisions the Congressional Budget Office (CBO) estimates would increase the number of Americans without health insurance;
- Rep. Amo's motion to amend the bill by adopting Donald Trump's own proposal to raise the income tax rate on millionaires;
- Rep. McGarvey's motion to amend the bill by removing all provisions CBO projects would reduce participation in the Supplemental Nutrition Assistance Program (SNAP); and
- Rep. Jayapal's motion to add a point of order prohibiting the use of a current policy baseline to
  mislead the public about the true cost of Republican tax cuts in the final reconciliation package.

It is expected that manager's amendment of the bill will be presented for House Rules Committee consideration on Wednesday at 1:00 am, in which the Committee will aim to advance the package and set the ground rules for floor debate. It is the goal of Republican leadership to bring the bill to the floor on Thursday and indicated that members will not be allowed to go home for Memorial Day until the package is approved by the House.

Congress will then be in recess until after Memorial Day. The Senate returns on June 2, which will mark the beginning of its work on the reconciliation package, including the "Byrd Bath," in which the Senate Parliamentarian will determine which provisions break the Byrd Rule. Where the House side has members pushing for the bill to go farther on overall spending cuts and Medicaid, many moderate Senators have expressed opposition to such an approach, and will seek to temper the included Medicaid cuts. The overall goal remains to have the budget reconciliation package on the President's desk by July 4.

#### FDA MAHA Updates

Last week, the Food and Drug Administration (FDA) announced several updates to "Make America Healthy Again" (MAHA) workstreams.

• FDA <u>initiated action</u> to remove concentrated ingestible fluoride prescription drug products for children from the market. FDA reasons that these products are swallowed and ingested unlike toothpaste and fluoride rinses, which they are concerned may impact the developing gut microbiome. The Center for Drug Evaluation and Research will look at evidence about systemic fluoride exposure from ingestible prescription products with a goal date of October 31 for completion.

- FDA <u>launched</u> a systematic review process for food chemicals already on the market. The agency
  will release a draft for public comment soon. FDA will also expedite its review of chemicals
  currently under review and will share the status of its work on a <u>public website</u>.
- FDA <u>announced</u> that it will hold a roundtable discussion with an independent panel of scientific
  experts to discuss the safety and necessity of talc in food, drug, and cosmetic products. This will
  be held on Tuesday, May 20<sup>th</sup> and will be open to the public.

#### Regulatory Update

The Office of Management and Budget is reviewing the following:

- Medicare. Proposed CY 2026 payment updates for <u>physicians</u>, <u>hospital outpatient departments</u>
   and <u>ambulatory surgical centers</u>, <u>home health agencies</u>, and <u>end-stage renal disease facilities</u>.
   These proposed rules are typically published in June or July.
- ACA Marketplace. A <u>final rule</u> with a series of proposals intended to address improper enrollments in Marketplace coverage and reduce improper federal spending on advanced premium tax credits (<u>IHPP summary</u>). If finalized as proposed, 750,000 to 2 million fewer individuals would enroll in Marketplace coverage in 2026.
- Transparency. A prerule titled "Transparency in Coverage," likely with proposed changes to health plan price transparency requirements. The prerule would implement President Trump's executive order directing the Departments of Treasury, Labor, and Health and Human Services to strengthen price transparency requirements (<a href="https://linearchy.com/strengths/">IHPP summary</a>). At the prerule stage, agencies typically submit an "Advanced Notice of Proposed Rulemaking" to allow the public the opportunity to comment on whether or not a rulemaking should be initiated.

#### This Week in Health Policy

#### Mon. (5/19)

• 2:30pm – Brookings Discussion: Payer-Provider Vertical Integration – The Brookings Institution Center on Health Policy holds a discussion to assess the evidence on payer-provider vertical integration and explore policy responses. Panelists will examine the motives, potential efficiencies, and competitive risks of payer-led integration. <u>Details</u>.

## Tue. (5/20)

- 10:00am Congressional Black Caucus Discussion: Chronic Disease Management and Prevention - The Congressional Black Caucus Foundation holds its 2025 Policy for the People Health Equity Summit: Access and Affordability in Chronic Disease Management and Prevention. Reps. Terri Sewell (D-AL) and Robin Kelly (D-IL) will participate and lead a discussion on Black health equity. Details.
- 10:00am Hearing: IRA Mandates on Energy and Medicine The House Oversight and Government Reform Subcommittee on Economic Growth, Energy Policy, and Regulatory Affairs holds a hearing to discuss the Inflation Reduction Act's (IRA) impact on business taxes, environmental spending, and Medicare premiums. <u>Details</u>.

- **10:00am Hearing: EPA FY 2026 Budget** The House Energy and Commerce Subcommittee on the Environment holds a hearing to examine the proposed budget estimates for fiscal year 2026 for the Environmental Protection Agency (EPA) with EPA Administrator Lee Zeldin Details.
- 10:00am Hearing: HHS FY 2026 Budget The Senate Appropriations Subcommittee on Departments of Labor, Health and Human Services, and Education, and Related Agencies holds a hearing to examine the proposed budget estimates for fiscal year 2026 for the Department of Health and Human Services (HHS) with HHS Secretary Robert F. Kennedy, Jr. <u>Details</u>.
- 11:00am A4H Discussion: Accountable Care Accountable for Health (A4H) holds a discussion with the Centers for Medicare and Medicaid Services (CMS) Innovation Center Director Abe Sutton on approaches to and perspectives on accountable care. Details.
- 1:00pm CMS Meeting: Improving Technology Solutions for Medicare Beneficiaries CMS holds a Q&A session on the recent CMS Request for Information (RFI) on Improving Technology to Empower Medicare Beneficiaries. The session will also review how to submit responses to the RFI. Details.
- 2:00pm Hill Discussion: Financial Barriers in Clinical Trial Participation The Hill holds a discussion with lawmakers and patient advocates on actions Congress can take to make clinical trials more accessible to patients, focusing on substantial economic barriers to participation. Rep. Chrissy Houlahan (D-PA) will participate. Details.
- 6:00pm Axios Discussion: Future of Oncology Axios holds a discussion to examine how the
  Trump Administration can impact evolving oncology research, focused on the challenges and
  opportunities in advancing innovation and equitable access to cancer treatments. Rep.Debbie
  Wasserman Schultz (D-FL) will participate. Details.

#### Wed. (5/21)

- 8:30am Hill Discussion: Safety Net Programs The Hill holds a discussion on recent
  Administrative and Congressional activity and its impact on health safety net programs for older
  adults, focused on proposed cuts to Medicaid and workforce cuts across federal agencies. Rep.
  Judy Chu (D-CA) will participate. Details.
- 10:00am Hearing: ED FY 2026 Budget The House Appropriations Subcommittee on Labor,
  Health and Human Services, Education, and Related Agencies holds a hearing to examine the
  proposed budget estimates for fiscal year 2026 for the Department of Education (ED) with ED
  Secretary Linda McMahon. Details.
- 10:00am Hearing: FCC Oversight The House Appropriations Subcommittee on Financial Services and General Government holds an oversight hearing of the Federal Communications Commission (FCC) with FCC Chairman Brendan Carr. <u>Details</u>.
- 10:00am Hearing: State of Higher Education The Senate Health, Education, Labor, and Pensions holds a hearing to examine the state of higher education. <u>Details</u>.
- 10:15am Hearing: DEI/Education The House Education and the Workforce Subcommittee on Higher Education and Workforce Development holds a hearing titled "Restoring Excellence: The Case Against Diversity, Equity, and Inclusion (DEI)." <u>Details</u>.

- 10:15am Hearing: Al Regulation The House Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade holds a hearing to discuss artificial intelligence (Al) regulation, focused on promoting a pro-innovation agenda that encourages domestic Al development and deployment and supports U.S. Al leadership abroad. <u>Details</u>.
- 2:00pm Hearing: COVID-19 Vaccine Adverse Events The Senate Homeland Security and Governmental Affairs Subcommittee on Investigation holds a hearing to examine science and Federal health agencies, focusing on Myocarditis and other events associated with the COVID-19 vaccines. <u>Details</u>.
- 2:30pm Hearing: SBA FY 2026 Budget The Senate Appropriations Subcommittee on Financial Services and General Government holds a hearing to examine the proposed budget estimates for fiscal year 2026 for the Small Business Administration (SBA) with SBA Administrator Kelly Loeffler. <u>Details</u>.
- 4:00pm Hearing: Veterans Health Care Access The Senate Veterans' Affairs (VA) Committee
  holds a hearing to examine several pieces of legislation, including a bill to improve the ability of
  veterans to access care in facilities and by providers of their choosing. <u>Details</u>.

#### Thurs. (5/22)

- 8:30am FDA Meeting: 2025-20256 Formula for COVID-19 Vaccines The Food and Drug Administration (FDA) holds an advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee to discuss and make recommendations on the selection of the 2025-2026 Formula for COVID-19 vaccines for use in the United States. <u>Details</u>.
- 10:30am Hearing: FDA FY 2026 Budget The Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies holds a hearing to examine the proposed budget estimates for fiscal year 2026 for the Food and Drug Administration (FDA) with FDA Commissioner Martin Makary. <u>Details</u>.
- 1:00pm JHU Discussion: MAHA/Integrating Social and Clinical Care The Johns Hopkins University (JHU) Bloomberg Center holds a discussion on the Trump Administration's goals around "Make America Health Again" (MAHA), focused on the financial and health implications of a reimagined health care system that pushes the boundaries of traditional care to include investments in mitigating harmful social determinants of health. Details.

# Featured Analysis

- Litigation Update: Legal Cases in Response to Trump Administration Executive Actions In Policy Hub Insight Bank here.
- 100 Days of Disruption: Health Policy Under Trump 2.0 In Policy Hub Insight Bank here.
- Impact Update on HHS RIF and Reorganization In Policy Hub Insight Bank here.
- Impact Memo on Potential Budget Reconciliation Spending Cuts: Medicaid, ACA, Immigration, Commercial Insurance and More Available here.
- Insights for Impact: Federal Nutrition Programs In Policy Hub Insight Bank here.

• Impact Overview of President Trump's Day One EO – In Policy Hub Insight Bank here.

#### Congressional Lookback

#### Fri. (5/16)

• The House Budget Committee failed to advance the budget reconciliation package. Details.

# Wed. (5/14)

• The House Appropriations Committee and the Senate HELP Committee held hearings to review the FY 2026 budget for the HHS with Secretary Robert F. Kennedy Jr. <u>Details</u>.

#### Tues. (5/13)

- The House E&C Committee <u>advanced</u> its budget reconciliation package. <u>Details</u>.
- The House W&M Committee advanced its budget reconciliation package. Details.
- The House Agriculture Committee <u>advanced</u> its budget reconciliation package. <u>Details</u>.
- The Senate Judiciary Committee convened a <u>hearing</u> that examined competition issues in the prescription drug supply chain, with a focus on PBMs. <u>Details</u>.

#### Mon. (5/12)

- The House E&C Committee released its <u>draft text</u> for its portion of the <u>budget reconciliation</u> package. <u>Details</u>
- The House W&M Committee released <u>amendment in the nature of a substitute (AINS)</u> to its budget reconciliation legislation. <u>Details</u>.
- The House Agriculture Committee released a <u>committee print</u> of its budget reconciliation legislation. <u>Details</u>.

# Regulatory Lookback

# Fri. (5/16)

The FDA issued an RFI to begin its process of reviewing nutrition requirements in infant formulas.
 Comments are due September 11. Details.

## Thurs. (5/15)

 The GAO has <u>released</u> a report highlighting a lack of clarity and support for minors who provide unpaid care to family members with health conditions, disabilities, or functional limitations. <u>Details</u>.

# Tues. (5/13)

- **CMMI** released <u>information</u> about its <u>new strategic direction under the second Trump</u> Administration. <u>Details</u>.
- CMS and ASTP/ONC issued an RFI seeking input to shape future policies and infrastructure to support digital health innovation. Comments are due June 15. <u>Details</u>.

• **HHS and FDA** issued an RFI as part of a major initiative to reduce regulatory burdens across the health care system. Comments are due July 12. Details.

## Mon. (5/12)

- **President Trump** signed an <u>executive order</u> entitled "Delivering Most-Favored-Nation (MFN) Nation Prescription Drug Pricing to American Patients." <u>Details</u>.
- CMS released a <u>proposed rule</u> entitled "Medicaid Program; Preserving Medicaid Funding for Vulnerable Populations – Closing a Health Care-Related Tax Loophole Proposed Rule. Comments are due July 14. <u>Details</u>.
- **CMS** released <u>draft guidance</u> for initial price applicability year (IPAY) 2028 of the Medicare Drug Price Negotiation Program and effectuation of maximum fair prices (MFPs) in IPAYs 2026, 2027, and 2028. Comments are due June 26. Details.
- **The FDA and NIH** announced a new joint initiative, the Nutrition Regulatory Science Program, to study diet and chronic diseases. <u>Details</u>.

# Comment & Application Deadlines

- June 10: CMS released the FY 2026 IPPS and LTCH PPS proposed rule. Details.
- June 10: CMS released the FY 2026 IPF PPS proposed rule. Details.
- June 10: CMS released the FY 2026 IRF PPS proposed rule. Details.
- June 10: CMS released the FY 2026 Hospice Payment Rate Update proposed rule. Details.
- June 13: NIST released the Initial Public Draft (IPD) update of the Privacy Framework Version 1.1,
  a voluntary guidance tool aimed at helping organizations identify and manage privacy risks.
  Details.
- **June 15:** CMS and ASTP/ONC issued a <u>request for information (RFI)</u> seeking input to shape future policies and infrastructure to support digital health innovation. <u>Details</u>.
- June 26: CMS released <u>draft guidance</u> for initial price applicability year (IPAY) 2028 of the Medicare Drug Price Negotiation Program and effectuation of maximum fair prices (MFPs) in IPAYs 2026, 2027, and 2028. <u>Details</u>.
- **July 1:** The CDC <u>seeking nominations</u> for <u>membership on the Clinical Laboratory Improvement Advisory Committee (CLIAC). <u>Details</u>.</u>
- **July 12:** HHS and FDA issued an RFI as part of a major initiative to reduce regulatory burdens across the health care system. Comments are due July 12. <u>Details</u>.
- **July 14:** CMS released a <u>proposed rule</u> entitled "Medicaid Program; Preserving Medicaid Funding for Vulnerable Populations Closing a Health Care-Related Tax Loophole Proposed. <u>Details</u>.
- **September 11:** The FDA issued an RFI to begin its process of reviewing nutrition requirements in infant formulas. Details.