

Impact Health Policy Weekly

Please Note: Impact Health Policy Partners will be closed December 23-January 3 for the Holidays. We hope you and your families have a wonderful holiday season and a very happy new year. We look forward to continuing our working relationships with you 2025!

Framing the Week

Congress is in session this week finalizing details to an end of the year package before the current Continuing Resolution expires on Friday at midnight. The Senate will also be voting on the National Defense Authorization Act on Wednesday.

Text of the end of the year package has not yet been released as leaders are still ironing out details on provisions such as economic assistance to farmers as part of a one-year extension to the farm bill. We do know that the CR will likely extend into March, and the package will also include tens of billions of dollars in disaster relief for areas in the southeast hit hard by hurricanes this fall. Timing is critical, and agreements will have to be reached very soon to move the measure through both the House and the Senate before midnight on Friday.

The health care part of the overall package, which has been in flux for the past two weeks, started to take shape over the weekend, though the situation remains fluid. The agreement is said to include a two-year extension for expiring telehealth provisions; telehealth coverage under high deductible health plans for one year; two years of funding for funding for community health centers, the public health service and HRSA's Teaching Health Center GME program; a one year delay for scheduled cuts to disproportionate share hospitals (DSH) that serve communities most vulnerable members; and a 2.5% pay boost for the Medicare physician payment fee schedule. It is also said to include a two-year reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) and a five-year reauthorization for the SUPPORT Act for Programs for Opioid Response. Pharmacy benefit manager and patent reforms, reduced funding in the Medicare Improvement Fund (MIF), and other cost saving measures such as requiring the use of a National Provider Identifier (NPI) by Off-Campus Hospital Outpatient Clinics are being used to offset the cost of the package.

Impact Health Policy Partners will be putting out a comprehensive memo on the health care package with more details when the text becomes available.

119th Congress: Last week the Republican House Steering Committee met to finalize the <u>Committee</u> <u>Leadership positions</u> for the next Congress. Representative Brett Guthrie (R-KY) was named the new Chair of the House Energy & Commerce Committee and Rep. Tim Walberg (R-MI) was named the new Chair of the House Education and the Workforce Committee. New members of the Ways and Means Committee include Rep. Aaron Bean (R-FL); Rep. Max Miller (R-OH); Rep. Nathaniel Moran (R-TX); and Rep. Rudy Yakym (R-IN). New Republican members of the Energy and Commerce Committee include Rep. Cliff Bentz (R-OR); Rep. Erin Houchin (R-IN); Rep. Russell Fry (R-SC); Rep. Laurel Lee (R-FL); Rep. Craig Goldman (R-TX); Rep. Rep. Tom Kean (R-NJ); Rep. Julie Fedorchak (R-ND); Rep. Nick Langworthy



(R-NY); Rep. Gabe Evans (R-CO); and, Rep. Mike Rulli (R-OH). The Democratic Steering Committee should be making their leadership and committee roster announcements as soon as this week.

Regulatory Update

The Office of Management and Budget (OMB) completed review two FDA final rules:

- Nonprescription Drug Product The <u>final rule</u> is intended to increase options for applicants to develop and market safe and effective nonprescription drug products, which could improve public health by broadening the types of nonprescription drug products available to consumers. The final rule would establish requirements for a drug product that could be marketed as a nonprescription drug product with an additional condition for nonprescription use (ACNU) that an applicant must implement to ensure appropriate self-selection, appropriate actual use, or both by consumers.
- Nutrition The <u>final rule</u> would update the definition for the implied nutrient content claim
 "healthy" to be consistent with current nutrition science and federal dietary guidelines. The rule
 would revise the requirements for when the claim "healthy" can be voluntarily used in the
 labeling of human food products to indicate that a food, because of its nutrient content, may be
 useful in achieving a total diet that conforms to current dietary recommendations and helps
 consumers maintain healthy dietary practices.

OMB is also reviewing the following:

- Notice of Benefit and Payment Parameters for 2026 The <u>final rule</u> 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.
- Healthcare System Resiliency and Modernization The proposed rule would revise and update national emergency preparedness requirements for Medicare - and Medicaidparticipating providers and suppliers (was set for December 2023).
- Cybersecurity The proposed rule would make modifications to the Security Standards for the Protection of Electronic Protected Health Information (the Security Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). These modifications will improve cybersecurity in the health care sector by strengthening requirements for HIPAA regulated entities to safeguard electronic protected health information to prevent, detect, contain, mitigate, and recover from cybersecurity threats.

This Week in Health Policy

Mon. (12/16)



- 1:00pm Health Affairs Discussion: Health Disparities Health Affairs holds a discussion with health professionals to explore how efforts designed to increase access to and quality of care for underserved communities may align with efforts to address the rising cost of health care. <u>Details</u>.
- 2:00pm HHS Meeting: Federal Race and Ethnicity Collection Standards The Department of Health and Human Services (HHS) holds a meeting of the Advisory Committee on Minority Health (ACMH) to discuss recommendations on the implementation of the updated Office of Management and Budget (OMB) Federal race and ethnicity data collection standards (SPD 15) that is focused on opportunities for engagement with racial, ethnic, and Tribal community level organizations to support increased awareness of OMB SPD 15 and their intended goals within their communities. <u>Details</u>.
- **2:00pm AEI Discussion: Opioid Epidemic** The American Enterprise Institute for Public Policy Research holds a discussion on best practices for local governments to prevent and treat drug abuse, specifically on how to manage opioid settlement funding. <u>Details</u>.

<u>Tue. (12/17)</u>

- **12:00pm ITIF Discussion: Tech Policy Outlook in the Trump Administration** The Information Technology and Innovation Foundation (ITIF) holds a discussion on the outlook for tech policy in the incoming Trump administration. <u>Details</u>.
- **2:30pm Hearing: VA Health Care –** The House Veterans' Affairs Subcommittee on Health holds a legislative hearing to discuss several bills related to veterans' health care, including suicide prevention, menopause care, and support for medical students and VA workforce. <u>Details</u>.
- **3:00pm Hearing: Antitrust Reform –** The Senate Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights holds a hearing to examine a bipartisan path forward for antitrust enforcement and reform. <u>Details</u>.

Wed. (12/18)

- 9:30am CSIS Discussion: Reduction in Fentanyl Overdose Deaths The Center for Strategic and International Studies (CSIS) holds a discussion with Rahul Gupta, Director of the White House Office of National Drug Control Policy, on the 15 percent decline in overdose deaths in 2024, 70 percent of which are caused by fentanyl overdose, and what factors are driving this change. Details.
- 10:15am Heritage Discussion: MAHA/Chronic Disease Epidemic The Heritage Foundation holds a discussion on policy to Make America Health Again (MAHA). Includes conversations with Sen. Ron Johnson (R-WI) on public health institutions and a panel discussion on "Food, Drugs, and America's Chronic Disease Epidemic." <u>Details</u>.
- 10:15am Hearing: VA Post Chevron The House Veterans' Affairs Committee holds an oversight hearing titled: "Restoring Congressional Power over VA After Loper Bright Enterprises v. Raimondo." <u>Details</u>.
- 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. <u>Details</u>.
- **2:00pm Hearing: Access to Reproductive Health Facilities** The House Judiciary Subcommittee on the Constitution and Limited Government holds a hearing to "examine the



Biden-Harris Department of Justice's unequal application of the Freedom of Access to Clinic Entrances (FACE) Act." <u>Details</u>.

• **2:30pm – Hearing: Effects of Trump's Tariffs –** The Senate Joint Economic Committee holds a hearing on "Trade Wars & Higher Costs: The Case Against Trump's Tariffs." <u>Details</u>.

Featured Analysis

- *NEW* Policy Round-Up: CBO, GAO Reports on ACA Premium Tax Credits; DACA Marketplace Eligibility Available <u>here</u>.
- Impact Budget Reconciliation Primer In Policy Hub Insight Bank <u>here</u>.
- 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. (12/13)

- MedPAC held day two of its <u>December 2024 public meeting</u> and held sessions on assessing payment adequacy for home health, hospice, and ESRD. All Impact Health session summaries are available in Policy Hub <u>here</u>.
- MACPAC convened virtually for day two of its <u>December 2024 public meeting</u> and held sessions on HCBS. All Impact session summaries are available on Policy Hub <u>here.</u>

<u>Thurs. (12/12)</u>

- MedPAC held day one of its <u>December 2024 public meeting</u> and held sessions on assessing payment adequacy for physicians, OPPS, IPPS, SNF, and IRF. All Impact Health session summaries are available in Policy Hub <u>here</u>.
- MACPAC convened virtually for day one of its <u>December 2024 public meeting</u> and held sessions on managed care, external quality review, the CY 2026 MA and Part D proposed rule, selfdirected services, and HCBS. All Impact session summaries are available on Policy Hub <u>here</u>.

Regulatory Lookback

Weds. (12/11)

- **CMS** <u>released a brief</u> on the health outcomes of Medicaid and CHIP enrollees aged 15-49 who experienced preterm births or severe maternal morbidity in 2021. <u>Details</u>.
- **ASTP** released the TEFCA <u>final rule</u>. <u>Details</u>.



Tues. (12/10)

- **The USDA** released the <u>Scientific Report</u> of the 2025 Dietary Guidelines Advisory Committee. Details.
- **The GAO** released a <u>report</u> comparing employer-sponsored plans to Healthcare.gov Marketplace plans. <u>Details</u>.
- SAMHSA released several updates. <u>Details</u>.

Comment & Application Deadlines

- **December 27:** HHS, DOL, and the Treasury released <u>proposed rules</u> to expand access to coverage of recommended preventive services without cost sharing in the commercial market, with a focus on OTC contraceptives. <u>Details</u>.
- December 27: CMS released an information collection request (ICR) on the Medicare Transaction Facilitator (MTF) to be used in 2026 and 2027 in the Medicare Drug Price Negotiation Program. <u>Details</u>.
- 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 25: CMMI released an <u>RFA</u> for the Cell and Gene Therapy Access Model. <u>Details</u>.
- **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>.