

Impact Health Policy Weekly

Framing the week

As Affordable Care Act (ACA) marketplace open enrollment begins and Supplemental Nutrition Assistance Program (SNAP) funding lapses, bipartisan talks are underway on the fiscal year (FY) 2026 appropriations bills, in hopes that an agreement on funding will lead to a reopening of the government. However, President Trump remains adamant that no health care “fix” will be pursued until the Democrats agree to reopen the government, and has urged Republicans to “terminate the filibuster.” It is the hope that the government will reopen this later week, but the fate of the enhanced premium tax credits and a broader health care package once reopen still remains unclear.

340B Rebate Model Pilot Program Participants

The Health Resources and Services Administration (HRSA) [announced](#) that it has approved eight plans for participation in the 340B Rebate Model Pilot Program, beginning January 1, 2026. For 2026, the model is limited to Medicare Drug Price Negotiations Program selected drugs, and the manufacturers of eight of the ten selected drugs will participate.

Under the program, HRSA detailed that covered entities will continue to make purchases through their 340B wholesaler account and ensure they are only requesting rebates on the pilot program drugs dispensed to 340B eligible patients after a purchase is made. Manufacturers will then work with their distributor partners to:

- Ensure the wholesale acquisition cost (WAC) price is loaded in the 340B wholesaler account where purchases will be made by covered entities to then obtain a rebate; and
- Obtain necessary data from the 340B wholesaler account to monitor purchases in that account.

Additionally, HRSA explains that it will provide a mechanism for 340B Program stakeholders to provide feedback on their experience utilizing the rebate model. The pilot program page also has frequently asked questions (FAQs) section that address various details of the program, including how rebates are calculated, compliance tracking, and reconciliation of claims.

MAHA Update

Last week, the Food and Drug Administration (FDA) [announced actions](#) to restrict the sale of unapproved ingestible fluoride prescription drug products for children, pursuant to the [Make Our Children Health Again Strategy](#). This includes sending [notices](#) to four companies outlining the FDA’s intention to take enforcement action against companies marketing unapproved fluoride-containing ingestible drugs labeled for use in children under age 3 or older children at low or moderate risk for tooth decay. The agency has also published a [scientific evaluation](#) of the current use of unapproved ingestible fluoride drug products and their potential benefits and risks.

Regulatory Update

The Office of Management and Budget (OMB) completed reviewing the following:

- **Medicaid and Immigration Status.** A [final rule](#) titled, “Medicaid Eligibility Changes Under the Affordable Care Act of 2010; Giving States Freedom to Use Immigration Information to Determine State Residency for Medicaid Eligibility.” The final rule is part of the Trump administration’s efforts to [increase federal oversight](#) on states using Federal Medicaid funding for the health care of undocumented immigrants.

OMB is also reviewing the following:

- **Medicare:**
 - **CY 2027 Medicare Advantage/Part D Policy.** [Proposed CY 2027 policy and technical changes](#) to Medicare Advantage, Medicare Prescription Drug Benefit, Medicare Cost Plan, and PACE
 - **Medicare Payment Rules.** The CY 2026 Hospital Outpatient PPS [final rule](#), the CY 2026 ESRD [final rule](#), and the CY 2026 Home Health PPS [final rule](#).
 - **Procurement of Domestic PPE.** An [advance notice of proposed rulemaking](#) that would detail program incentives and requirements for Medicare providers and suppliers to invest and phase-in the procurement of American made personal protective equipment (PPE) and essential medicine to secure our nation’s health and safety.
- **Medicaid:**
 - **Gender-Affirming Care.**
 - A [proposed rule](#) titled, “Medicaid Program; Prohibition on Federal Medicaid Funding for Sex Trait Modification Procedures Furnished to Children and Youth.”
 - A [proposed rule](#) titled, “Medicare and Medicaid Programs; Hospital Condition of Participation: Limiting Participation Based on the Performance of Sex Trait Modification Procedures on Children.”
 - **State Directed Payments.** A [proposed rule](#) titled, “Medicaid Managed Care-State Directed Payments.” The proposed rule appears intended to advance a [presidential memorandum](#) released on June 6, which directs HHS to “eliminate waste, fraud, and abuse in Medicaid, including by ensuring Medicaid payments rates are not higher than Medicare, to the extent permitted by applicable law.”
- **Prescription Drugs:**
 - A [proposed](#) rule titled, “Improving Transparency into Pharmacy Benefit Manager Fee Disclosure” and a [proposed rule](#) addressing Transparency in Coverage requirements.
 - **CMMI Drug Pricing Models.** A [proposed rule](#) for a Global Benchmark for Efficient Drug Pricing (GLOBE) Model and a [proposed rule](#) for Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model
- **Nutrition:**
 - **Head Start.** A [notice](#) from the Administration for Children and Families titled, “Publish Request for Information: Nutrition Services in Head Start Programs
- **Immigration:**
 - **Unaccompanied Children.** An [interim final rule](#) titled, “Unaccompanied Children Program Foundational Rule; Update to Include Proof of Identity and Income Verification Standards.”

This Week in Health Policy

Mon. (11/3)

- **9:30am – AEI Discussion: Parental Substance Use** – The American Enterprise Institute (AEI) holds a discussion examining the impact of parental substance use on child safety, including an analysis of maltreatment fatality cases involving substance use. [Details.](#)
- **2:00pm – CQ RollCall Discussion: Fall 2025 Health Care Policy Outlook** – CQ RollCall and FiscalNote hold a discussion on what to expect in health care policy for the rest of the fall legislative session, including the outlook on Affordable Care Act premium subsidies, health care price transparency, Medicare Advantage upcoding, hospital payments, and the 340B Drug Pricing Program. [Details.](#)

Wed. (11/5)

- **10:00am – Hearing: Registered Apprenticeships** – The Senate Health, Education, Labor, and Pensions Committee holds a hearing to examine registered apprenticeship, focusing on scaling the workforce for the future. [Details.](#)
- **10:00 am – Supreme Court Hearing: Tariffs** – The Supreme Court will begin oral arguments on [Learning Resources Inc. v. Trump](#), a case challenging President Trump's power to impose tariffs under the International Emergency Economic Powers Act (IEEPA). [Details.](#)
- **2:30pm – Hearing: President Trump's Regulatory Rollback** – The Senate Small Business and Entrepreneurship Committee holds a hearing to examine Trump's regulatory rollback with Casey Mulligan, Chief Counsel for Advocacy at the Small Business Administration (SBA). [Details.](#)
- **3:30pm – Hearing: Families Living with Aging-Related Diseases** – The Senate Special Committee on Aging holds a hearing to examine how the Older Americans Act uplifts families living with aging-related diseases. [Details.](#)

Thurs. (11/6)

- **8:00am – Axios Discussion: Future of Alzheimer's Care** – Axios holds a discussion examining the latest advancements and challenges around the future of Alzheimer's care, including how improvements in diagnostic tools, health systems and policy alignment can better support patients, caregivers and families. Reps. Vern Buchanan (R-FL) and Paul Tonko (D-NY) will participate. [Details.](#)
- **8:30am – NASEM Meeting: Value-Based Payment for Serious Illness** – The National Academies of Sciences, Engineering, and Medicine (NASEM) holds a discussion to explore value-based payment for serious illness care, including ways that value-based financing arrangements currently impact individuals with serious illness, their families, and care partners, as well as opportunities to improve the quality and cost of care in the future. [Details.](#)
- **9:00am – FDA Meeting: Generative AI-Enabled Digital Mental Health Medical Devices** – The Food and Drug Administration (FDA) holds a meeting of the Digital Health Advisory Committee to discuss the benefits, risks to health, and risk mitigations that might be considered for generative

artificial intelligence (AI) enabled digital mental health medical devices, including premarket evidence and postmarket monitoring considerations. [Details.](#)

- **2:00pm – Hearing: Assessing Obamacare** – The Senate Homeland Security and Governmental Affairs Subcommittee on Investigations holds a hearing titled “Assessing the Damage Done by Obamacare.” [Details.](#)
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. MedPAC’s daily operations have been affected by the lapse in appropriations, and the status of the Commission’s November meeting is pending. [Details.](#)

Fri. (11/7)

- **Meeting: MedPAC** – MedPAC meets to discuss Medicare issues and policy questions. MedPAC’s daily operations have been affected by the lapse in appropriations, and the status of the Commission’s November meeting is pending. [Details.](#)

Additional Multi-Day Events

- **Nov 2-Nov 5 – APHA Discussion: Public Health** – The American Public Health Association (APHA) holds its 2025 Annual Meeting & Expo, with the theme “Making the Public’s Health a National Priority.” [Details.](#)

Featured Analysis

- **Impact Health Government Shutdown Risks and Implications** – In Policy Hub [here.](#)
- **Impact Health Spring 2025 Regulatory Outlook** – In Policy Hub [here.](#)
- **Insight for Impact: Vaccine Policy Under RFK Jr.** – In Policy Hub [here.](#)
- **OBBA Medicaid Provisions and Timeline for Implementation** – In Policy Hub [here.](#)
- **Changes to ACA Premium Tax Credit Policy in 2026 and Beyond** - In Policy Hub [here.](#)

Congressional Lookback

Wed. (10/29)

- **The Senate HELP Committee** held a [hearing](#) to discuss the future of biotechnology and the steps needed to maintain U.S. leadership in biomedical innovation. [Details.](#)

Mon. (10/27)

- **Democrat Senators** [sent a letter](#) calling on the Administration to immediately open “window shopping” ahead of Affordable Care Act (ACA) Marketplace open enrollment. [Details.](#)

Regulatory Lookback

Fri. (10/31)

- **CMS** released the CY 2026 Medicare Physician Fee Schedule [final rule.](#) [Details.](#)

- **Two federal judges** ruled that the Trump administration's suspension of SNAP during the ongoing government shutdown was unlawful. [Details.](#)

Wed. (10/29)

- **CMS** opened [window shopping](#) for consumers on HealthCare.gov. [Details.](#)
- **The FDA** released new [draft guidance](#) to accelerate development of biosimilars by addressing the necessity of comparative efficacy studies. [Details.](#)
- **HHS OIG** [found](#) that the CMS Specialty Focus Facility program has not led to lasting improvements in quality or compliance. [Details.](#)

Tues. (10/28)

- **The U.S. District Court for the Northern District of California** issued a PI in [American Federation of Government Employees, AFL CIO v. United States Office of Management and Budget](#), continuing to block the Trump administration from implementing RIFs. [Details.](#)
- **The CFPB** issued an [interpretive rule](#) reaffirming that the Fair Credit Reporting Act generally preempts state laws that address broad areas of credit reporting. [Details.](#)

Comment & Application Deadlines

- **November 3:** The FTC issued an [RFI](#) to examine the use and impact of employer noncompete agreements and to help shape potential future enforcement actions. [Details.](#)
- **November 5:** CMS released a [NOFO](#) for the [Rural Health Transformation \(RHT\) Program](#). [Details.](#)
- **December 1:** The FDA issued an [RFC](#) to gather input on how AI-enabled medical devices perform in clinical settings after deployment. [Details.](#)
- **June 3:** CMMI released a [NOFO](#) for the second cohort of the Innovation in Behavioral Health Model. [Details.](#)