



Issues for the week ending December 12, 2025

Federal Issues

Legislative

ACA Extension Fails in Senate, House Votes This Week

On Thursday, the Senate failed to advance two health care proposals, <u>S. 3386</u>, Health Care Freedom for Patients Act (Republican) and <u>S.3385</u>, Lower Health Care Costs Act (Democrat), with both procedural votes failing 51-48, well short of the 60 votes needed to advance.

The Democrats' bill would have extended the Affordable Care Act's (ACA) Enhanced Premium Tax Credits (EPTC) for three years while the Republican bill would have placed up to \$1500 in a health savings account for individuals enrolled in bronze or catastrophic plans.

The votes were largely along party lines, although Senator Rand Paul (R-KY) opposed the GOP bill, while Senators Josh Hawley (R-MO), Dan Sullivan (R-AK), Susan Collins (R-ME), Lisa Murkowski (R-AK) joined Democrats in supporting theirs.

Why this matters: The outcome leaves negotiations at an impasse, though some still hold out hope for a bipartisan deal next month. Congress will have to pass government funding legislation ahead of the January

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New York Legislative 30 government deadline, which could provide a vehicle for a health care deal, if the numerous differences can be resolved.

House up next: The House is planning a vote this week before adjourning for the year. House GOP leadership have released their health care package, which does not include an ACA extension but includes a mix of policies that have passed the House before, including Association Health Plans (AHPs), Individual Coverage Health Reimbursement Arrangement (ICHRAs), and allowing self-funded plans to purchase stop-loss coverage. The proposal also funds ACA cost-sharing reductions (CSRs) beginning in 2027, as well as bipartisan Pharmacy Benefit Manager (PBM) transparency reforms.

It is unclear if leadership will allow moderate Republicans to offer an amendment consisting of bipartisan proposals they have negotiated to extend the EPTCs with some reforms to address GOP fraud concerns.

 If not, GOP moderates are threating to join with Democrats in using a discharge petition to force a floor vote.

The two leading bipartisan bills are the Bipartisan Health Insurance Affordability Act or the Common Ground for Affordable Health Care Act. The former includes a two-year ACA extension but faces GOP resistance The latter proposes a one-year modified extension with marketplace reforms and an expedited pathway to negotiating a longer extension. In the event a discharge petition succeeds, the House vote would be held when Congress returns in January.

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Federal Issues

Regulatory

Executive Order Targeting State AI Laws Issued

What's happening: President Trump signed an executive order (EO), <u>Ensuring a National Policy</u>
<u>Framework for Artificial Intelligence</u>, directing federal agencies to challenge state artificial intelligence (AI) laws and advance a unified national standard to AI regulation. The order establishes new federal processes to evaluate state AI laws, impose funding restrictions on states with "onerous" laws and develop a legislative proposal to establish a uniform federal AI framework that preempts state AI laws.

Why it matters: The EO addresses concerns with a patchwork of state AI requirements. Plans should anticipate federal scrutiny of state AI laws and the possibility of shifting compliance expectations as this process unfolds. These developments may impact the <u>ongoing work on AI</u> at the National Association of Insurance Commissioners (NAIC), including the development of an AI systems evaluation tool.

The details: The EO establishes six federal actions that shape how agencies will evaluate and respond to state AI laws:

- Al Litigation Task Force: Within 30 days, the Attorney General will form a task force dedicated to challenging state Al laws viewed as inconsistent with federal Al policy.
- Evaluation of State Al Laws: Within 90 days, the Secretary of Commerce must publish an assessment identifying "onerous" state Al laws and recommend which should be referred to the Al Litigation Task Force.
- **Funding Restrictions:** States with laws identified as onerous may become ineligible for certain Broadband Equity Access and Deployment (BEAD) program funds. Additionally, agencies must review discretionary grants to determine whether funding can be conditioned on states refraining from enacting or enforcing AI laws that conflict with the policy of the EO.
- Federal Al Reporting/Disclosure Standard: The Federal Communications Commission will consider establishing a federal standard for Al model reporting and disclosure that would preempt conflicting state laws. This may impact NAIC's work to develop an Al Systems Evaluation Tool which relies on states' existing market conduct and financial exam authority.
- **FTC Preemption Statement:** The Federal Trade Commission must issue a policy statement explaining when state laws that mandate alteration of AI outputs are preempted by federal prohibitions on deceptive practices.
- **Federal Legislation Development:** The Administration will prepare a legislative recommendation for a uniform federal AI framework that preempts state AI laws. Preemption would not extend to certain categories (e.g., child safety, state procurement, data center permitting).

What's next: States are likely to push back on the EO, resulting in a potentially contentious implementation - a number of bipartisan state policymakers had urged the Administration not to move forward with the EO prior to it being signed.

CMS Releases Guidance on Medicaid Community Engagement Requirements

On December 8, CMS released a Center for Medicaid & CHIP Services (CMCS) <u>Informational Bulletin</u> providing guidance to states on requirements to establish Medicaid Community Engagement requirements

for certain Medicaid beneficiaries as passed in <u>H.R. 1</u>, the *One Big Beautiful Bill Act*. The letter largely reiterated the statutory language and did not address outstanding questions around the potential for self-attestation, medical frailty definitions, verification sources and other areas in which states will need further guidance before proceeding with implementation.

Highlights Include:

- Clarity that other than the prohibition against states using MCOs to determine beneficiary compliance, CMS does not see any other prohibition on states delegating some support activities to MCOs to support states' implementation of community engagement requirements. CMS expects to issue further guidance on the potential role that MCOs can play in activities not related to determining compliance.
- For states that are interested in postponing the implementation date past January 1, 2027, CMS indicated requests would be considered on a case-by-case basis and CMS approval would be limited to states that are making meaningful efforts toward implementation and experience severe and/or unexpected issues that hinder their progress.

Go Deeper: See AHIP's <u>letter</u> sent to CMS ahead of the guidance and see AHIP's <u>detailed toolkit</u> for states to use in implementing the Medicaid community engagement requirements.

CMS is still required to release an interim final rule on community engagement requirements by June 1, 2026, and may need to provide additional subregulatory guidance before then to enable states to complete the system and process changes needed to implement work requirements by Jan.1, 2027.

IRS Releases Guidance on New HSA Provisions of One Big Beautiful Bill Act

On Dec. 9, 2025, the Internal Revenue Service (IRS) released <u>Notice 2026-5</u>, which provides guidance on changes to health savings accounts (HSA) enacted under the One Big Beautiful Bill Act (OBBBA). These changes expand the availability of HSAs.

Why this matters: The guidance is necessary for Plans and other stakeholders to implement the OBBBA's changes in alignment with high-deductible health plan (HDHP) rules, which ensure members can utilize HSAs. Policymakers on Capitol Hill may also take interest as discussions on health care affordability and the health care tax credit continue.

The Treasury Department and the IRS are accepting comments on all aspects of the notice by March 6, 2026.

Further details on the guidance can be found in the memo shared with Plans on December 9.

The OBBB expands access to HSAs by making the following changes:

• **Telehealth and Remote Care Services**: The OBBB made permanent the ability to receive telehealth and other remote care services before meeting the high-deductible health plan (HDHP) deductible while remaining eligible to contribute to an HSA, effective for plan years beginning on or after Jan. 1, 2025.

- Bronze and Catastrophic Plans Treated as HDHPs: As of Jan. 1, 2026, bronze and catastrophic
 plans available through an Exchange are considered HSA-compatible, regardless of whether the
 plans satisfy the general definition of an HDHP. This expands the ability of people enrolled in these
 plans to contribute to HSAs, which they generally have not been able to do in the past. Notice 202605 clarifies that bronze and catastrophic plans do not have to be purchased through an Exchange to
 qualify for the new relief.
- **Direct Primary Care Service Arrangements:** Beginning Jan. 1, 2026, an otherwise eligible individual enrolled in certain direct primary care (DPC) service arrangements may contribute to an HSA. In addition, they may use their HSA funds tax-free to pay periodic DPC fees.

CMS Issues Proposed Rule on Updates to Increasing Organ Transplant Access Model What's happening: On Dec. 9, the Center for Medicare & Medicaid Services (CMS) issued a proposed rule to update and revise the Increasing Organ Transplant Access (IOTA) Model. Comments will be due around Feb. 6, 2026.

Why this matters: IOTA is a six-year mandatory Medicare fee-for-service (FFS) payment model that began July 1, 2025, and aims to test whether performance-based incentive payments for kidney transplant hospitals increases access to kidney transplants for patients with end-stage renal disease. This proposed rule updates parameters for Performance Year (PY) 2 of the IOTA Model, which will start July 1, 2026, and future PYs. Most notably, CMS seeks feedback on the potential inclusion of Medicare Advantage (MA) beneficiaries within the definition of Medicare kidney transplants.

Key Highlights:

- Participant Eligibility: CMS is proposing to remove Department of Veterans Affairs and Military
 Treatment Facility transplant programs from inclusion since Medicare does not reimburse those
 facilities. CMS also proposes to increase the minimum transplant volume required for model
 eligibility from 11 to 15 adult kidney transplants performed annually across each of the three
 baseline years.
- Payment: Downside payments would be due within 60 days of CMS request, after which any remaining amount owed would be considered delinquent debt. CMS also proposes expanding its extreme and uncontrollable circumstances flexibilities to 1) apply to areas under a public health emergency or Stafford Act declaration; 2) extend payment and reporting accommodations to IOTA participants impacted by EUC; and 3) adjust the upside / downside risk payment amount when such an emergency period has been declared.
- Calculating Composite Graft Survival Rate: CMS is seeking comments on whether a risk-adjustment methodology that considers transplant recipient and donor characteristics (e.g., age, diabetes status, sex, kidney function) in addition to time-to-event data would be appropriate for calculating the composite graft survival rate in the quality domain and the best approach to use.
 Additionally, whether the proposed risk adjustment methodology should also include a time-to-event model when calculating the composite graft survival rate in the quality domain.

- Health Equity: CMS proposes to remove the voluntary Health Equity Plan requirement as well as all health equity related provisions.
- **Transparency:** CMS proposes several updates to increase transparency, including the posting of living donor selection criteria by the end of PY 2 and each subsequent PY.

MA Inclusion: CMS seeks public comment on several questions including:

- Are there any innovative transplant-related strategies being tested by MA organizations (MAOs)?
- What are the anticipated effects that implementation of this contemplated policy modification would have on the kidney transplant strategic initiatives currently under consideration by MAOs?
- How does the growth of MA compared to Medicare FFS affect participation and incentives in the IOTA Model?
- What do MA plans consider as their role in the kidney transplant process?
- What performance metrics do MA plans consider when evaluating kidney transplant hospitals and which are the most important?
- How do the IOTA Model performance metrics play a role in the relationship between an MA plan and a contracted provider?
- If any, what are potential effects that MA inclusion in the model could have on a contracting relationship between providers and MA plans (for example, negotiation of terms)?
- If any, what are potential unintended consequences of MA inclusion on utilization management tools employed by MAOs?
- Would an MA plan consider implementing similar performance metrics to those included in the IOTA Model?
- Under what circumstances is it appropriate for CMS to consider directly incentivizing a behavior change from a provider contracted in an MA plan?

CMS Releases Guidance on Use of Segregated Abortion Funds

On Dec. 9, 2025, CMS released <u>Frequently Asked Questions (FAQs) on Usage of Funds in Section 1303</u> <u>Segregated Accounts by Qualified Health Plan (QHP) Issuers in the Individual Market</u> to clarify how QHP issuers may use funds segregated to cover non-Hyde abortion services, as well as funds segregated to cover all other services.

Why this matters: CMS recognizes funds in non-Hyde abortion segregated accounts have accumulated because the cost of covering non-Hyde abortion services is generally less than the mandated amount under Affordable Care Act regulations. The FAQs clarify for what purposes QHP issuers may use the accumulated

funds. The FAQs may also serve to provide assurances to policymakers on Capitol Hill who have raised concerns about QHP issuer segregation practices as a reason not to extend tax credits.

CMS Releases 2026 SSI, Spousal Impoverishment and Medicare Savings Program Resource Standards

CMS released a bulletin outlining 2026 Supplemental Security Income (SSI), Spousal Impoverishment Standards and resource standards for the Medicare Savings Program (MSP). Under the Medicaid spousal impoverishment provisions, when spouse enters nursing home care, a certain amount of a couple's combined resources is protected for the spouse remaining in the community. Effective Jan.1, 2026, the resource standards for single and married Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Beneficiaries (SLMBIs) and Qualified Individuals (QIs) will be \$9,950 and \$14,910, respectively. The bulletin also includes a chart outlining the SSI Federal Benefit Rate (FBR), the SSI Resource Standard, Income Cap Limit, and Spousal Impoverishment Monthly Maintenance Needs Allowances. Read More

CMS Announces the Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-based Approaches Through Evidence (MAHA ELEVATE) Model

CMS <u>announced</u> the voluntary model for Original Medicare designed to test whole-person functional and lifestyle medicine interventions not covered under Original Medicare for Original Medicare beneficiaries. CMS plans to release a Notice of Funding Opportunity (NOFO) in early 2026 with a launch date of Sept. 1, 2026. The voluntary model will provide approximately \$100 million to fund three-year cooperative agreements for up to 30 proposals that promote health and prevention for Original Medicare beneficiaries. The model will not include Medicare Advantage nor alter benefits, coverage or rights in Original Medicare. All proposals must incorporate nutrition or physical activity as part of the design and three awards will be reserved for interventions that address dementia.

State Issues

New York

Legislative

2025 Session End of Year Activity; Legislation Sent to Governor

The final few bills of note for health plans were sent to the Governor late last week, including:

- A.3319/S.1001 Requires outpatient care provided by creative arts therapists be included in certain insurance policies.
- A.3986-A/S.2105-A Requires health plans to provide notice of a fee when using a credit card, virtual credit card or other electronic fund transfers to make payments to a provider and offer an alternative that does not include fees.
- A.7038-A/S.6897-A Requires the Office of Mental Health (OMH) and the Office of Addiction Services and Supports (OASAS) to publish a fee schedule for commercial health plans to utilize

in reimbursing services for outpatient mental health and substance use disorder treatment at certain in-network facilities.

S.929/A.2141 – New York Health Privacy Act. A coalition of nearly 50 organizations, including
the NY Health Plan Association and the Business Council of NYS (Highmark is members of
both) requested a veto via a memo submitted to the Governor.

The above bills must be signed or vetoed by 12/19/2025. The Health Privacy Act and Virtual Credit Card bills both have proposed chapter amendments currently being negotiated.

All 2025 passed legislation must be acted upon by the Governor by 12/31/25.

State Issues

Pennsylvania

Legislative

Legislative Update

- Al Legislation: The House Communications & Technology Committee will hold a hearing this week to discuss Representative Venkat's House Bill 1925. This bill would regulate the use of Artificial Intelligence by both insurers and healthcare practitioners.
- Representative Venkat, the Insurance Federation of Pennsylvania, Independence Blue Cross, the Department of Insurance, Office of Attorney General and other practitioner and interest groups are expected to provide verbal testimony at the hearing.
- Highmark, as well as other interested parties including the Departments of Human Services and Health, have provided written testimony. Considering President Trump's executive order last week regarding the state regulation of artificial intelligence, this piece of legislation has an uncertain future in the General Assembly with no further action planned.
- House Health Committee Activity: The House Health Committee will be meeting on Wednesday
 to consider legislation which would amend the state Vital Statistics Law, allowing for midwives to file
 death certificates, as well as legislation to establish a state based medical stockpile of supplies to
 have available to healthcare facilities and other qualifying groups in the event of pandemic akin to
 COVID-19.

Following this week's session, both chambers are adjourned until January 6th, when they will hold their Constitutionally mandated reorganization session, and will return to voting session on January 26th.

Regulatory

State Releases New Guidance to Standardize Child Abuse, Neglect Certifications

Last week, the Office of Children, Youth, and Families released guidance for physicians to help assess when a child is in serious or critical condition due to suspected abuse or neglect.

A near-fatality is defined as a report of abuse or neglect of a child who has been designated by a physician to be in serious or critical condition. The guidance clarifies that a child is in serious or critical condition if the suspected abuse or neglect:

- Resulted in unstable vital signs which required treatment (e.g., hypotension which required IV Fluid, hypothermia which required rewarming) **OR**
- Required life-saving medical intervention (e.g., CPR, Narcan, intubation or ventilation, surgical intervention) **OR**
- Required admission to an intensive care unit for treatment. This would NOT include admission to an ICU for observation only, transfer to a tertiary care center for observation/evaluation, ICU admission due to hospital resource availability, or because the entire unit (e.g., a burn unit) is considered a critical care/intensive care unit regardless of injury severity.

Why this matters: Physicians' interpretation of what it means to be in serious or critical condition is variable leading to differences in how the term "serious or critical condition" has been applied over time and across Pennsylvania. The guidance—developed with input from physicians around the state—is intended to standardize reporting to ChildLine of children who have a near-fatality due to suspected abuse or neglect.

Questions or concerns should be directed to <u>Dr. Rachel Berger</u>, medical director, Pennsylvania Office of Children, Youth and Families.

Industry Trends

Policy / Market Trends

CivicaScript: BCBS Patients Benefit as Competition Lowers Generic Costs
CivicaScript just released its 2024 Annual Savings Report, spotlighting the impact of "disruptive collaboration" to make generic medicines more affordable for members with prostate cancer.

Why this matters: CivicaScript, a partnership among Blue Cross Blue Shield Association and 23 BCBS companies, was created to lower drug costs and improve access for patients nationwide. The analysis of CivicaScript's abiraterone for prostate cancer shows the model is delivering on its promise: bringing high-quality, lower-cost generics directly to consumers.

By the numbers:

- Patients and participating health insurers saved \$17.8 million in 2024.
- Patients who switched to CivicaScipt's abiraterone saved **64%** compared to other generics, or about **\$700 per person** for the year.
- Health insurers saved **91%** on average, or about **\$1,125 per claim**.
- If all eligible patients had switched, total savings could have reached \$60.4 million.

The big picture: By driving competition in the market, CivicaScript abiraterone appears to be having a ripple effect, bringing down drug prices across the board. After its launch, the average cost of abiraterone from other manufacturers dropped 19%.

What they're saying:

- "The first CivicaScript generic in the market has significantly lowered out-of-pocket costs for our members," said Corey DeLuca, VP of clinical and specialty pharmacy services for Highmark Inc., parent company of Highmark BCBS Plans. "Now, even more Highmark members will benefit through new CivicaScript drugs for a wider range of health conditions."
 - Highmark shared in a <u>press release</u> that Highmark members, group customers and the Plan collectively saved over \$8 million since the lower-cost version of abiraterone acetate first became available.

What's next: CivicaScript and BCBS companies are just getting started. CivicaScript is expanding its portfolio with two new biosimilars in January 2026, insulin glargine-yfgn and ustekinumab-aauz (interchangeable with Stelara).

Summary of MedPAC's December 2025 Public Meeting

What's happening: The Medicare Payment Advisory Commission (MedPAC) held its December public meetings last week on Thurs. Dec. 4 and Fri. Dec. 5. The December meeting transcript and slides are available here. A detailed summary of each session is included.

Note: The October and November public meetings were canceled during the government shutdown.

Why this matters: The public meetings are a venue for MedPAC to present research and policy options for Commissioner discussion. There are typically seven meetings held during the meeting cycle that runs from September through April. While MedPAC's recommendations do not automatically become law, they are reviewed by Congress and the Centers for Medicare and Medicaid Services (CMS) and have the potential to influence future policy through legislation or regulations.

The details: Seven of the eleven sessions during the December meeting were focused on MedPAC's required annual review of Medicare Fee-for-Service (FFS) payment policies.

Many of the sessions offered draft recommendations for Medicare FFS payment systems that will be included in MedPAC's March 2026 Report to Congress. The draft recommendations can change prior to voting, which occurs in early 2026.

While there were no sessions focused specifically on MA, two sessions did have some discussions related to MA:

- Session 9, Improving Medicare's Payment Approaches: Highlights MA as one of three
 distinct Medicare payment structures (FFS, Alternative Payment Models (APMs) and MA).
 This was proposed as a new conceptual chapter to lay out what can and cannot be done in
 each sector relative to payment approaches.
- Session 3, Post-Acute Care: Trends and Key Issues: Differences across three postacute care settings in FFS versus MA, were noted. Commissioners also agreed that more

data should be collected on the relationship between the three settings, patients and either their FFS or MA coverage.

CMS Posts First Open Enrollment Snapshot for ACA Marketplaces

On December 5, CMS released the first Enrollment <u>Snapshot</u> for the ACA Health Insurance Marketplaces 2026 Open Enrollment Period (OEP). Since the start of Open Enrollment on November 1, over 5,750,000 enrollees have signed up for Marketplace, including approximately 950,000 new enrollees and 4.8 million returning enrollees.

The 2026 Marketplace OEP runs from November 1, 2025, to January 15, 2026, for states using the HealthCare.gov platform. Consumers must enroll by December 15, 2025, for coverage that starts January 1, 2026, or by January 15, 2026, for coverage that starts February 1, 2026.

Campaign for Sustainable Rx Pricing Highlights the Value of Skinny Labeling

The Campaign for Sustainable Rx Pricing (CSRxP) published a <u>new article</u> highlighting the *Skinny Labels, Big Savings Act*, bipartisan federal legislation that would strengthen protections for "skinny labeling," a regulatory pathway that enables generic and biosimilar manufacturers to seek FDA approval for uses of drugs no longer under patent protection.

Why this matters: Skinny labeling has fostered competition for decades by helping more affordable generic and biosimilar alternatives to high-priced brand name drugs enter the market, generating substantial savings for patients, taxpayers, and the health care system.

Bill Spotlight: The *Skinny Labels, Big Savings Act* (H.R. 6485, S. 43) would preserve legitimate patent rights by ensuring that generic manufacturers who obtain FDA approval for skinny label uses are not held liable for method-of-use patent infringement when operating by federal law. By reinforcing the skinny labeling pathway, the bill would help prevent anti-competitive abuse of the system that keeps drug prices high.

Go Deeper: Read the House sponsors' press release on the bill <u>here</u> and read more from CSRxP about manufacturers' patent abuse <u>here</u>.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: http://legis.delaware.gov/.
New York Legislation: https://nyassembly.gov/leg/
Pennsylvania Legislation: www.legis.state.pa.us.
West Virginia Legislation: http://www.legis.state.wv.us/

For copies of congressional bills, access the Thomas website – http://thomas.loc.gov/.

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