Highmark's Weekly Capitol Hill Report

Issues for the week ending October 3, 2025

Federal Issues

Regulatory

White House Announces Steps on Drug Pricing

The White House announced its first agreement with a major pharmaceutical manufacturer to align prices for prescription drugs in the U.S. with those paid by other developed nations ("most-favored-nation").

Key Takeaway: The agreement will provide state Medicaid programs with access to most-favored-nation drug prices on the manufacturer's products.

TrumpRx.gov: The White House also announced the future launch of a new direct-to-consumer website, TrumpRx.gov, that would allow patients to directly buy certain drugs at reduced prices.

Background: President Trump signed an Executive Order in May that called for HHS to enable direct-to-consumer sales of prescription drugs to American patients at the most-favored-nation price along with other measures. President Trump also sought to implement a most-favored-nation policy in Medicare Part B during his first term. A proposed rule, Global Benchmark for Efficient Drug Pricing (GLOBE) Model, is currently under review at OMB.

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Judge Vacates Final Medicare Advantage RADV Rule

On September 25, Judge Reed O'Connor granted Humana's motion for summary judgment in its challenge to the Final RADV Rule (Final Rule) issued by CMS on February 1, 2023. *Humana v. Becerra*. (N.D. Tex.). Judge O'Connor concluded the Final Rule violated the procedural requirements of the Administrative Procedure Act (APA) because it was not a "logical outgrowth" of the proposed rule. Consequently, he vacated the Final Rule.

- The ruling focuses on Humana's challenge of CMS's decision to not utilize a Fee for Service Adjuster (FFS Adjuster) when it extrapolated sampling results in RADV audits. This decision reflected a change in policy for CMS, which previously had indicated that an FFS Adjuster would be utilized to meet its statutory obligation of "actuarial equivalence." CMS justified this change in the proposed rule with the results of an empirical analysis and with an argument that an FFS Adjuster would introduce inequities between audited and unaudited plans. Commenters raised a number of concerns about this proposal, including significant flaws in CMS's empirical analysis. In the final rule, CMS no longer relied on the reasons put forth in the proposed rule, instead asserting that actuarial equivalence did not apply in this context and that the Coding Intensity Adjustment forecloses the use of an FFS Adjuster.
- Humana had challenged the Final Rule, arguing it was invalid because CMS abandoned the justifications used in the proposed rule for abandoning an FFS adjuster and utilized new justifications in the Final Rule. AHIP filed an amicus brief supporting Humana's arguments on summary judgment. Judge O'Connor agreed. He found that neither CMS's justifications in the proposed rule, nor a request for comment made by the agency, met the government's obligation to

provide the public notice with reasonable specificity of its intention to utilize alternative justifications. As a result, the Final Rule violated the APA's "logical outgrowth" requirement and was vacated.

In the wake of the decision, CMS postponed its RADV Audits webinar that was scheduled last week.

CMS Releases 2026 MA and Part D Landscape Files

Each year, CMS publishes the Medicare Advantage and Part D Landscape files, outlining plan options, premium details, and enrollment projections ahead of the annual Medicare enrollment period. On September 26, CMS released the Medicare Advantage and Part D Landscape files for calendar year 2026.

Medicare Advantage (MA)

- **Premiums:** CMS projects the average monthly MA premiums to decrease from $16.40 in 2025 to $14.00 in 2026.
- **Access:** Over 99% of Medicare beneficiaries will have access to an MA plan; 97% will have access to 10 or more plan choices.
- **Enrollment:** Projected enrollment is 34 million in 2026, down from 34.9 million in 2025, though CMS expects actual enrollment to be more robust.
- **Plan Availability:** Total MA plans will decrease from 5,633 to approximately 5,600.

Medicare Part D

- **Standalone Part D Plans:** Average premium projected to decrease from $38.31 in 2025 to $34.50 in 2026.
- **MA-Part D Plans:** Premiums expected to decrease from $13.32 in 2025 to $11.50 in 2026.

CMS Announces Comment Opportunity on Surprise Billing Complaints Process

CMS announced an opportunity for public comments on a Paperwork Reduction Act (PRA) notice. CMS is proposing to reinstate without change a previously approved information collection around how CMS receives complaints regarding violations of balance billing requirements under the No Surprises Act. This includes CMS' process to receive complaints regarding violations of the application of QPA requirements by group health plans and health insurance issuers offering group or individual health coverage, and CMS' process to receive consumer complaints regarding violations by health care providers, facilities, and providers of air ambulance services regarding balance billing requirements and to respond to such complaints within 60 days.

The notice has a 60-day comment period and will close on or around Nov. 24, 2025.

CMS Issues Final Guidance for Third Cycle of Medicare Drug Price Negotiation

CMS issued final guidance on key elements of the third cycle of negotiations and the first cycle of renegotiations for the Medicare Drug Price Negotiation Program, which begin in 2026, with negotiated maximum fair prices (MFPs) taking effect on January 1, 2028. The final guidance also includes provisions addressing manufacturer effectuation of the MFP in 2026, 2027 and 2028. In the fact sheet, CMS states

that “[n]ew for initial price applicability year 2028, in accordance with the law, this final guidance addresses how drugs or biological products payable under Part B will be eligible for negotiation as well as the requirements and process for renegotiation.”

Notably, the final guidance outlines how Medicare Advantage expenditures will be used in the process to identify and select negotiation-eligible Part B drugs. In its press release, CMS states that “[t]he final guidance marks a shift from draft guidance in calculating Total Expenditures for drugs and biological products payable under Part B, where Total Expenditures are one of several criteria used to select drugs for negotiation. The final guidance describes a framework for including both Medicare Advantage (MA) encounter data for Part B items and services and traditional Fee-for-Service (FFS) Part B claims data in Total Expenditure calculations under Part B. Including MA encounter data with traditional FFS claims data will ensure equitable treatment of expenditures in selecting drugs for negotiation across Medicare Parts B and D.”

In the final guidance, CMS states that the Medicare Transaction Facilitator “could be expanded to support MFP effectuation for drugs payable under Part B beginning with initial price applicability year 2028. CMS will provide detailed policy on providing access to the MFP for selected drugs payable under Part B in the future and will consider comments and recommendations related to MFP effectuation for drugs payable under Part B in CMS’ policy development.”

Consistent with BCBSA’s recommendation, CMS is maintaining its existing policy for Part D sponsors to use formulary design policies such as tiering and utilization management for selected drugs consistent with existing statutory and regulatory requirements.

CMS Presentation on Open Enrollment Transaction Summary for 2026

On September 29, 2025, CMS gave a presentation providing updates on open enrollment (OE) for 2026. CMS specifically reviewed updates to the Batch Auto Re-enrollment (BAR) overview and timeline. Key dates for BAR are below:

- Late October: BAR wave 1 begins
- November 1: OE begins
- Early December: BAR Cancel Jobs, Failure to File and Reconcile processing and recheck operations
- Mid/late December: December BAR processing
- Late December: BAR Eligibility Determination Notices and Consumer Confirmation Messages sent out to enrollees
- January – March: Post BAR Reinstatements

The full presentation can be viewed here. Please note that you must have an active REGTAP account in order to access the presentation.

CMS Releases Shutdown Contingency Plan

The Department of Health and Human Services (HHS) and CMS released shutdown contingency plans. The plans largely align with what previous federal administrations planned ahead of potential funding lapses. Specifically, CMS said the Medicare Program will continue. CMS will have sufficient funding for

Medicaid to fund the first quarter of FY 2026, based on the advance appropriation provided for in the Full-Year Continuing Appropriations and Extensions Act, 2025. CMS will also maintain the staff necessary to make payments to eligible states for CHIP. Regarding policymaking, "CMS payment rule development and other policy decisions would depend on the funding source and duration of a lapse in appropriation. With limited staff to review and provide operational support, we would expect delays in rule-making and other policy development." A total of 3,105 (50%) CMS staff will be exempt from furlough. This includes all CMS staff who support activities that have funding available during a lapse in appropriations (e.g., those funded by the Health Care Fraud and Abuse Control Program, Quality Improvement Organizations, Inflation Reduction Act, and user fees) in addition to a small number of staff who are considered essential. Read More

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CMS Issues Guidance on Emergency Medicaid Coverage and Managed Care Payments

The Centers for Medicare & Medicaid Services (CMS) issued a State Medicaid Director letter (SMD #25-003), "Medicaid Managed Care Payments and Emergency Medical Condition Coverage for Aliens Ineligible for Full Medicaid Benefits." The letter announces that CMS will no longer permit MCOs to cover or MCO capitated rates to reflect the cost of covering "emergency Medicaid", i.e., medical assistance provided to individuals who are not eligible for Medicaid coverage due to immigration status, and who receive care and services necessary for treatment of emergency medical conditions.

Under the guidance, states may pay for emergency Medicaid through:

- FFS coverage, or
- Non-risk contracts with PIHPs or PAHPs, however FFP is only available for the cost of the claims paid for actual care and services for the treatment of an emergency medical condition, and not for any other costs including prospective payments or any administrative costs of the PIHPS or PAHPs.

CMS also indicates that state directed payments and in-lieu of services may not be made for individuals ineligible for full Medicaid benefits because of their immigration status

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Federal Court Vacates New CMS State Directed Pay Hold Harmless Regulations

In a decision last week, a Texas federal district court struck down new CMS regulations related to state directed payment (SDP) hold harmless arrangements. The lawsuit, *Texas v. CMS*, involves a challenge to certain provisions in a recent Final Rule and related 2023 and 2024 Bulletins that broaden the scope of hold harmless arrangements to include guarantees by private parties in private agreements (*i.e.* wholly private arrangements where the state has no involvement) as well as new attestation requirements.

The court found that the expanded scope and new attestation requirements both exceeded the agency's authority under relevant statutes and that it acted arbitrarily and capriciously in doing so, both in violation of the Administrative Procedure Act (APA). In addition, the court also found that new regulations requiring SDP disputes to be heard by a Departmental Appeals Board (DAB) improperly removed such disputes from the courts' jurisdiction and also violated the APA.

As a result, the court vacated the Final Rule provisions expanding the scope of SDP arrangements and new attestation requirements (42 C.F.R. §§ 438.6(c)(2)(ii)(G),(H)) and establishing DAB jurisdiction over related

disputes (42 C.F.R. § 430.3(e)) as well as related 2023 and 2024 Bulletins. In addition, the district court also issued a nationwide injunction preventing the government from enforcing the interpretation of the statutory hold harmless provision found in those same 2023 and 2024 Bulletins. It remains to be seen if the government will appeal the decision. An appeal must be filed within 60 days of last week's decision.

Note that the ruling addresses CMS regulatory efforts from 2024 to limit certain types of provider tax and SDP arrangements; it does not address the other limits on provider taxes and SDPs in reconciliation legislation enacted in July.

State Issues

New York

Regulatory

Superintendent Adrienne Harris to Depart Department of Financial Services

Governor Hochul announced Superintendent Harris will be leaving DFS on October 18, after serving as Superintendent for four years. The Governor is appointing Kaitlin Asrow as Acting Superintendent. Asrow currently serves as Executive Deputy Superintendent of Research & Innovation, overseeing the regulation of virtual currency companies. More information can be found here.

State Issues

Pennsylvania

Legislative

Legislative Update

The state budget impasse approaches day 100 with no potential end nearing. The House of Representatives and the Senate return for a three-day session week this week with various committee meetings.

The House Health Committee will be meeting this week to consider a package of bills to update state epinephrine laws regarding training and placement in public places to allow for the use of new intranasal epinephrine delivery systems.

The House Insurance Committee will be meeting to consider two pieces of legislation by Representatives Gallagher and Venkat, updating colorectal cancer screening requirements as well as mandating vaccination coverage.

After this week the Senate will adjourn until the 20th with the House not returning until the 27th.

Regulatory

Gov. Shapiro Signs Executive Order Regarding Vaccines

Governor Josh Shapiro last week signed Executive Order **2025-02** regarding vaccine access for Pennsylvanians.

The Executive Order:

- **Creates a Pennsylvania-based safety net for children:** Directing DOH to establish a state-level program to guarantee children eligible for the federal Vaccines for Children (VFC) program maintain access to all recommended vaccines without cost sharing, even if ACIP removes vaccines from the federal list.
- **Requires state agencies to align with trusted medical experts:** Ensuring Pennsylvania regulations, guidance, and communications reflect recommendations from the AAP, AAFP, ACOG, and FDA.
- **Launches a central vaccine portal:** Creating a one-stop online resource at **pa.gov/vaccines** with evidence-based information for families, providers, and the public.
- **Establishes a Vaccine Education Workgroup:** Convening pediatricians, family physicians, obstetricians, pharmacists, parents, public health leaders, and community representatives to strengthen public communication and combat misinformation.
- **Ensures** health insurers and Medicaid cover all recommended vaccines with no cost-sharing or new barriers; **Directs** the Department of Aging to use its programs to expand older adults' vaccine access; and **ensures** school-entry vaccination requirements remain consistent with trusted medical associations.
- **Strengthening Pennsylvania's public health leadership:** Coordinating with local health departments and regional partners to maintain consistent, evidence-based vaccine guidance across the Commonwealth and the Northeast.

Background: In August, due to federal vaccine recommendation changes, major pharmacies halted some vaccinations. Shortly after, the State Board of Pharmacy convened and subsequently voted to permit pharmacists to follow guidance from the **American College of Obstetricians and Gynecologists (ACOG)**, **American Academy of Pediatrics (AAP)**, **American Academy of Family Physicians (AAFP)**, and **U.S. Food & Drug Administration (FDA)**, instead of just recommendations from the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices' (ACIP).

- In September, the **Pennsylvania Department of Health** expanded the list of trusted authorities that health care providers could rely on and issued new immunization guidance — which the **State Board of Medicine**, **State Board of Nursing**, and **State Board of Osteopathic Medicine** quickly endorsed.
- Also, to prevent new financial barriers, the **Pennsylvania Insurance Department** secured commitments from insurers to continue covering all previously recommended vaccines through at least 2026.

Read more about **Executive Order 2025-02**, Protecting Pennsylvanians' Health and Freedom by Ensuring Access to Safe and Effective Vaccines.

Industry Trends
Policy / Market Trends

GAO: Provider Consolidation Driving Up Costs Without Improving Quality of Care
A recent report from the U.S. Government Accountability Office (GAO) underscores that provider consolidation is driving health care costs higher without corresponding improvements in quality or access of care for patients.

Key Findings:

- **Consolidation Drives Up Costs:** Mergers, especially involving hospital systems and private equity-backed providers, are linked to higher prices within Medicare and the market.
- **Provider Consolidation Does Not Lead to Better Patient Outcomes:** Consolidation does not consistently lead to better care; patients often face longer wait times, more complications, and no reduction in preventable hospital visits.

By the Numbers:

- Nearly **half of U.S. physicians**are now employed by or affiliated with hospital systems, up from less than 30% in 2012.
- Additionally, **private equity ownership**of physician practices has grown to **5% nationally**, up from 4.5% in 2022.

The Bottom Line: Provider consolidation reduces competition and drives-up prices for consumers, employers, and public programs—without delivering better care for patients.

Go Deeper: Read the report from GAO here.

AHIP Highlights EPTC Impact on Rural America & Low- and Middle-Income Families
AHIP is emphasizing how the enhanced premium tax credits have been a lifeline for rural communities, drastically reducing health care costs for working families and making health care affordable and accessible.

With the tax credits set to expire at the end of the year and families receiving notices of impending premium increases ahead of open enrollment, rural America is projected to experience disproportionate consequences without their extension.

The Impact on Rural America:

- **$22 billion** in losses for rural hospitals.
- A **30% decrease in marketplace enrollment and a 37 percent increase in uninsured populations** for most rural states.
- **15% of Americans** who would lose the tax credits live outside cities.
- **27%** of farmers, ranchers and other agricultural managers obtain their health care coverage through the individual market and may lose the tax credits.

- **2.8 million rural consumers** risk losing health coverage, including 776,000 adults nearing retirement age and more than 223,000 children.

Go Deeper: Read more from Keep Americans Covered on the rural impact here.

Get the Facts: EPTCs Are a Low- and Middle-Income Family Benefit: Keep Americans Covered (KAC) is highlighting a recent report from the Joint Committee on Taxation, Congress's official scorekeeper on tax matters, that confirms 95% of health care tax credits go to consumers making under $200,000 per year, while 86% go to those making under $150,000 and the majority go to those making under $80,000 annually.

Tax Credit Demographics:

- Almost half of Marketplace consumers are small business owners and self-employed Americans, and a growing number rely on premium tax credits for their coverage. Over 285,000 small business owners and self-employed workers with incomes above 400% of the FPL receive enhanced premium tax credits.
- More than 6 million middle-income Americans with incomes above 400% of the FPL rely on premium tax credits to make health care coverage affordable.
- Nearly half (42%) of these consumers are over age 55, meaning they are too young to qualify for Medicare, may live on a fixed income, and often face higher premium costs than younger individuals.

Go Deeper: Read the AHIP article and KAC spotlight to learn more.

AFHC Spotlight on Site-Neutral Payments

AHIP coalition partner the Alliance to Fight for Health Care (AFHC) is highlighting a provision in CMS' 2026 Hospital Outpatient Prospective Payment System (OPPS) proposed rule that expands site-neutral payments and protects patients from paying hospital prices for doctors' office visits.

Key Excerpt: "The Alliance strongly supports CMS's proposal to expand site-neutral payments to drug administration services provided in off-campus HOPDs. We believe CMS's proposal to expand site-neutral payments to outpatient drug administration services serves as an important first step toward: (1) protecting patients from paying hospital-level prices for outpatient care provided outside of the hospital; and (2) removing financial incentives driving consolidation among health care providers."

AHIP Reaction: AHIP's OPPS comments also supported site neutral drug administration payments and also suggested other site neutral payment reforms.

Go Deeper: Read more on the benefits of site-neutral payment reform here.

GAO Report Examines Medicaid Section 1115 Demonstration Spending

The U.S. Government Accountability Office (GAO) released a report examining CMS expenditure data on Medicaid Section 1115 demonstration spending, and how CMS policy changes from 2020 through 2024

would affect federal spending. Notably, longstanding CMS policy requires that demonstrations be budget neutral to the federal government – a policy that was codified in statute as part of the federal reconciliation bill (H.R. 1) and is expected to be addressed through forthcoming regulations. GAO recommended CMS's budget neutrality policies should "use valid methods." Additionally, GAO recommended CMS should revise the agency's section 1115 budget neutrality policy to stop treating costs for populations or services that could not have otherwise been covered under existing Medicaid authorities as hypothetical when setting demonstration spending limits. Instead, CMS should require the costs of those populations or services to be offset by other reductions in demonstration spending. CMS said it will consider GAO's recommendations as it implements new budget neutrality requirements enacted by H.R. 1. Read More

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/.**