Highmark's Weekly Capitol Hill Report

Issues for the week ending September 12, 2025

Federal Issues

Legislative

Shutdown Looms as Negotiations Reach Critical Point

Congress is on a collision course with a government shutdown on Oct. 1, as Republicans and Democrats dig in their heels over spending priorities and policy riders. How it pays out this week will be critical -- Congress is in recess next week for Rosh Hashanah, leaving little time to resolve major issues.

The plan: House Republicans are set to release a continuing resolution (CR) to fund the government through Nov. 20. The bill is expected to include increased lawmaker security funding, while some members of Congress are also pushing for Russia sanctions to be included.

The problem: Democrats, led by Senate Majority Leader Chuck Schumer and House Minority Leader Hakeem Jeffries, are demanding bipartisan negotiations and the inclusion of healthcare-related provisions, specifically an extension of enhanced Affordable Care Act (ACA) tax credits. Republicans are thus far refusing to include Democratic priorities in the CR, hoping to pass a "clean" bill through the House with only GOP votes and pressure Senate

In this Issue:

Democrats to avoid a shutdown, like they did earlier this year.

The wildcard: After facing criticism for supporting the similar GOP-led deal in March, Schumer is signaling a tougher stance, warning that a CR without extending the enhanced ACA tax credits is a "deal-breaker."

What to watch: Whether House Speaker Mike Johnson can secure enough Republican votes to pass the CR, and how Senate Democrats will react, considering the tight timeline and the looming recess.

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Federal Issues

Regulatory

White House and FDA Signal Stronger Standards for DTC Drug Ads

What's new: President Trump issued a memorandum to the Secretary of Health and Human Services (HHS) and the Food and Drug Administration (FDA) to strengthen oversight of direct-to-consumer (DTC) prescription drug advertisements, ensuring they provide fair, balanced and complete information about drug risks and benefits.

Why this matters: The announcement challenges the status quo for drug manufacturers and may result in consumer ads that more accurately depict a drug's safety and efficacy.

Go deeper: The FDA announced plans to rein in misleading pharmaceutical advertising by: (1) sending thousands of warning letters calling on drug companies to remove misleading ads, and (2) issuing approximately 100 cease-and-desist letters to companies with deceptive ads. These actions aim to restore transparency and accountability in drug marketing, especially in digital and social media, where deceptive practices have eroded public trust and led to "increased demand for medications regardless of clinical appropriateness."

This action on DTC ads was also referenced in last week's Make America Healthy Again (MAHA) Commission strategy report.

BCBSA is pushing for reforms that limit DTC advertising, as such ads are linked to increased use of costly brand-name drugs over generics and other more affordable alternatives. A recent *JAMA Network* study found that fewer than one-third of DTC ads promote drugs with high therapeutic value.

What's next: The FDA is initiating rulemaking to close the "adequate provision" loophole, which FDA noted has allowed drug companies to obscure safety risks. For more information about this regulatory provision and FDA oversight of drug advertising, see these FDA FAQs.

Go deeper: A recent CSRxP analysis found that restricting DTC drug ads could increase federal tax revenues by more than $1.5 billion every year.

AHIP Summary of Updated OMB Federal Regulatory Agenda

AHIP has developed a detailed summary of the Updated 2025 Unified Agenda of Expected Federal Regulatory Actions released by the White House Office of Management and Budget on September 4.

Highlights include:

- **Commercial Markets and Exchanges:** Several proposed rules regarding implementation of the No Surprises Act, including those related to Federal Independent Dispute Resolution Operations, provider nondiscrimination, and advanced explanation of benefits.
- **Tri-Departments:** No regulatory action related to the Mental Health Parity and Addiction Equity Act (MHPAEA) was included in the Unified Agenda, despite the Tri-Departments' release of non-enforcement guidance earlier this year.
- **Drug Enforcement Agency:** Proposed changes for telemedicine prescribing of controlled substances.
- **Assistant Secretary for Technology Policy:** A final rule to address certain remaining parts of the HTI-2 proposed rule related to standards adoption and expanded uses of certified application programming interfaces (APIs), such as for electronic prior authorization, care management, and care coordination. Proposed rule to address potential deregulatory actions and codify recent enforcement discretion guidance.
- **Office for Civil Rights:** No rulemaking on the ACA's Section 1557 Nondiscrimination in Programs and Activities was included in the Unified Agenda. A final rule to modify Security Standards under HIPAA to improve cybersecurity in the health care sector.
- **Medicare and Medicaid:** Two proposed rules on CMS Innovation Center models. A 2026 final rule and 2027 proposed rule on policy and technical changes impacting MA and Part D, both noted as economically significant. Proposed rules on state directed payments in Medicaid managed care and other provisions.
- **Office of Inspector General:** A proposed rule establishing new safe harbors under the Anti-Kickback Statute (AKS) that would protect certain bona fide mental health and behavioral health improvement or maintenance programs established for clinicians.

Go Deeper: Read AHIP's detailed summary here.

CMS Issues QHP Certification Updates in Response to *City of Columbus v. Kennedy*

On September 5, 2025, CMS provided updates to issuers and states regarding required action that may need to be taken for Plan Year 2026 in order to meet actuarial value requirements pursuant to the stay issued by the U.S. District Court for the District of Maryland in *City of Columbus v. Kennedy*. The updates include instructions covering changes that may be required to qualified health plan (QHP) data, rates, and form fillings, as well as recommendations for when states should approve such changes to preserve the ability to revert to current filings depending on further outcomes from the case.

CMS additionally released an updated actuarial value calculator and methodology and will make a brief window, from September 30 through October 1, available for issuers to refile to comply with the court's order.

CMS Delays Enforcement of Mid-year Notice of Supplemental Benefits

CMS announced on Sept. 8 via HPMS memo that it is suspending enforcement of supplemental benefit notification requirements while it reconsiders the regulatory requirements. Medicare Advantage plans were required to notify enrollees annually (June 30–July 31) about unused supplemental benefits starting Jan. 1, 2026. CMS is suspending enforcement for contract year 2026 and beyond citing logistical concerns with current requirements.

CMS Releases Rural Health Transformation Program Notice of Funding Opportunity

The Centers for Medicare & Medicaid Services (CMS) released the Notice of Funding Opportunity (NOFO) for the Rural Health Transformation Program (RHT) via grants.gov.

The full announcement for the RHT clarifies that all 50 U.S. States are eligible, even if they do not have a large rural population or any rural hospitals and that states should focus on how the funding could benefit its rural populations. The announcement also outlines the eligibility, application and program requirements.

Additionally, the notice highlights that CMS retains sole discretion in selecting recipients of the grant (unless the authorizing statute says otherwise). When making funding decisions, CMS will consider "review results" and the past performance of an applicant. CMS notes it may choose not to fund applicants with management or financial problems.

CMS retains the right to fund applications in whole or in part, applications at a lower amount than requested, decide not to allow a prime recipient to a subaward if they may not be able to monitor and manage subrecipients properly, and/or choose to fund no applications under the NOFO. It specifies that "there will be no administrative or judicial review under section 1116 (42 U.S.C. 1316) or otherwise of amounts allotted or redistributed to States, payments to States withheld or reduced, or previous payments recovered from States."

Moreover, the notice stipulates that the application must come from a state government agency or office and must include a letter of endorsement signed by the governor.

Applications are due no later than November 5, 2025 by 11:59 pm ET and awardees will be determined by December 31, 2025. CMS has scheduled applicant webinars for September 19 and September 25.

For more information a program overview presentation, an FAQ document and the RHT website are available to the public.

HHS Expands Eligibility for Catastrophic Coverage Exemptions

HHS released updated guidance for most federal and state exchanges detailing changes to hardship exemptions for catastrophic health coverage.

Why this matters: Catastrophic coverage has, to date, been limited to individuals who are under the age of 30 and a limited population qualified for an exemption.

- **This updated guidance would** allow for eligibility for hardship exemptions regardless of age and has the potential to create major changes in risk calculations for products for which issuers have already set their rates.

The details: The guidance expands the definition of who can apply for a hardship exemptions, allowing individuals with incomes falling below 100% or above 250% of the federal poverty level to enroll in catastrophic plans for 2026 and beyond.

Yes, and: Eligibility for exchange coverage and financial assistance will be determined online based on projected annual income, streamlining the paper application process.

Dig deeper: HHS also released a fact sheet highlighting key information included in the guidance.

CMS Issues Guidance to States for Medicaid State Directed Payments

The Centers for Medicare & Medicaid Services (CMS) released a Dear Colleague letter to states providing preliminary guidance for handling State Directed Payments (SDPs) to aid state planning as CMS prepares a notice of proposed rulemaking to revise 42 CFR part 438 as required in section 71116 of the OBBBA.

- Under OBBBA, states must limit the total payment rate for SDPs for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center to 100 percent of the specified total published Medicare payment rate for an expansion state or 110 percent of the specified total published Medicare payment rate for a non-expansion state SDP. The letter describes in detail CMS's grandfathering criteria for existing SDPs, and what constitutes a good-faith effort by states to receive approval for an SDP to be eligible for grandfathering.
- The phase down for grandfathered SDPs is effective for rating periods beginning on or after January 1, 2028. Until then, the total dollar amount of a grandfathered SDP cannot increase, and a state cannot increase this amount under any change or revision to the grandfathered SDP, including a revision to the preprint, amendment SDP, or renewal SDP. States may choose to decrease the SDP amounts at any time.

In addition to the services covered by OBBBA (inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center), CMS notes it is considering changes to the total payment rate limit for SDPs for other services and will address this during the rulemaking process.

Hospital Industry Comments to HRSA on Proposed 340B Rebate Model Program

The American Hospital Association (AHA) wrote in comments to the Health Resources and Services Administration that it should abandon its proposed 340B Rebate Model Pilot Program.

HRSA July 31 announced the pilot program, which will provide certain drugmakers the option to effectuate access to 340B discounted pricing for certain drugs under a rebate model. The agency accepted comments through Sept. 8 and has asked drug manufacturers to submit rebate model plans by Sept. 15.

In a letter last week, the Hospital & Healthsystem Association of Pennsylvania (HAP) called on HRSA to reconsider the proposed 340B Rebate Model Pilot Program and pursue alternative approaches that support access to care across the commonwealth. The letter noted several steps HRSA should take, including delaying implementation, addressing provider costs, and establishing better guardrails around the Administrative Dispute Resolution process.

Why this matters: Hospitals believe the proposed rebate model program is a 'solution' in search of a problem. More accurately, it is a 'solution' that will create a host of problems for those who provide care for rural and other underserved Americans. But given the agency's apparent interest in forging ahead, HRSA must impose stronger, inescapable safeguards — including a method to ensure that drug companies pay for the *full range* of costs and administrative burdens associated with a rebate model. And it must incorporate strict enforcement mechanisms to address drug companies' inevitable noncompliance.

Additionally, hospitals are deeply concerned that guidance provided by HRSA gives drug manufacturers the opportunity to unilaterally make programmatic changes that will substantially impact the ability of these hospitals to remain afloat, jeopardize covered entities' ability to maintain 340B programs and significantly limit patient access to care.

FTC Sends Warning Letters to Health Care Employers on Noncompete Agreements

The Federal Trade Commission announced last week that it sent letters to many large health care employers and staffing firms, urging them to review their employment agreements — including any noncompete agreements — to ensure they are in compliance. The commission's announcement follows one from Sept. 5, when it moved to vacate a 2024 noncompete final rule, voting 3-1 to dismiss appeals initiated by the previous administration attempting to uphold it.

On Sept. 4, the FTC issued a request for information on noncompete agreements, seeking to "better understand the scope, prevalence, and effects of employer noncompete agreements, as well as to gather information to inform possible future enforcement actions." Comments must be submitted by Nov. 3.

Why this matters: The agency last year issued a final rule that would ban, as an unfair method of competition, contractual terms prohibiting workers from pursuing certain employment after their contract with an employer ends. The American Hospital Association (AHA) and Federation of American Hospitals in February urged the U.S. Court of Appeals for the 5th Circuit to vacate the rule nationwide.

AHA Urges FTC, DOJ to Investigate Anticompetitive Activity by Drug Companies on 340B Rebate Models

The American Hospital Association (AHA) Sept. 8 urged the Federal Trade Commission and Antitrust Division of the Department of Justice to investigate several drug companies' concerted efforts to impose rebate models within the 340B Drug Pricing Program, saying the actions may violate antitrust laws.

The AHA letter details a timeline of many actions taken by several drug companies over a six-month period highlighting a potential antitrust conspiracy to limit 340B discounts.

"We urge you to investigate this behavior and take the necessary steps to address any and all antitrust violations," AHA wrote.

Why this matters: Certain drug companies sought to switch from providing 'upfront discounts' on 340B drugs to a model in which 340B hospitals must purchase even the costliest drugs at full price and then submit for a rebate. If successful, this concerted effort would essentially obligate America's safety-net hospitals to advance interest-free loans to the world's largest and most profitable drug companies. This new 'rebate model' would inflict untold harm on hospitals, patients and communities. Hospitals believe these pharmaceutical manufacturers are engaging in potentially anticompetitive activity.

State Issues

New York

Regulatory

Changes to Essential Plan Coverage Proposed

The state last week announced it was submitting a proposal to the Centers for Medicare and Medicaid Services to suspend the state's expansion of the Essential Plan, which extended EP eligibility to New Yorkers earning up to 250 percent of the federal poverty level, and revert the program to its original design, which has eligibility up to 200 percent of FPL.

State officials said the move is necessary due to Medicaid funding cuts in the federal tax and spending bill passed earlier this year, adding that the change will enable New York to continue covering 1.3 million of the nearly 1.7 million people currently enrolled in the EP program. Officials also said that they hope some of the 450,000 New Yorkers who became eligible for the EP under the expansion will be able to obtain other coverage through the NY State of Health exchange. More information can be found here.

Industry Trends

Policy / Market Trends

AHIP Files Amicus Brief in ERISA Case

On September 8, AHIP, together with several employer associations, filed an amicus brief in *McKee Foods Corp. v. Lawrence* (No. 25-5416)(6th Cir.). The brief supports McKee's efforts to challenge two provisions of

Tennessee law. The first provision subjects self-insured ERISA plans to the state's any willing pharmacy statute. The second provision prevents such plans from steering participants to lower cost pharmacies. *McKee* prevailed at the district court, and the case was appealed to the Sixth Circuit.

Why this matters: This joint amicus brief highlights the importance of ERISA preemption to employer plan sponsors, the TPAs administering such plans, and employees and their dependents who rely upon ERISA plans for coverage.

- It underscores that the decision to offer health care coverage under ERISA is voluntary and explains how ERISA preemption encourages employers to offer such coverage by providing them with a single, national benefits law, instead of varying state laws.
- The brief also demonstrates how the Tennessee laws at issue are preempted under ERISA under both express and implied preemption standards. Among other items, it discusses the importance of pharmacy networks to plan design and administration, and how such networks allow plans to deliver lower costs and protect the safety of plan enrollees.

Go Deeper: Read the full amicus brief here.

White House Releases MAHA Report

The White House MAHA Commission released a strategy report titled Make Our Children Healthy Again.

Key Takeaways: Building on the first report from May that examined the rise in childhood chronic disease, the new MAHA report identifies several areas of focus, including:

- Structuring the federal government's response to the childhood disease crisis.
- Calling for additional research to inform government efforts, including related to Food for Health, nutrition and dietary issues, oral health and chronic disease, and mental health and addiction.
- Launching education campaigns on key topics that impact families, including fertility issues.
- Developing a framework to ensure the U.S. has the best childhood vaccine schedule, addresses vaccine injuries, modernizes scientific standards, and improves data collection and analysis.

Impact: The strategy can inform future research initiatives and may lead to changes in school-based and childhood nutrition programs as tools to improve the health of America's children.

Health Care Tax Credits: Americans Can't Afford Congressional Inaction

AHIP published a new article highlighting the unaffordable costs consumers and families throughout America could face if Congress lets the enhanced premium tax credits (EPTC) expire.

State-by-state: AHIP spotlights six key states – Texas, California, Georgia, North Carolina, Ohio, and Pennsylvania – to showcase the number of consumers impacted and the financial costs families face from coast to coast.

- **For example:** In Texas, more than **3 million consumers** will face higher costs if Congress lets the tax credits expire. For a 60-year-old couple earning $82,800 a year, that means they will face a **264% increase or $17,663 more per year** in premium costs.

Go Deeper: See the data across all 50 states from AHIP coalition partner Keep Americans Covered to see the costs families could face without an EPTC extension.

The Bottom Line: Congress must act as quickly as possible to extend the tax credits before they expire and protect these Americans from skyrocketing cost increases that will cause many to lose coverage altogether.

Factors Influencing 2026 Rising Individual Market Premiums

A new AHIP resource spotlights the significant uncertainty and cost pressures facing the individual market for plan year 2026.

Key Takeaway: The potential expiration of the enhanced premium tax credits (EPTC), rising medical inflation, prescription drug prices, and regulatory changes have been identified as the main drivers influencing individual market rates.

The Clock Is Ticking: Open Enrollment starts on November 1st. The new resource lays out all the key dates associated with rate setting, setting the stage as to why quick Congressional action is needed.

Go Deeper: Read the full resource for more detailed information on the cost pressures impacting 2026 premiums, including more information on provider consolidation and the growing demand for GLP-1s.

Generic and Biosimilar Medications Saved Patients Billions in 2024

The Campaign for Sustainable Rx Pricing (CSRxP) is highlighting a new report that underscores how competition lowers prescription drug prices by providing more affordable alternatives to high-price brand name drugs.

By the Numbers:

- Generic and biosimilar medications saved American patients $467 billion in 2024 by reducing reliance on higher priced brand name drugs.
- Generics delivered $142 billion in savings to Medicare and $62.1 billion to Medicaid in 2024.

Savings over the last decade amounted to $3.4 trillion.

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/.**