# Highmark's Weekly Capitol Hill Report

**Issues for the week ending October 31, 2025**

## Federal Issues

Legislative

### Government Shutdown Update

As the government shutdown enters its fifth week, negotiations remain stalled. The Senate once again failed to pass H.R. 5371, the Republican-backed continuing resolution (CR), before adjourning last week. The House remains in recess, with no immediate plans to return.

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### Senate Committee to Hold Hearing to Examine ACA

On Thursday, the Senate Homeland Security and Governmental Affairs Committee's Permanent Subcommittee on Investigations, chaired by Ron Johnson (R-WI), will hold a hearing titled "Assessing the Damage Done by Obamacare."

The hearing will examine the Affordable Care Act's impact on premiums, consumer choice, and federal spending. Witnesses have been officially announced; however, Brian Blase, President of the Paragon Health Institute and vocal critic of the Affordable Care Act is expected to testify.

## Federal Issues

Regulatory

### FDA Announces Efforts to Accelerate Biosimilar Approvals

The FDA announced new efforts aimed at accelerating biosimilar approvals, boosting competition, and lowering prescription drug prices.

**Actions Include:**

- Issuing new guidance to eliminate comparative efficacy study requirements and streamline biosimilar approvals, a move that could significantly reduce barriers to fostering greater competition from more affordable alternatives to high-priced biologic drugs.

- Signaling support for automatically designating all biosimilars as interchangeable with their reference products and taking steps to increase domestic biosimilar manufacturing.

**Why this Matters:** Together, these efforts can help speed patient access to lower-cost treatments, expand the role of biosimilars in reducing drug spending across the health care system, and add to a growing body of evidence that greater biosimilar competition can deliver substantial savings for Americans.

**Go Deeper:** Read the FDA fact sheet here and read more about biosimilar competition from CSRxP here.

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**BCBSA Champions Unified AI Policies in Federal Regulatory Reform**
BCBSA recently responded to the Office of Science and Technology Policy's RFI seeking input on federal policies that hinder the development, deployment and adoption of artificial intelligence (AI).

**Why this matters:** This effort, which is part of the administration's AI Action Plan, will inform future federal regulatory reform to promote AI innovation and adoption.

**The details:** BCBSA's comments focused on creating a regulatory environment that promotes responsible AI use, including:

- Ensuring policies are risk-based and prevent disruption of current systems
- Encouraging HHS to collaboratively update requirements for care decision support tools
- Calling for streamlined cyber incident reporting between agencies
- Avoiding broad HIPAA data opt-out mandates until feasibility is assessed
- Supporting the creation of voluntary privacy, testing and consumer notification standards to ensure consistent implementation and foster trust and safety

**Yes, and:** The Confidentiality Coalition submitted comments , which align with BCBSA's support of flexible, risk-based policy approaches and federal leadership to prevent a patchwork of conflicting AI regulations across states.

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## 340B Rebate Models Approved for January 2, 2026, Implementation

On October 30, 2025, the Office of Pharmacy Affairs (OPA) posted information on its website announcing that they have approved 340B rebate models applicable to eight drug manufacturers.

Consistent with the August Federal Register Notice announcing the 340B Rebate Model Pilot Program, the approved rebate models will apply to nine of the 10 drugs selected for the Inflation Reduction Act (IRA) negotiated drug prices for Medicare Part D, effective January 1, 2026. The rebate models announced on October 30 will also be effective January 1, 2026.

In addition to required claim level data fields to be submitted for the selected drugs when dispensed in a retail setting, OPA/HRSA has now provided information about the data fields that will be required for in-hospital dispensing of the selected drugs. A chart of the data fields that will be required for submission to manufacturers to obtain 340B rebates is now available on the OPA/HRSA website, linked above.

The information currently available about the rebate models from OPA/HRSA is quite limited. OPA/HRSA appears to be generally deferring to Beacon, the IT platform vendor that will be operationalizing all the rebate models announced on October 30, to provide operational details of the rebate models. As of October 30, however, there was also very limited information available from the Beacon website.

**Background:** The Health Resources and Services Administration (HRSA) July 31 announced a 340B rebate model pilot program that will provide certain drugmakers the option to effectuate access to 340B discounted pricing for certain drugs under a rebate model. This voluntary rebate program will be piloted starting Jan. 1, 2026, for at least one year, which will allow HRSA to understand the "merits and shortcomings" of a rebate model in the 340B program.

This announcement comes after five drug companies last year acted unilaterally to impose various forms of a 340B rebate model, which were all rejected by HRSA. Letters sent by HRSA to these drug companies outlined the agency's serious concerns with the scope, intent and structure of their proposed rebate schemes. Subsequently, each drug company sued the federal government, arguing that the agency lacked any authority to prevent drug companies from imposing their rebate models. In two separate rulings, federal district courts rejected the drug companies' arguments and clarified that the Health and Human Services (HHS) Secretary must explicitly authorize the use of any rebate model in the 340B program and directed the government to promulgate guidance to this effect. The July 31 notice announcing a 340B rebate model pilot program comes as these cases remain in active litigation at the federal appellate level.

**Why this matters:** Hospitals expressed concern that this rebate model authorizes a significant departure from how the 340B program has successfully operated for decades and sets a dangerous precedent for possible harmful expansions in the future. This pilot program is a response to a non-existent program integrity problem that the drug manufacturers have manufactured in the public discourse.

In a Sept. 30 letter, the American Hospital Association told HRSA that it vastly underestimated the costs the 340B Rebate Model Pilot Program will inflict on hospitals and asked the agency to delay implementation.

## State Issues

### Delaware

Regulatory

### DOI Issues Bulletin on Premium Grace Period and Continuity of Coverage for Federal Employees

The Delaware Department of Insurance (DOI) has issued Bulletin No. 160 urging all carriers to:

- Provide a minimum 60-day grace period for premium payments due during the shutdown, with
- longer grace periods encouraged where feasible.
- Refrain from canceling or nonrenewing policies solely due to non-payment of premiums.
- Provide flexible payment options.
- Suspend late fees, penalties, and interest charges related to delayed premium payments.
- Accept reasonable documentation from policyholders demonstrating their status as impacted
- federal employees or contractors, such as a furlough notice or pay stub.

The bulletin was effective October 23, and the DOI expects these accommodations to remain in effect for the duration of the federal shutdown and for an additional 30 days thereafter.

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### DOI Issues Bulletin on Filing Fee Requirements and SERFF Communication

The DOI has made the following updates to Bulletin No. 38:

- Fees should not be submitted with informational filings, which may include statements of variability, Medicare supplement refund calculation reports, long-term care recissions, and changes to company logos.
- Filing fees may be refunded if a filing is withdrawn prior to the DOI taking any administrative action and if the refund is requested via SERFF within seven calendar days of the requested withdrawal.
- If a carrier submits an insufficient filing fee, the DOI will notify the carrier via SERFF and the company will have seven calendar days to remediate, otherwise the filing will be withdrawn, and a refund will not be processed. During that 7-day period, the DOI will not complete its review of the filing.

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## State Issues

### Pennsylvania

Legislative

### Legislative Update

Last week the House passed several bills which are now destined for the Senate.

- First, Representative Venkat's HB1828, mandating vaccine coverage in line with ACA requirements, and establishing a state-based vaccine advisory board passed the House by a vote of 104-99. It has yet to be referred to a Senate committee, but is expected to be referred to the Senate Banking & Insurance Committee where it faces an uncertain future.

- Second, Representative Gallagher's HB 1123, mandating insurance coverage for colorectal cancer in line with standards published in 2017 passed the House by a vote of 197-6. It is expected that this bill will pass through the Senate in 2026.

Both chambers now stand in recess until Monday, November 17th.

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Regulatory

### Pennsylvania Insurance Department Urges Insurers to Offer More Flexibility

On Friday October 31st, the Pennsylvania Insurance Department issued Notice 2025 -11 to Insurance Companies urging them to offer more flexibility to Pennsylvanians who may be adversely affected by the ongoing partial shutdown of the federal government. The Department writes, "This has led to several negative consequences, including the furlough or displacement of federal employees and the interruption of regular salary payments and reimbursements. As a result, affected individuals might experience difficulty making timely payments on financial obligations, including payment of insurance premiums."

As a result, the Pennsylvania Insurance Department is encouraging insurers to assist those affected by the current situation by relaxing due dates for premiums payments; extending grace periods; waiving late fees and penalties; and allowing payment plans for premiums payments to otherwise avoid a lapse in coverage. Insurers are also urged to consider cancellation or nonrenewal of policies only after exhausting other efforts to work with policyholders to continue coverage.

The Notice applies to all personal lines property, casualty, life, accident and health insurance policies. Affected policyholders should notify their insurance carriers and agents and explain their individual situation and difficulties complying with payment schedules.

The full notice is available at: Notice 2025-11

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## Industry Trends

Policy / Market Trends

### AHIP/BCBSA Survey Shows Nearly 40% of Providers' Surprise Billing Disputes Are Ineligible Under *No Surprises Act*

AHIP and the Blue Cross Blue Shield Association (BCBSA) released the findings on a new survey that reveals nearly 40% of surprise billing disputes submitted to the federal Independent Dispute Resolution (IDR) process in 2024 were ineligible under the *No Surprises Act*.

**Why this Matters:** The IDR process was designed to resolve billing disagreements between health plans and out-of-network providers. But the flood of ineligible claims, often from private equity-backed providers, has overwhelmed the system, driving up costs and premiums for patients and employers.

**Other Highlights Include:**

- In 2024, there were nearly **20 million qualified IDR claims** across all provider types with emergency services accounting for the majority (61%) of qualified IDR claims.
- **39%** of all disputes were identified as ineligible by health plans, including 45% of non-emergency service disputes.
- $5 billion in wasteful spending to date has been attributed to misuse of the IDR process.
- Payments through IDR averaged 400% above contracted rates, with some reaching 10,000%.

**What's Next:** AHIP and BCBSA will continue to urge policymakers to reform the IDR system to curb abuse and ensure it functions as a fair backstop, not a loophole.

**Go Deeper:** To view the full survey, click here. To learn more about addressing waste, fraud, and abuse in the arbitration process, click here and here.

## AHIP Sets the Record Straight on MLR "Gaming"

AHIP published a new article debunking a recent *Health Affairs Forefront* piece that suggests without evidence that some insurers are "gaming" Medical Loss Ratio (MLR) requirements through integrated provider partnerships.

**Why this Matters:** The *Health Affairs Forefront* article speculates that vertically integrated companies may inflate affiliated provider payments to meet MLR thresholds, especially under value-based arrangements. In its rebuttal, AHIP outlines how the claims are hypothetical and ignore regulatory safeguards and market realities.

**The Facts:**

- **No evidence.** The authors offer no data that any improper actions are occurring and note that "the extent to which parent companies engage in such practices is yet unknown."
- **CMS oversight.** Medicare Advantage (MA) and Part D plans are subject to specific safeguards for related-party payments.
- **Market discipline.** Artificially inflating provider payments to provider affiliates would have the net effect of higher premiums or reduced benefits.
- **Stable rebates.** Since 2020, MA plans have returned nearly $2 billion in rebates, and importantly, that level has remained relatively stable over the past several years. In the commercial market, $13 billion in rebates have been issued, including $1 billion in 2024.

**The Big Picture:** MLR rules are designed to ensure value for consumers, not to be gamed. Existing safeguards, competitive pressures, and CMS scrutiny make widespread manipulation implausible.

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## Numerous Experts Rebut False 'Phantom Patients' Narrative

AHIP published a new article highlighting how numerous health policy experts have debunked recent claims of "phantom patients" in the marketplaces.

**Why this Matters:** With Open Enrollment beginning last Saturday, millions of Americans are at risk of losing their access to affordable, high-quality health care coverage if Congress fails to extend the enhanced premium tax credits.

**The Facts:**

- Zero-claim enrollees are common in all insurance markets. "It's not uncommon for healthy people in an insurance marketplace not to use their insurance in a given year," *KFF*
- Joseph Antos, a health policy expert at the American Enterprise Institute, explains, "The point is that for insurance to work, you need some people who are not making claims on the insurance.'"
- With regard to claims around improper enrollment, one health care expert in a *Bloomberg Government* piece points to "'big methodological errors in that analysis' [as] the survey data uses a different measure of income and is from a different time."

- Only 1.64% of households in states using the federal Exchange lost their tax credits for not filing and reconciling in 2023–24. If "phantom enrollments" were widespread, that number would be much higher.

**Policymakers Have Put Strong Safeguards in Place:**

- Federal systems verify income and eligibility, cross-check with Medicaid, and limit special enrollment periods.
- Broker oversight and ACA's medical loss ratio rule ensure accountability, returning $12 billion in rebates since 2020, including $1 billion in 2024.

**The Big Picture:** Enhanced tax credits have helped 22 million Americans access affordable coverage. Without an extension, millions of families would face unaffordable premiums and many would lose coverage altogether. Get the facts about the health care tax credits here.

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## ICER Analysis Finds Drug Launch Prices "Significantly" Exceed Inflation

AHIP is highlighting new analysis from the Institute for Clinical and Economic Review (ICER) and reported by *STAT* that finds the median net price of 154 newly launched drugs rose 51% between 2022 and 2024 — even after adjusting for inflation and manufacturer discounts. The report underscores growing concerns that many new treatments are priced far above their clinical value.

**By the Numbers:**

- ICER reviewed 23 of the 154 drugs and found that 16 exceeded its Health Benefit Price Benchmark. As a result, an additional **$1.26 billion to $1.49 billion** was spent in the first year of sales
- *STAT* points out, "if the excess costs had been passed along as premium increases, **97,400 to 115,100 people might have lost insurance coverage** and roughly **400 deaths** would have occurred."

**Go Deeper:** Read *STAT*'s full coverage here, and read the ICER analysis here.

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## Robert Wood Johnson Foundation: ICHRA at a Crossroad

When ICHRAs were established by an executive order in 2017, original projections were that 800,000 businesses and 11 million employees and family members would use the option by 2024. Actual uptake has fallen far short of these projections, with current estimates likely less than 1 million. Recent progress in the individual market and growing pressures in employer insurance may be creating the conditions under which the ICHRA concept can come closer to reaching its potential. Yet looming threats in the policy environment put this expansion at risk. The expiration of enhanced ACA subsidies and the unpredictability of individual market premiums place ICHRAs at a critical juncture - emphasizing that their success depends on a stable, affordable individual market. Read the full article.

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## Governors' Public Health Alliance Launched

On October 15, the following governors announced that they have joined to launch the Governors Public Health Alliance, a "nonpartisan, non-profit coalition of governors that works together to protect public health"

by bringing together groups to share best practices, discuss common challenges, and keep science at the forefront of national considerations regarding vaccine policy and regulatory solutions:

- California (Gov. Gavin Newsom); Colorado (Gov. Jared Polis); Connecticut (Gov. Ned Lamont); Delaware (Gov. Matt Meyer); Guam (Gov. Lou Leon Guerrero); Hawaii (Gov. Josh Green); Illinois (Gov. JB Pritzker); Maryland (Gov. Wes Moore); Massachusetts (Gov. Maura Healey); New Jersey (Gov. Phil Murphy); New York (Gov. Kathy Hochul); North Carolina (Gov. Josh Stein); Oregon (Gov. Tina Kotek); Rhode Island (Gov. Dan McKee); and Washington (Gov. Bob Ferguson).

- The Alliance seeks to complement existing mechanisms, to collaborate with entities such as the Northeast Public Health Collaborative and West Coast Health Alliance and welcomes further engagement with other governors and relevant groups.

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**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/.**