Highmark's Weekly Capitol Hill Report

Issues for the week ending September 27, 2024

Federal Issues

Legislative

Updates from Capitol Hill

Legislative Activity

Congress Passes Funding Through December 20 -- Last week Congress passed and President Biden signed into law H.R.9747, the bipartisan continuing resolution (CR), that funds the federal government at current spending levels through December 20, 2024. Following passage of the CR, the House and Senate recessed until November 12, 2024.

Key Senators Introduce Health Care Cybersecurity Legislation --Senate Finance Committee Chairman Ron Wyden (D-OR) and Senate Intelligence Committee Chairman Mark Warner (D-VA) on Thursday introduced legislation that seeks to improve cybersecurity in the American health care system amid a wave of increased cyberattacks. The "Health Infrastructure Security and Accountability Act" would require the Department of Health and Human Services (HHS) to develop and enforce a set of minimum cybersecurity standards for

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health care providers, health plans, clearinghouses and business associates, including stronger standards for systemically important entities and entities important for national security.

Go Deeper: With this one-page and section-by-section summary of the bill.

Hearings

Senate HELP Committee Examines Costs of GLP-1s -- The Senate Health, Education, Labor and Pensions Committee held a hearing titled, "Why Is Novo Nordisk Charging Americans with Diabetes and Obesity Outrageously High Prices for Ozempic and Wegovy?" Members of the Committee heard testimony from President and CEO of Novo Nordisk, Lars Fruergaard Jørgensen, on the cost of Novo's GLP-1 for people who need the medications.

Key themes included:

- **PBMs**: Chairman Bernie Sanders (I-VT) stated that he had received written commitments from the major pharmacy benefit managers (PBM) that if Novo Nordisk were to substantially reduce the list price of Ozempic and Wegovy, "they would be able to expand coverage." There were also bipartisan calls for increased scrutiny of PBMs on the high GLP-1 prices.

- **HSAs**: Ranking Member Bill Cassidy (R-LA) expressed concerns over the impact of the GLP-1s' price on health savings accounts (HSA), stating that the lists prices would drain individuals' HSAs and make them less useful.

- **Health Insurance Role**: While manufacturers and list prices were the primary subject of the hearing, Members on both sides of the aisle

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occasionally brought up the role of health plans, referencing high premiums and the need to look at benefit designs. Jørgensen also frequently mentioned health plans and PBMs as reasons Ozempic and Wegovy prices are high in the US.

Federal Issues

Regulatory

CMS Releases Final Rule on Medicaid Prescription Drug Transparency

The Centers for Medicare & Medicaid Services (CMS) released the pre-publication version of the final rule entitled Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program. The rule was published in the Federal Register on September 26. CMS has released a related fact sheet.

Why this matters: The final rule makes a number of changes related to the Medicaid drug rebate program. It implements certain statutory definitions and enforcement provisions from the Medicaid Services Investment and Accountability Act of 2019 (MSIAA) that are designed to address misclassification of drugs. It also includes other changes to address program integrity and program administration, impacting drug information reporting and data collection.

The final rule also includes Medicaid managed care organization (MCO) requirements:

- It requires the assignment and exclusive use by Medicaid managed care plans of a unique Medicaid Bank Identification Number/Processor Control Number (BIN/PCN) combination and group number on beneficiaries' pharmacy benefit identification cards. CMS modified a provision from the proposed rule that would have required unique BINs and PCNs rather than unique combinations.

- It requires PBMs to provide more detailed reporting to the MCOs regarding incurred claims, fees, and administrative costs, addressing issues CMS had raised about MLR calculations and spread pricing.

As previously announced by CMS, the final rule does not include a proposal for "stacking" discounts, rebates, or other arrangements when determining best price. The agency states that it intends to collect additional information about stacking methodologies to better understand and to potentially inform future rulemaking.

Insurer Perspective: The rule finalizes several provisions BCBSA previously supported, including a requirement to use Medicaid-specific beneficiary identify numbers and process control numbers (BIN/PCN) on member identification cards and requiring managed care plan subcontractors (including pharmacy benefits managers) that deliver or administer covered outpatient drugs (CODs) to report separately on incurred claims and administrative costs. While the proposed rule included provisions that would establish a manufacturer survey on high-cost drugs and change best price calculations to account for "stacking," CMS decided not to move forward with these proposals.

Next Steps: The final rule will go into effect on Nov.19, 2024, with provisions related to use of Medicaid-specific BIN/PCNs on member cards and reporting on subcontractors' costs associated with administration of CODs going into effect in the first rating period beginning on or after Nov.19, 2024.

CMS Announces SSN Requirement for Consumers Signing Up for Coverage Through an Agent

On September 19th, the Centers for Medicare and Medicaid Services (CMS) announced system updates that will impact applications for coverage submitted by agents on behalf of consumers.

Why this matters: Beginning in October, agents will be unable to submit an application unless it includes a verifiable Social Security Number (SSN) for any applicant who is over 90 days old. This update is intended to address the disproportionate number of applications submitted by agents that are missing SSNs. The Healthcare.gov pathway for consumers applying without an agent will not be impacted by this update.

CMS to Send Failure to Reconcile Notices to Enrollees

Beginning in late September into early October, CMS will begin sending Failure to Reconcile notices to enrollees who are at risk of losing tax credits due to failure to reconcile tax credits with the IRS. CMS notices, including the latest eligibility notices, can be found here. The FAQ file released on April 19, 2024, contains further information.

CMS Issues Guidance Setting National Dates for Medicaid Enrollment Requirement Compliance

The Centers for Medicare & Medicaid Services (CMS) issued an Informational Bulleting (CIB) providing updated information on the timing and expectations for all states to achieve compliance with all federal Medicaid renewal requirements, including states that implemented CMS-approved mitigation strategies and those who have since identified areas of non-compliance with renewal requirements.

Why this matters: Although the Medicaid unwinding process is essentially complete in most states, CMS is concerned that deficiencies and problems with states' renewal

processes remain in many states, such as in appropriate disenrollments and application backlogs. The agency is setting a new universal timeline for renewal compliance as follows:

- By Dec. 31, 2024, all states must assess compliance with renewal requirements and submit the completed template to CMS. This provides sufficient time for states to complete most unwinding-related renewals and review relevant guidance and tools to evaluate their compliance.

- States that identify deficiencies must submit updates to their approved compliance assessments and plans using the renewal compliance template every six months, until compliance with all requirements is confirmed by CMS.

- States with identified deficiencies must demonstrate compliance with all renewal requirements by Dec. 31, 2026.

To assist states in their efforts to comply with federal requirements, CMS will be issuing updated guidance in late 2024 providing clarity on renewal requirements across several key topics, including income verification, ex parte renewals and requirements related to renewal forms.

CMS Releases EPSDT Guide for Medicaid & CHIP

The Centers for Medicare & Medicaid Services (CMS) released a comprehensive guide to provide states with information they need to comply with Early and Periodic Screening, Diagnostic and Treatment (EPSDT) requirements for children and youth under the age of 21 enrolled in **Medicaid and CHIP**.

Under EPSDT, children and youth are entitled to a comprehensive array of prevention, diagnostic, and treatment services including well-child visits, mental health services, dental, vision, and hearing services, making Medicaid and CHIP some of the most comprehensive health coverage in the country for children. Medicaid and CHIP cover 38 million children as of May 2024.

The guide covers three broad topics:

- Promoting EPSDT awareness and accessibility;
- Expanding and using the child-focused workforce; and
- Improving care for EPSDT-eligible children with specialized needs, including children with behavioral health conditions, children in foster care, and children with disabilities or other complex health needs.

CMS notes that the guidance summarizes federal requirements and includes strategies and best practices states may consider in implementing the requirements. In addition, the guide notes that managed care plans may have a significant role in administering EPSDT, but the state retains ultimate responsibility for assuring compliance.

A new Issue Brief was published by HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) on the value of Medicaid coverage. Slides from the webinar a recent webinar hosted by HHS on this topic will be posted here.

Medicare Shared Savings Program (MSSP) Final Rule
CMS issued the final rule entitled, "Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023" (CMS-1799-F).

Why this matters: This final rule is part of a larger strategy to address significant, anomalous, and highly suspect (SAHS) billing activity within Accountable Care Organizations (ACOs) reconciliation. The final rule updates how CMS will assess MSSP ACOs financial performance for 2023 and new benchmarks for 2024-2026 due to likely fraudulent billing behavior related to 2 specific codes for urinary catheters. A proposal in the calendar year (CY) 2025 Physician Fee Schedule (PFS) proposed rule addresses SAHS billing activity for CY 2024 onwards.

Johnson & Johnson Cancels Illegal 340B Rebate Plan
Johnson & Johnson (J&J) notified the Health Resources and Services Administration that it is ceasing implementation of its proposed 340B rebate model after prompting widespread outcry and a government threat to cut off Medicaid and Medicare coverage for J&J drugs.

Background: Last month, J&J said it would stop permitting wholesaler 340B chargebacks for *Stelara* and *Xarelto* purchases by disproportionate share (DSH) hospitals starting Oct. 15, effectively replacing upfront discounts with backend rebates. Under the new program, these hospitals would be required to submit certain data to J&J when they purchase the drugs at full price. After J&J verifies the drug's 340B status, it will send disproportionate share hospitals a rebate for the difference between the amount paid and the discounted 340B price.

Last Friday, HRSA warned J&J that it would begin the process of imposing unprecedented punitive actions if the company did not back off its plans by September 30, including by ending Medicaid and Medicare Part B coverage of all J&J drugs. In today's email notice, J&J cited the HRSA threat to terminate J&J's pharmaceutical pricing agreement (PPA) as the reason why it is suspending its rebate plans.

Advocacy Efforts: Right after J&J's announcement, the American Hospital Association (AHA) and other key stakeholders asked HRSA to take "immediate enforcement action," including assessing civil monetary penalties on J&J for intentionally overcharging 340B hospitals. Hospitals also asked members of Congress to send a letter asking the Department of Health and Human Services to take action to stop J&J's illegal plan.

Why this matters: J&J's new policy was a unilateral move to undermine the 340B Drug Pricing Program and is a fundamental shift in how the program has operated for over 30

years thus potentially jeopardizing patients' access to these drugs. In addition, disproportionate share hospitals, which already operate on the thinnest of margins, would have been forced to develop pricey administrative mechanisms to make and track rebate requests.

CMS Releases 2025 MA and Part D Plan Landscape Files
The Centers for Medicare & Medicaid Services (CMS) released a press release, fact sheet, and state fact sheets providing information about Medicare Advantage (MA) and Medicare Prescription Drug plan options for CY 2025. More detailed information is displayed in CMS landscape files and related information is available on the agency's website. This page includes a link to the 2025 landscape files, which contain Part D, MA, Special Needs Plan (SNP), and Medicare-Medicaid Plan (MMP) information.

State Issues

Pennsylvania
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Pennsylvania Legislative Update: Return to Session
September 30 marks the first day in which the Senate and House of Representatives are back in voting session together. The House of Representatives swore in Representatives Andre Carroll and Keith Harris, both Democrats from Philadelphia, who won special elections on September 17th, filling the vacancies when Representatives Donna Bullock and Stephen Kinsey both retired early. These new members ensure that the Democrats retain their one-seat majority in the House of Representatives.

- **The House Insurance Committee will be meeting twice this week**, first for a voting meeting to consider legislation which would enshrine certain aspects of the ACA in Pennsylvania should Congress repeal the Act.
- The second meeting will be a public hearing on Representative Venkat's House Bill 1663 regarding the use of Artificial Intelligence in healthcare, with Highmark providing remarks at the request of the committee.

With 6 session days for both chambers before the General Election on November 5, and 2 session days in each afterwards, very little legislation is expected to make it to Governor Shapiro's desk.

Industry Trends

Policy / Market Trends

FTC Pursues Enforcement Action on PBMs over Insulin Prices

The Federal Trade Commission (FTC) announced it would sue three major pharmacy benefit managers (PBM), alleging that PBM rebates led to higher insulin list prices. The hearing is scheduled for August 27, 2025.

Role of Manufacturers: In a statement, the FTC also recognized the role drug manufacturers in driving up list prices: "*Indeed, all drug manufacturers should be on notice that their participation in the type of conduct challenged here raises serious concerns, and that the Bureau of Competition may recommend suing drug manufacturers in any future enforcement actions.*"

The Facts: PBM-negotiated rebates and other discounts can be passed on to plan enrollees in the form of lower premiums and/or reduced out-of-pocket costs, helping to make prescription drugs accessible. Both list and net prices of insulin have fallen in recent years, demonstrating the value of PBM price competition.

Go Deeper: Read the complaint here. Learn more about how manufacturers are driving the high cost of prescription medications here.

New Reports: Impact of Enhanced ACA Tax Credits

A new report from Oliver Wyman examines the impact of the marketplace's enhanced premium tax credits on those with chronic conditions.

By the Numbers: Oliver Wyman estimates that:

- Of the **3 million** people on the individual marketplace who have at least one chronic condition, roughly **1.7 million** "are projected to become uninsured after the expiration of the enhanced tax credits" at the end of 2025.

- Those with chronic conditions who become uninsured could see annual increases in health care costs of **up to 44%** of their annual household income – an increase of as much as **$10,700** per enrollee.

Go Deeper: Oliver Wyman published two additional blog posts highlighting the impact of enhanced premium tax credits on coverage by race and ethnicity and the impact on premiums for people enrolled through the marketplaces. The broad-based coalition Keep Americans Covered also highlighted the consequences if the enhanced premium tax credits are not renewed in a blog.

The Treasury Department also released a new report highlighting the number of small business owners and entrepreneurs who obtain coverage through the Affordable Care Act (ACA) health insurance marketplaces and benefit from enhanced premium tax credits.

By the Numbers:

- The report shows that **2 million** small business owners and self-employed workers have coverage through the marketplaces, up from 3.3 million in 2022 and 1.4 million in 2014.

- Entrepreneurs are about **three times** as likely as other Americans to get health coverage through the marketplaces, with **nearly one in five getting coverage there**.
- **82% of entrepreneurs** in 2022 claimed the premium tax credit to reduce their cost of coverage by an average of about **$700 each year, including 285,000 taxpayers with incomes over 400% FPL**.

Go Deeper: Read the press release and fact sheet here.

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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