Highmark's Weekly Capitol Hill Report

Issues for the week ending September 29, 2023

Federal Issues

Legislative

Congress Passes CR to Extend Government Funding for 45 Days

On Saturday evening, Congress averted a government shutdown and passed a Continuing Resolution (CR) to fund federal agencies at fiscal year 2023 levels until November 17. The House passed the bill on a vote of 335-91 with 90 Republicans voting against it along with a single Democrat. The bill was subsequently passed by a wide margin in the Senate and signed by the President.

Senate Finance Committee Leaders Formally Introduce PBM Bill

Senate Finance Committee Chairman Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID) introduced the *Modernizing and Ensuring PBM Accountability (MEPA) Act*, legislation related to pharmacy benefit managers (PBMs), transparency, and other health care issues important to our industry.

An early version of the bill was advanced by the Finance Committee in July by a 26-1 vote. The legislative text introduced today reflects the Chairman's Mark that was reported out of the Committee.

In this Issue:

The legislation includes provisions on the following:

- **De-Linking PBM Compensation:** The bill would prohibit PBMs and affiliates from deriving remuneration related to Part D drugs in any form other than bona fide service fees (BFSF).
- **PBM Reporting to Part D Sponsors:** The bill would require PBMs to annually report information to Part D plan sponsors and HHS; the reported information mirrors, in part, information required in the commercial market bills considered in other Committees.
- **Audit Rights for Part D Sponsors:** The bill would allow Part D plan sponsors to annually audit PBMs, including price information and relationships with affiliates.
- **Pharmacy Performance Standards and Pricing Information:** The bill would require the development of standardized pharmacy performance standards and prohibit Part D plans from using other performance standards in their pharmacy contracts.
- **Spread Pricing Prohibition:** The bill would prohibit PBMs from using spread pricing in their contracts with Medicaid managed care organizations and pharmacies.
- **Report on Drug Price Markups in Medicare Part D:** The bill would require an Office of Inspector General study on drug price markups in the Medicare Part D program, focusing on vertically integrated entities.

- **CMS Releases New Medicaid Transportation Coverage Guide**
- **Novavax's Updated Vaccine under FDA Review**
- **CMS Releases June Medicaid Redetermination Data**

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- **COVID-19 Vaccine Medicaid Coverage Updates**

Judge Denies Request to Block Medicare Drug Price Negotiations

A federal judge denied a preliminary injunction sought by the US Chamber of Commerce to block the Biden administration from implementing the Medicare drug price negotiation program under the Inflation Reduction Act (IRA), allowing the program to begin as scheduled on Sunday. US District Judge Michael Newman, however, denied the federal government's motion to dismiss the lawsuit altogether.

Judge Newman wrote that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice" and that “The Court is not convinced that granting Plaintiffs preliminary injunctive relief will protect them from imminent and irreparable harm. Any economic harm — which, on its own, is insufficient to satisfy this prong of a preliminary injunction analysis — will not occur for years in the future.”

Why this matters: The decision preserved the Biden administration's timeline for negotiations with pharmaceutical manufacturers, including a requirement that manufacturers of the first 10 selected drugs submit data to consider in the negotiation of maximum fair price. CMS will use that data to craft its initial price offer by Feb. 1, 2024. The negotiated prices for the drugs are set to take effect in 2026.

Federal Issues

Regulatory

BCBSA & AHIP Emphasize Commitment to COVID-19 Vaccine Access

Following recent reports of some patients having challenges accessing new COVID-19 boosters without cost sharing, the **Blue Cross Blue Shield Association, AHIP**, the Alliance of Community Health Plans, and the Association for Community Affiliated Plans sent a joint letter to Xavier Becerra, Secretary of the Department of Health & Human Services. **The letter includes the following key messages:**

- **Reiterates the commitment to providing access to the new COVID-19 boosters, as required, with no cost sharing when consumers access them from a network provider or receive them through an out-of-network provider when in-network options are unavailable.**
- **Confirms** that plans have worked quickly to resolve technical and coding issues and that health plans will continue to monitor any barriers to coverage and swiftly address any access challenges.
- **Commits** to continuing to partner with HHS and others across the health care system to ensure quick, convenient and affordable access to the updated COVID vaccines.

Background: The Department of Health and Human Services (HHS) sent a letter on Sept. 22 to the health insurance community with updates on COVID-19 vaccine coverage. HHS emphasized their ongoing collaboration, including communications from CMS, to find solutions to reports from consumers that they were experiencing insurance coverage denials when seeking their updated COVID-19 vaccines. In the letter:

- HHS said they are committed to continuing to work with payers to solve issues with processing payments for people seeking COVID-19 vaccines whether related to coding/technical issues or a

lack of consumer understanding that the networks for COVID vaccines may be narrower than what was experienced over the past 3 years.
- HHS reminded payers of their obligation to cover the updated COVID-19 vaccine as of the Food and Drug Administration (FDA) authorization of the new vaccine on September 11, 2023.
- Additionally, they emphasized the requirement of a plan or issuer to cover vaccinations furnished by out-of-network providers if they do not have a provider in network who can provide a qualifying coronavirus preventive service.

FDA Proposes Increased Oversight of Lab-Developed Tests

The Food and Drug Administration (FDA) on Friday proposed a plan to more strictly regulate lab-developed tests (LDTs).

Why this matters: FDA stated the rule would ensure tests are accurate and save billions of dollars annually.

Background: Similar bipartisan legislation (The VALID Act) has been introduced to establish a similar FDA review system for LDTs, which has been active in Congress since 2018 but has failed to pass.

- Currently, testing laboratories are regulated by the Centers for Medicare and Medicaid Services, but the agency doesn't evaluate the accuracy of a test, require adverse event reporting or provide protections to patients in clinical trials.
- Citing increased concerns about the quality of lab tests, FDA is seeking to regulate them as medical devices.
- FDA cites a number of studies demonstrating variability in the accuracy and validity of LDTs across therapeutic areas; FDA cites specific patient and provider reports of incorrect, inappropriate, or missed treatments due to inaccurate LDTs.
- FDA has previously stated it has the authority to regulate lab-developed tests and issued draft guidance in 2014 that was eventually withdrawn after opposition from the lab testing industry.
- The American Clinical Laboratory Association – which represents labs such as Quest Diagnostics and LabCorp – opposes the plan, stating that regulation of lab tests should be through legislation and believes the proposed rule exceeds FDA's authority.

Next Steps: FDA plans to phase in the regulation over five years. The proposed rule is scheduled to be published in the Federal Register on October 3. Comments on the proposal are due 60 days after publication.

Updated Guidance on Prescription Drug Machine-Readable File (MRF) Released

The Departments of Labor, Health and Human Services, and the Treasury (Departments) released frequently asked questions (FAQs) on the implementation of the Transparency in Coverage (TiC) Final Rules. The new FAQs include the following updated guidance:

- **The Departments are now rescinding the previous guidance deferring enforcement of the TiC prescription drug MRF requirement**. Moving forward, the Departments will address enforcement decisions on a case-by-case basis and intend to develop technical requirements and an implementation timeline in future guidance. The Departments have indicated additional rulemaking is not expected.

- **The Departments will not continue to maintain an "enforcement safe harbor"** as described in FAQs part 53. They clarify that whether a plan is able to comply with the requirement to disclose certain rates as dollar amounts is a fact-specific determination. Therefore, the Departments intend to exercise enforcement discretion on a case-by-case basis, without any categorical "safe harbor." However, the Departments are unlikely to pursue enforcement action if a plan or issuer can demonstrate that compliance would have been extremely difficult or impossible. Plans that are unable to determine dollar amounts for the in-network rate element should continue to follow the existing technical guidance on GitHub for percentage-of-billed-charges arrangements located here.

The impact of this updated guidance will not be immediate, and we will provide updates on the development of the Departments' implementation timeline in future guidance.

In light of the updated guidance to require the prescription drug MRF, it is almost certain that the prescription drug MRF requirements will remain included in the legislative efforts to codify the TiC Final Rules (e.g., H.R. 5378).

Previous FAQs and resources on the Transparency in Coverage requirements are available here. A full list of Affordable Care Act implementation FAQs can be found here.

Updates on Commercialization of COVID-19 Therapeutic

The Administration for Strategic Preparedness and Response (ASPR) within HHS provided updated information regarding the transition of the COVID-19 treatment Lagevrio (molnupiravir) to the commercial market. The transition from government-managed distribution to traditional commercial distribution will occur in November 2023.

Why this matters: The government will start winding down the federal distribution of Lagevrio in November. In mid-November government purchasing for Lagevrio will close and the product will be available for commercial purchase in November.

ASPR is working with their partners to ensure those who are uninsured have access to the medication. The Merck Patient Assistance Program intends to provide Lagevrio free of charge to eligible patients. ASPR urges providers to leverage their government-purchased supply through its depletion or until expiration, whichever comes first. Government-distributed therapeutics will continue to be free for patients.

CMS Releases 2024 Medicare Advantage & Part D Premiums

The Centers for Medicare & Medicaid Services (CMS) released key information on 2024 premiums and deductibles for Medicare Advantage (MA) and Medicare Part D prescription drug plans.

Why this matters: CMS projects **the average premium for all 2024 MA plans will be $18.50 per month**, a slight increase from the 2023 average premium of $17.86 and indicated MA supplemental benefit offerings will increase in 2024. The agency also released a series of state-specific fact sheets, which include Medicare Advantage and Part D plan premium information, important dates, and enrollment resources for 2024 Medicare Open Enrollment.

In addition, CMS noted more than 1,500 MA plans will participate in the Center for Medicare and Medicaid Innovation's (CMMI) MA Value-Based Insurance Design (VBID) Model in 2024, which tests the effect of

customized benefits that are designed to better manage diseases and meet a wide range of health-related social needs, from food insecurity to social isolation.

CMS also highlighted the value and choice MA provides to enrollees. They stated in their press release, "If enrollees choose to stay in their plan, most will experience little or no premium increase for next year, with nearly 73% of beneficiaries not seeing any premium increase at all. Plan choice is also increasing, and people with Medicare continue to have the ability to switch Medicare options." CMS expects MA enrollment will increase to an **estimated 33.8 million people in 2024**.

According to the release, Medicare Open Enrollment for 2023 will begin on October 15, 2023, and ends on December 7, 2023. The full notice can be read here.

Departments Release RFI on Over-the-Counter Preventive Items & Services

The Departments Treasury, Labor, and Health and Human Services (the Departments), issued a request for information (RFI) regarding the application of the Affordable Care Act preventive services requirements to over-the-counter (OTC) preventive items and services available without a prescription by a health care provider.

Why this matters: The RFI follows the recent Food and Drug Administration (FDA) approval of the Opill tablet, the first daily hormonal contraceptive pill for sale over-the-counter (OTC) without a prescription, and an Executive Order (EO) signed by President Biden directing the Secretaries of the Departments to consider new actions to improve access to affordable OTC contraception, including emergency contraception.

In response to these events, the Departments believe requiring plans and issuers to cover, without cost sharing, OTC preventive products without a prescription under section 2713 of the Public Health Service Act is an important option to consider for expanding access to contraceptive care.

The RFI is seeking comment to:

1. Gather input from key stakeholders regarding the potential benefits and costs of requiring non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover OTC preventive items and services without cost sharing and without a prescription by a health care provider.
2. Understand any potential challenges associated with providing such coverage.
3. Understand whether and how providing such coverage would benefit consumers.
4. Assess any potential burden that plans and issuers would face if required to provide such coverage.

Court Rules for Plaintiffs in Accumulator Case

Judge Bates of the U.S. District Court for the District of Columbia granted plaintiffs' motion for summary judgment in litigation challenging a provision of the 2021 Notice of Benefit and Payment Parameters.

Background: The final rule had allowed health insurers to determine whether to count direct financial assistance from drug manufacturers toward a patient's annual cost-sharing limitation (the Accumulator Rule). In response, AHIP filed an amicus brief in the matter, providing important policy context about that Rule.

The decision vacates the Accumulator Rule and remands it to the Department of Health and Human Services (HHS) to interpret the statutory definition of "cost-sharing." Plaintiffs raised 3 arguments:

1. The Accumulator Rule is contradictory to statute (specifically the Affordable Care Act's (ACA) definition of cost-sharing)
2. The Accumulator Rule is inconsistent with existing regulations (specifically regulations defining cost-sharing), and
3. The promulgation of the Accumulator Rule was impermissibly arbitrary and capricious under the Administrative Procedures Act (APA).

The Court agreed with the plaintiffs on their third argument: that promulgation of the Accumulator Rule is arbitrary and irregular under the APA, specifically because it defines the same statutory and regulatory language in two conflicting ways. The Court ruled that these opposing interpretations of the same statutory and regulatory provisions violate the APA.

Why this matters: The Court disagreed with the plaintiffs' arguments that the Accumulator Rule was demonstrated to be contrary to statute and regulation. It rejected their argument that the ACA's definition of "cost-sharing" unambiguously encompasses manufacturer assistance. Given this, and because HHS has not yet made a final judgment on the competing meanings of "cost-sharing" under the statute, the Court returned the matter to HHS to permit it to interpret the statutory definition in the first instance.

CMS Announces 2024 Medicare Advantage VBID Participation

The Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) issued a fact sheet announcing the CY 2024 participants in the Medicare Advantage (MA) Value-Based Insurance Design (VBID) model. CMS states that "the estimated number of MA enrollees covered by the 69 MA organizations (MAOs) participating in the VBID Model in 2024 will increase by 47% in 2024 compared to 2023." The agency further indicates that of the 69 MAOs participating in VBID in 2024,13 are participating in the hospice benefit component. More information is included in the fact sheet.

CMS Releases New Medicaid Transportation Coverage Guide

The Centers for Medicare & Medicaid Services (CMS) released a State Medicaid Director Letter (SMDL) with a new Medicaid Transportation Coverage Guide. The guidance offers states a comprehensive one-stop resource on Medicaid transportation policy, federal requirements, and state flexibilities.

The Medicaid Transportation Coverage Guide (which begins on page 4 of the SMDL) covers both existing and new policies, including scenarios such as extended wait times and long-distance trips, and non-Medicaid eligible adults needing transportation to participate in a Medicaid eligible child's care.

CMS encourages states to use the Guide as an aid in developing and updating appropriate policies and procedures that facilitate robust transportation programs.

Novavax's Updated Vaccine under FDA Review

An updated version of the Novavax COVID-19 Vaccine, targeting the XBB strain, is currently under review by the U.S. FDA for EUA to prevent COVID-19 in individuals aged 12 and older. Similar to the recent

transition to the mRNA COVID-19 vaccines, health plan coverage will be required immediately upon FDA approval. Additional information is below on pricing and coding:

- **Pricing:** The company indicated the list price for the vaccine is $130; we are currently awaiting CMS release of Medicare payment amounts.
- **Coding:** The American Medical Association's (AMA) CPT Editorial Panel revised the coding structure for reporting COVID-19 vaccine administration and products. However, it instructs that it "retained the existing Novavax Product Code (CPT code 91304) for currently authorized vaccine product available for use in the U.S. and the updated (XBB.1.5) vaccine." Administration of the Novavax vaccine product should be reported using the existing administration code (90480). This should be used for all vaccine products, including Moderna and Pfizer products.

The CDC has listed the NDC and CVX codes crosswalked to CPT codes for the Fall 2023 vaccines here.

CMS Releases June Medicaid Redetermination Data

The Centers for Medicare & Medicaid Services (CMS) reported the latest batch of Medicaid Redeterminations data reported under the Consolidated Appropriations Act, 2023, here. **CMS posted a summary of outcomes for the renewals initiated in June 2023, including:**

- More than 6.5 million people went through the renewal process.
- Of those, just over half (50.8%) were successfully reenrolled in Medicaid and CHIP, and more than half (57.8%) of those renewed were done automatically (through an ex parte data review).
- Approximately one quarter (25.1%) lost their Medicaid and/or CHIP coverage. Within that group, 73.7% of terminations were for procedural reasons.
- Another 24% of people due for renewal in June were still pending with the state at the end of the month.

CMS shares additional detail about the 24% of pending terminations in the accompanying June 2023 National Summary of Renewal Outcomes, here. On slide 5, there is a list of states that had paused some or all procedural terminations in each month, including the following states in the June cohort: AR, DC, DE, IA, IL, KS, KY, ME, MI, MN, MO, NJ, NY, OK, SC, WV, and WY.

The June summary report and other related reports are available under the Monthly Data Reports tab from the main Data Reporting page.

State Issues

New York

Regulatory

COVID-19 Vaccine Medicaid Coverage Updates

The Department of Health last week published an updated "Medicaid Coverage Policy Guidance for the 2023-2024 COVID-19 Vaccine" with information for providers on billing for the new COVID vaccine.

- The guidance reiterates that providers are prohibited from charging Medicaid members a co-payment or any cost sharing responsibility for the COVID-19 vaccine or the administration of the COVID-19 vaccine.
- It also highlights that for members in Medicaid managed care plans, COVID-19 vaccines administered by a pharmacy provider should be billed to NYRx, and that non-pharmacy providers with questions about MMC administration reimbursement, billing, and/or documentation requirements should check with the enrollee's plan.

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/.**