Highmark's Weekly Capitol Hill Report

Issues for the week ending April 21, 2023

Federal Issues

Legislative

Senators Release Bipartisan Framework for PBM Reform

Sens. Ron Wyden (D-OR) and Mike Crapo (R-ID) have released a bipartisan framework for legislation addressing drug prices through greater transparency and a realignment of incentives within the supply chain. The release comes on the heels of a hearing last month that focused on the role Pharmacy Benefit Managers (PBMs) play in the supply chain.

Why this matters: Several committees on Capitol Hill have begun scrutinizing the operations of PBMs with calls for greater transparency and reform of certain business practices. It is shaping up to be one of the few areas of bipartisan agreement in the health care space.

The goal of the senators is to make prescription drug spending under federal programs more efficient for patients and taxpayers. The framework identifies four key challenges to the supply chain in that regard: misaligned incentives; insufficient transparency; hurdles to pharmacy access; and behind-the-scenes practices that impede competition and increase costs.

In this Issue:

The senators outline several policy solutions that they are considering addressing in upcoming legislation. They include:

- Delinking PBM compensation from drug prices to align incentives for lower costs;
- Enhancing PBM accountability to health plan clients to drive cost-cutting competition and produce better choices for beneficiaries;
- Ensuring discounts negotiated by PBMs produce meaningful savings for seniors;
- Addressing and mitigating practices that unfairly inflate the prices patients and government programs pay for prescription drugs;
- Modernizing Medicare's "Any Willing Pharmacy" requirements to improve options and access for seniors; and
- Increasing transparency to foster a better understanding of how financial flows across the prescription drug supply chain impact government health care programs.

It is anticipated that legislation addressing these issues will be unveiled later this summer.

New York
Legislative

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Federal Issues

Regulatory

Courts Issue Rulings on Health-related Cases

Late last week, the Northern District of Texas deferred a request for stay in *Braidwood Management, Inc. v Becerra,* a case challenging coverage of certain ACA preventive services, while the U.S. Supreme Court ruled the abortion pill mifepristone could remain on market, pending further legal review.

Why this matters: Final decisions in both court cases could greatly impact how millions of Americans access certain health care services.

The details: Highlights of the separate decisions are:

Braidwood decision: Judge O'Connor deferral on the DOJ's request for a stay was predicated on the government providing more evidence demonstrating that insured individuals will lose preventive services coverage without an emergency stay.

- **The judge** also cited recent news coverage indicating health plans would likely continue ACA preventive services coverage without a stay.

- **Dig deeper:** The Tri-Agencies issued clarifying guidance on coverage of certain preventive services while the case winds its way through the courts.

Mifepristone access: In a 7-2 ruling, the Supreme Court preserved the FDA's authority to approve mifepristone—a drug often used for the medical termination of a pregnancy up to 10 weeks or for treating miscarriage—as well as recent changes to the drug's administration, such as mail delivery of the drug.

- **The stay** is pending a decision from the Fifth Circuit Court of Appeals, which has scheduled oral arguments for next month.

HHS Releases 2024 Notice of Benefit and Payment Parameters

The U.S. Department of Health and Human Services released a pre-publication version of the 2024 Notice and Benefit Payment Parameters (NBPP) final rule, which is expected to be published in the *Federal Register* on April 27.

Why this matters: As required annually under the Affordable Care Act (ACA), the rule finalizes standards for issuers of qualified health plans and the Marketplaces, including the federally facilitated marketplace and state-based marketplaces as well as requirements for agents and brokers.

- The NBPP specifies payments under the HHS-operated risk adjustment and risk adjustment data validation programs, as well as 2024 user fee rates for QHP issuers.

The details: The 2024 NBPP touches on a wide range of provisions for health plans intending to offer products on the federally facilitated and state-based exchange, including:

- **Limiting** the number of non-standardized plans that can be offered on the federal exchange (per product network type and metal level in any service area) at four (4) for 2024 and two (2) beginning in 2025.

- **Allowing** exchanges to automatically re-enroll certain consumers

- **Permitting** extended special enrollment periods for those losing Medicaid or CHIP coverage

- **Setting** user fee rates for qualified health plans sold on the federally facilitated marketplace and state-based marketplaces on the federal platform

- **Delaying** application of appointment wait time standards until 2025

- **Finalizing** 2024 risk adjustment models

The final rule takes effect 60 days following publication in the Federal Register. The Biden-Harris Administration released this fact sheet and press release to accompany the 2024 NBPP. Additionally, the 2024 Final Actuarial Value (AV) Calculator and Methodology was released.

FDA and CDC Release Simplified COVID-19 Vaccine Recommendations

Following Food and Drug Administration (FDA) regulatory action to amend the Emergency Use Authorizations of the Moderna and Pfizer-BioNTech COVID-19 vaccines, the Centers for Disease Control and Prevention (CDC) simplified COVID-19 vaccine recommendations to allow more flexibility for higher risk individuals who want to receive an additional vaccine dose and discontinue use of monovalent mRNA vaccines. The changes include:

- Allowing an additional updated (bivalent) vaccine dose for adults ages 65 years and older and those who are immunocompromised
- No longer recommending use of monovalent (original) COVID-19 mRNA COVID-19 vaccines
- Recommending that everyone ages 6 years and older receive an updated (bivalent) mRNA COVID-19 vaccine regardless of whether they previously completed their (monovalent) primary series
- Individuals ages 6 years and older who have already received an updated mRNA vaccine do not currently need any further vaccines unless they are 65 years or older or immunocompromised
- For young children, multiple doses continue to be recommended and will vary by age, vaccine, and which vaccines were previously received

For information about Plan coverage of COVID-19 vaccines following the end of the Public Health Emergency (PHE), please see BCBSA's resource, CMS fact sheet, and Tri-Agency FAQs.

CMS Releases Guidance for States to Apply for Medicaid Reentry Section 1115 Demonstration Opportunity

The Centers for Medicare & Medicaid Services (CMS) announced a new opportunity for states to help increase care for individuals who are incarcerated in the period immediately prior to their release.

Why this matters: Under the Medicaid Reentry Section 1115 Demonstration Opportunity, states would be allowed to cover a package of pre-release services for up to 90 days prior to the individual's expected release date that could not otherwise be covered by Medicaid due to longstanding statutory exclusion prohibiting Medicaid payment for most services provided to most people in the care of a state or county carceral facility. CMS notes it will not approve a state's proposal unless the pre-release benefit package includes at minimum: 1.) case management to assess and address physical, behavioral, and health-related social needs, 2.) medication assisted therapies and accompanying counseling for all types of substance use

disorders, and 3.) a 30-day supply of all prescription medications prescribed to the beneficiary at time of release.

President Biden Issues Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers

On Tuesday, President Joe Biden signed an executive order that contains more than 50 directives to increase access to childcare and long-term care and improve the work life of caregivers. Among other directives, the order directs the HHS Secretary to consider issuing guidance to improve the quality of home care jobs by leveraging Medicaid funding to ensure there are enough home care workers to aid seniors and people with disabilities enrolled in Medicaid. Additionally, the order directs HHS to consider testing a new dementia care initiative that will include support for respite care and provide more support to family caregivers when a loved one is being discharged from the hospital. The order does not require any new spending.

HHS Makes Ownership Data for All Medicare-Certified Hospice and Home Health Agencies Publicly Available

On Thursday, HHS announced that it is releasing ownership data for all Medicare-certified hospice and home health agencies.

For the first time, anyone can now review detailed information on the ownership of more than 6,000 hospices and 11,000 home health agencies certified to participate in the Medicare program on the CMS website.

Why this matters: The action is in support of President Biden's Executive Order on promoting competition and commitment to transparency. According to HHS, "making ownership information transparent benefits researchers and enforcement agencies by allowing them to identify common owners that have had histories of poor performance, analyze data and trends on how market consolidation impacts consumers with increased costs without necessarily improving quality of care, and evaluate the relationships between ownership and changes in health care costs and outcomes."

CMS Issues Final 2024 Part C Bid and Operational Instructions

On April 14, the Centers for Medicare & Medicaid Services (CMS) released Contract Year (CY) 2024 final bid and operational instructions for Medicare Advantage (MA) organizations. CMS notes that the agency "received comments from two organizations regarding the Total Beneficiary Cost (TBC) evaluation (addressed in that section) and are finalizing the CY 2024 policies discussed in this memorandum." The agency further states that "CMS is including administrative information regarding the TBC calculation, benefit policies and updates to plan benefit package software as an appendix to this document."

CMS notes that the agency recently released the CY 2024 MA & Part D final rule, but that the provisions in that final rule do not affect the specific guidance in this memorandum.

The agency reminds plans that bids are due June 5.

New Postal Services Health Benefits Interim Final Rule

The Office of Personnel Management's (OPM) recently released an Interim Final Rule (IFR) and Request for Comments on establishing and administering the Postal Service Health Benefits (PSHB) Program—a new program for the 1.7 million Postal Service employees, annuitants and their eligible family members.

Why this matters: OPM will now contract with FEP, which will offer plans for both traditional FEHB Program and the PSHB Program. Because BCBSA's Federal Employee Program (FEP) plans have more than 1,500 Postal Service employees and annuitants, FEP is required to offer plans under both FEHB and PSHB programs and will use this IFR to guide benefit and pricing decisions for the products it will offer.

The details: Under the Postal Service Reform Act of 2022, eligibility for enrollment or coverage in FEHB plans based on Postal Service employment will end on Dec. 31, 2024, and eligible members will be able to enroll in or be covered only by PSHB plans after that time.

- **Coverage for the PSHB Program**, which will remain under the FEHB Program umbrella, begins in January 2025, with the first open season running from Nov. 11 – Dec. 9, 2024.

What's next: Comments are due June 5, the same day the interim final rule is effective.

HHS Announces 'Bridge Access Program For COVID-19 Vaccines and Treatments' to Maintain Access to COVID-19 Care for the Uninsured

On Tuesday, HHS announced the 'HHS Bridge Access Program For COVID-19 Vaccines and Treatments Program'("Program") to maintain broad access to COVID-19 vaccines for millions of uninsured Americans. The program will create a unique $1.1 billion public-private partnership to help maintain uninsured individuals' access to COVID-19 care at their local pharmacies, through existing public health infrastructure, and at their local health centers.

The program has two major components:

1. Provide support for the existing public sector vaccine safety net, which is implemented through local health departments (LHDs) and Health Resources and Services Administration (HRSA) supported health centers.
2. Create a novel, funded partnership with pharmacy chains that will enable them to continue offering free COVID-19 vaccinations and treatments to the uninsured through their network or retail locations as has been done during the COVID-19 Public Health Emergency (PHE).

State Issues

New York

Legislative

Budget Negotiations Continue

Legislators are expected to pass another extender this week as agreement on the budget remains stalled mostly due to disagreements over policy provisions. Last week, a new provision was inserted into budget discussions related to defining who can act as a clinical peer reviewer during appeals of adverse determinations. This is compromise language that was developed late last year to amend the bill approved by the Legislature (A.879/S.8113 of 2022), which was ultimately vetoed.

Bills In Committee

As lawmakers wait for a final budget agreement to consider, they continue work on other legislation. There are a couple of bills of interest on committee agendas this week.

- **PrEP PA prohibition`(S.3227/A.6059)** — prohibits prior authorization for coverage of pre-exposure prophylaxis (PrEP) used to prevent HIV infection.

Rx price notification (A.1707/S.599) — requires drug manufacturers to provide the Superintendent of the Department of Financial Services at least 60 days' notice of their intention to raise the cost of a drug more than 10%. (In Assembly; it has already passed the Senate).

Regulatory

New York Marketplace Enrollment Report

Enrollment in NY State of Health programs has grown by more than two million people — a 41% increase — since March of 2020, the start of the COVID-19 pandemic. As of January 31, 2023, NY State of Health enrollment was more than 6.9 million, or more than one in three New Yorkers across the state. Those figures come from a new *2023 Health Insurance Coverage Update* report released last week. The following is a breakdown of the NYSOH enrollment.

Program Type	March 2020 Enrollment	January 2023 Enrollment
Medicaid	3,387,348	5,204,182
CHPlus	456,214	377,598
QHP	265,071	214,052
Essential Plan	792,935	1,123,110
Total	4,901,568	6,918,942

State Issues

Pennsylvania

Regulatory

Pennsylvania Insurance Department Seeks Comments on Proposal to Suspend the Current Reinsurance Program

The Pennsylvania Insurance Department (Department) is proposing to submit a request to the Centers for Medicare & Medicaid Services (CMS) and the Department of the Treasury for suspension of the reinsurance program in the individual market as approved as part of the Affordable Care Act (ACA) Section 1332 Innovation Waiver (2020 Waiver).

Background: The Department's approved 2020 waiver was submitted in 2019 and it authorized the Department to create and implement a reinsurance program for the individual health insurance market's Qualified Health Plans (QHP). The 2020 waiver is valid for a period of up to five (5) years, which began with Plan Year (PY) 2021 and is set to end with the conclusion of PY 2025, with the option to extend the program.

PID's proposal: In advance of 2025, the department now seeks public comment on a proposed plan to suspend the 2020 Waiver beginning on January 1, 2024.

- The department believes that several pieces of federal legislation, specifically, the American Rescue Plan Act (ARPA) and the Inflation Reduction Act (IRA), increased the number of individuals who qualify for ACA Advanced Premium Tax Credits or subsidies through the state-based health insurance exchange, Pennie® and increased the amount of the subsidies available through 2025.
- As a result, according to the Department, this important Federal legislation had the unintended consequence of minimizing the impact of the reinsurance program on insurance affordability.

Pennsylvania's Reinsurance program (PA-Re) currently reimburses eligible individual health insurers for a percentage of individual qualified claims between an attachment point and a cap. Before ARPA, reinsurance saved about 4% to 6% of premium for Pennie® customers with incomes above 400% of the Federal poverty level (FPL) as well as for individuals that purchased individual market coverage outside of Pennie®, since these populations are not eligible for subsidies. However, ARPA and IRA eliminated the "subsidy cliff," meaning that health insurance premiums for individuals at any income level (including above 400% FPL) are capped at 8.5% of household income.

According to the Department, customers previously benefiting from reinsurance saw the impact of reinsurance minimized and, instead, the ARPA subsidies available through Pennie® are now the main mechanism to ensure affordability. The Department asserts that following ARPA and IRA, nine out of ten Pennie® enrollees now qualify for enhanced subsidies.

Why this matters: In light of these assumptions and observations, the Department is considering the possibility of a State subsidy wrap, to address and meet the unique needs of its markets and its residents.

- As ARPA/IRA subsidies continue to provide financial relief to customers above 400% FPL, the Department believes the State funding currently allocated to reinsurance could be put to better use by addressing affordability challenges experienced by lower income customers enrolling in coverage through Pennie®.
- The Department believes that having the flexibility to adjust to market needs will allow the Department to provide stability to consumers in these times of uncertainty especially for those impacted by the unwinding pf the public health emergency and as individuals are impacted by Medicaid redetermination. The hope is that a focused subsidy program could also substantially

increase enrollment and limit the number of uninsured. However it is worth noting that while many may benefit from a proposed subsidy wrap, others may see an increase of 4%-6% in premiums.

Next Steps: To develop this proposed flexibility, legislation is needed by July of 2023. If legislation is passed, the State portion of the reinsurance program funding would be redirected to a State-affordability program for lower income populations beginning January 1, 2024. Without the passage of legislation, reinsurance will continue for PY 2024. The request to suspend the reinsurance program will reserve an option to revert back to the reinsurance program in the future if deemed a beneficial option.

- The Department is accepting public comments beginning Monday, April 24, 2023, and ending Wednesday, May 24, 2023.

- The Notice, including the Phase Out Plan is available at: https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol53/53-16/550.html

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Pennsylvania Insurance Department Issues Notice Regarding Medigap Guaranteed Issue Expectations

The Pennsylvania Insurance Department (Department) has published Notice 2023-04 in the *Pennsylvania Bulletin*, regarding Medicare Supplement guaranteed issue eligibility following the end of and unwinding of the COVID-19 public health emergency (PHE) and its expectations for the insurance industry.

- Considering the end of the PHE and the beginning of redetermination for individual enrolled in Medicaid, the Department is focusing on individuals who could have enrolled in Medicare Supplement/Medigap coverage on a guaranteed issue basis but for the PHE Medicaid continuous coverage requirements.
- These individuals were enrolled in Medicaid, and therefore may not have enrolled in Medicare Part B. During the PHE, Medicaid was not permitted to redetermine the eligibility of any individual for Medicaid coverage, resulting in many remaining enrolled in Medicaid when they might otherwise have transitioned to Medicare coverage separate from any Medicaid program, regardless of eligibility changes.
- As a result, some of the impacted individuals may have missed or may miss their initial enrollment period for Part B coverage due to their Medicaid enrollment or may have been precluded from purchasing a Medicare supplement policy for a variety of reasons.

Why this matters: For those deemed as Medicaid redetermination individuals, the Department expects each insurer issuing Medicare Supplement coverage in the Commonwealth to treat impacted individuals as having a guaranteed issue enrollment period for Medicare Supplement coverage consistent with Federal and State law. The Department issued Frequently Asked Questions that elaborate on expectations for specific situations.

The Notice with FAQs is available at: https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol53/53-16/551.html

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/.**