Highmark's Weekly Capitol Hill Report

Issues for the week ending June 16, 2023

Federal Issues

Legislative

Senate Finance Committee Unveils Bipartisan PBM Bill

Senate Finance Chairman Ron Wyden (D-OR), Ranking Member Mike Crapo (R-ID) and several other senators on Wednesday introduced the "Patients Before Middlemen (PBM) Act," which would delink the compensation of pharmacy benefit managers (PBMs) from drug price and utilization under the Medicare Part D program.

Why this matters: The introduction builds on the committee's announcement earlier this year of a legislative framework to address PBMs and the drug supply chain.

- The committee expects to release additional legislation associated with the framework, building on the work of several other committees on both sides of the Capitol that have take up the issue.

Next Steps: While next steps for the legislation are unclear, the bill comes as Majority Leader Charles Schumer (D-NY) continues working on a potential health care package that could see floor action in mid-July. The package could include an insulin co-pay cap

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for the commercial market, PBM transparency legislation and bills to increase generic and biosimilar competition.

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Federal Issues

Regulatory

Appeals Court Enters Partial Stay in *Braidwood*; ACA Preventative Services Mandate Remains in Effect Nationwide

The U.S. Court of Appeals for the Fifth Circuit issued a partial stay in *Braidwood Management, Inc. v. Becerra*. This follows and replaces a temporary administrative stay entered in mid-May while the appeals court considered the federal government's request for a partial stay.

Why this matters: The stay, which was stipulated to by the parties in the lawsuit following a hearing held on June 6, **has the effect of temporarily restoring the requirements of the preventive services mandate for all non-grandfathered individual and small group health insurance coverage and group health plans under section 2713 of the Affordable Care Act (ACA)** - except for the plaintiffs named in the case - while the Fifth Circuit continues to consider the merits of the appeal.

- **The settlement generally reflects the health care industry's response to date to retain the preventive services mandate in whole in benefit packages.**

Background: On March 30, 2023, Judge O'Connor issued a decision in *Braidwood*, with an order enjoining the federal government from enforcing certain preventative services mandated by the ACA, namely the mandatory requirement for group health plans and health insurance issuers to cover, without cost-sharing, services rated "A" or "B" by the U.S. Preventive Services Task Force (USPSTF) since March 23, 2010. The decision largely focused on the scope of the remedy available to plaintiffs in light of a prior ruling made by the same court last year. That earlier decision found the United States USPSTF violates the Constitution's Appointments Clause. The lower court also found in favor of several individual plaintiffs who alleged the mandated coverage of PrEP violated the Religious Freedom Restoration Act (RFRA).

Next steps: Opening briefs in the appeal are scheduled to be filed on June 20 with briefing set to conclude in early November. A hearing has not yet been scheduled. We will continue to closely monitor this litigation and report on any significant developments.

CMS to Launch New Outreach Campaign for Expanded Prescription Drug Savings Program

The Biden Administration announced new tools to build on the prescription drug reforms enacted as part of the Inflation Reduction Act.

A few provisions have already taken effect, such as the inflationary rebate provision for Part B drugs, as well as the $35 per month copay cap for covered Part B and D insulin. CMS intends to focus on an outreach campaign to increase public awareness of these reforms as well as the 2024 reform that expands the low-income subsidy (or Extra Help) program to provide full LIS benefits (e.g., no Part D deductible, $0 premium if enrolled in a benchmark plan) to enrollees with incomes up to 150% of the federal poverty level.

HHS's announcement notes that up to 3 million people are eligible for Extra Help but are not yet enrolled. Given the yearly savings are on average $300 per year, it is an administration priority to reach those who are eligible but not enrolled. The Administration for Community Living will target outreach efforts to individuals in rural and underserved communities, while CMS released national, deidentified demographic data on Part D enrollees who are likely eligible for Extra Help. CMS also released an outreach toolkit for stakeholders and will continue to train partners and update key Medicare materials like the Medicare & You handbook and 1-800 MEDICARE call center scripts.

CMS Releases New Guidance & Resources to Support Medicaid Unwinding

On June 12, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra sent a letter to governors announcing new flexibilities that states can adopt to help coverage retention through the Medicaid redetermination period.

Why this matters: Flexibilities announced include:

- **Allowing** managed care plans to assist in completion of renewal forms
- **Permitting** states to delay procedural terminations for one month

• **Enabling** pharmacies and community-based organizations to facilitate reinstatement of coverage based on presumptive eligibility criteria

• **Enabling** Medicaid agencies to make presumptive eligibility determinations for individuals disenrolled for procedural reasons

• **Allowing** states to reinstate eligibility effective on the individual's prior termination date

• **Suspending** certain requirements that may contribute to enrollee churn and state staff burden

States must request and receive CMS approval of a 1902(e)(14)(A) waiver in order to leverage any of these flexibilities.

A full list of the flexibilities can be found here. The Centers for Medicare & Medicaid Services (CMS) also updated the Outreach and Educational Resources Page on Medicaid.gov/Unwinding with new resources for kids and families, information about fraud/scams, and educational videos.

Call to Action: In announcing these flexibilities, HHS and CMS reiterated their call for partnership in the redeterminations process. In the letter to governors, Secretary Becerra urged states to leverage all available flexibilities and to partner with schools, faith-based organizations and other community groups to help share information about the Medicaid and CHIP renewal process. Additionally, CMS issued a fact sheet, *All Hands on Deck: Keeping People Covered as States Restart Routine Medicaid Renewals*, identifying actions public and private sector partners can take to help prevent coverage loss.

MACPAC Releases June Report to Congress

On June 15, the Medicaid and CHIP Payment and Access Commission (MACPAC) released its June 2023 Report to Congress on Medicaid and CHIP, with recommendations in four areas: payment policy for safety net hospitals, integrated care for dually eligible beneficiaries, access to Medicaid coverage for adults leaving incarceration, and access to Medicaid home- and community-based services (HCBS).

- In Chapter 1, the Commission makes recommendations on providing automatic adjustments to disproportionate share hospital (DSH) payments when there are changes in the state's federal medical assistance percentage (FMAP).
- In Chapter 2, the Commission continues its work on strategies to make integrated care the standard for dually eligible beneficiaries and describes the delivery system mechanisms available for integrating care in order to support states in developing an integrated care strategy, as recommended by the Commission in June 2022.
- Chapter 3 focuses on state efforts to provide timely Medicaid coverage and access to care for adults leaving state prisons and jails, and considerations for implementing prerelease Medicaid services.

- The final chapter continues the Commission's work on access to Medicaid HCBS and provides an overview of state coverage of HCBS and research findings on barriers to access for beneficiaries, and state challenges in administering these programs, highlighting areas for further work.

Biden Administration Releases Spring 2023 Updated Unified Agenda of Expected Regulatory Actions

On June 14, the White House Office of Management and Budget (OMB) posted the Spring 2023 regulatory agenda. In a detailed summary, AHIP highlights several noteworthy actions and developments of interest to health plans since the Fall Agenda was posted in January.

Why this matters: Major themes for health care regulations include a retreat in COVID-specific regulations given the termination of the COVID-19 public health emergency in May 2023, as well as an incredibly busy summer of 2023 which many Medicare and private insurance regulations expected to be published, including: the rule reinterpreting federal standards related to short-term limited duration insurance; mental health parity law for individual and group health insurance and employer-based plans; rules regulating the No Surprises Act's independent dispute resolution process; and provider nondiscrimination standards.

Some highlights include:

- **Commercial Markets & Exchanges:** A proposed rule on Independent Dispute Resolution Operations regarding the No Surprises Act.
- **Department of Labor:** A proposed rule to make improvements to the Form 5500 under ERISA that includes potential changes to group health plan annual reporting requirements.
- **Office of the National Coordinator for Health Information Technology:** Rulemaking to expand the certification of health IT to support expanded uses of application programming interfaces (APIs), such as electronic prior authorization, patient engagement, and interoperable public health exchange.
- **Office for Civil Rights:** Rulemaking to establish a methodology for the distribution of civil monetary penalties (CMPs) and monetary settlements to those harmed by an offense under the HIPAA Rules relating to privacy or security.
- **Centers for Medicaid and Medicare Services:** Release of a proposed rule regarding potential remedies for 340B drug reimbursement for payment years 2018 through 2022.

Timing: Relevant to health care stakeholders, a number of the rules are currently under OMB's interagency clearance process which means the rules are expected relatively soon.

- Generally speaking, major rules will be finalized by Spring 2024 when the administration will enter a relatively quiet period leading up to the November 2024 general election.

- This deadline is also important due to the potential for a newly elected Congress to claw back rules that are finalized after Spring 2024 pursuant to its authority under the Congressional Review Act.

National Committee on Vital & Health Statistics Notice on Proposed Use of ICD-11 for Morbidity Coding

The Department of Health and Human Services (HHS) issued a Notice of Meeting and Request for Information (RFI) for the National Committee on Vital and Health Statistics' Workgroup on Timely and Strategic Action to Inform ICD-11 Policy.

Why this matters: On August 3, the Workgroup will meet for an International Classification of Diseases (ICD-11) expert roundtable to gather information, identify gaps in currently available information, and collect research necessary to inform policy decisions on the U.S. approach to support adoption and implementation of ICD-11 for morbidity. To support this meeting, HHS has issued an RFI addressing the potential use of ICD-11 for morbidity coding in the U.S.

Responses to the RFI are due June 30. More information about attending the public meeting will be posted on NCVHS's website here.

CMS & FDA Updates

- **CMS Releases 2021 RADV Results:** On June 13, 2023, the Centers for Medicare & Medicaid Services (CMS) released the '2021 Benefit Year Department of Health and Human Services Risk Adjustment Data Validation (HHS-RADV) Results' memo on the CCIIO website and issuers' 2021 benefit year HHS-RADV final results in the Audit Tool. This memo provides summary information on issuers' 2021 benefit year HHS-RADV results. The memo is posted on the Center for Consumer Information and Insurance Oversight (CCIIO) website here.

- **FDA Votes to Update COVID-19 Vaccine Formulation:** The U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted unanimously to update the COVID-19 vaccine for the fall season. The Committee voted 21-0 to recommend an update to the current vaccine composition to a monovalent vaccine of the XBB-lineage, from the current bivalent vaccine.

    - The data presented during the meeting showed the current vaccine was less effective against the XBB-lineage types of the virus. The Committee determined the original "Wuhan strain" was no longer circulating and did not need to be included in the vaccine.

    - The Committee had debated about terminology which seemed to indicate the vaccine would follow a "season" and the vaccines would require "periodic" updates. The data does not support there are "seasons" of the virus or that any vaccine updates will occur at regular intervals.

    - The Committee expressed support for including the XBB.1.5 strain in the vaccine update, based on data presented during the meeting. The FDA will use this information to formally

recommend to manufacturers which strain to include in the updated vaccine. The vaccines will then need to be evaluated for safety and effectiveness by the FDA, which will occur around September.

- Next, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) next will determine for which populations and at what intervals the updated vaccine would be recommended.

State Issues

Delaware

Legislative

Senate Files Prior-Authorization Bill to Be Considered Next Year

Senate Bill 10 was introduced during the final weeks of this year's legislative session. The sponsor of the bill agreed to delay action on SB 10 until next year to allow for stakeholder meetings.

What the Bill Does:

Expands the hours insurers must be available to review PA requests

- To perform utilization review over the weekend.
- Provides access to a medical director or another clinical decision maker during week days between 7:00 am and 7:00 pm

Shortens review times of PAs:

- UR entity requiring PA of a pharmaceutical must complete its review process or give an adverse determination and notify the covered person's health care provider within 48 hours (vs. original 2 business days).
- UR entity must notify the covered person's health care provider of the determination of a PA request for a health-care service within 4 days (vs. 8 business days) of a clean PA request that is not submitted through ePA (electronic prior authorization).
- For ePA, a UR entity must notify the covered person's health care provider of the determination of a PA request for health care services within 72 hours of receipt of the clean PA request (vs. the original 5 business days).
- UR entity must notify the covered person's health care provider of the determination of a PA request for an urgent health-care service or patient transfer within 24 hours of a clean PA request. Urgency is defined in bill as being deemed urgent by the provider.

Extends length and scope of PA

- PA for a health care service is valid for no less than 7 months (60 days originally) from the date the health-care provider receives the PA request.

- Continuity of Care – when a covered individual obtains coverage from a new insurer that uses a different UR entity than their previous insurer's, the new insurer must comply with any PA for health care services approved by the previous insurer during the first 60 days.
- Limitation per episode of care – An insurer may not require more than one PA for an episode of care.
- An insurer cannot apply changes made to a coverage plan until the next plan year for any covered person who received pre-authorization for a health-care service using the coverage terms or clinical criteria in currently in effect before the effective date of the change.

This act would take effect January 1 of the calendar year following its enactment

Why this matters: In addition to the requirements above it discourages use of PA by stipulating that an insurer may not deny or limit coverage of a healthcare service already delivered to a covered individual based on a lack of PA if the service would have otherwise been covered by the insurer had the PA been obtained.

It also creates restrictive of requirements for physicians reviewing appeals, such as "Knowledgeable of and has experience with providing health care services under review in the appeal."

SB 10 also applies to both the State of Delaware and Medicaid accounts, which could trigger a fiscal note.

State Issues

New York

Legislative

Assembly Returns to Session this Week

The Assembly is set to return to Albany this week for two days to address "unfinished legislative business."

Advocates are pushing for passage of the bill (S.2237-A/A.3020-A) directing the Department of Health to amend its recently submitted 1332 waiver request to include undocumented New Yorkers currently excluded from any coverage due to their immigration status to enroll in the Essential Plan (EP). Sponsors of the bill say that a recent letter from the Centers for Medicare & Medicaid Services indicated that if New York amended its waiver application, the state could use federal dollars to cover the undocumented population. However, there is some disagreement on the interpretation of the CMS letter and the Hochul administration has expressed concerns about both the potential overall cost of the expanded coverage and the possibility that the state would ultimately be responsible for paying the total price tag.

2023 Legislative Session Recap

In the closing days of the legislative session the legislature passed a number of bills affecting health plans, including:

- **Direct ambulance reimbursement (A.250/S.1466-A)** —requires health plans to directly reimburse ambulance service providers regardless of whether they are in-network or out-of-network providers. The bill gained traction in the final days of session.

- **Drug price increase notice (A.1707-A/S.599-A)** — requires pharmaceutical manufacturers to provide advance notice of prescription drug price increases of 16% or more. The bill would require 60-days' notice in advance of the proposed price increase, including the date of the increase, the current price and proposed increase, and an explanation on the need for the increase.

- **Medicaid rate data (A.5381/S.6075)** — expands the level of detail the Department of Health provides to Medicaid managed care plans as part of the rate development process, which will provide greater transparency, allowing plans to better analyze the adequacy of the rates set by the Department and understand the state's assumptions.

- **Medicaid quality incentive program (A.6021/S.3146)** — codifies in statute the quality incentive program for Medicaid managed care plans. The bill represents an important step to ensure funding would continue to be available for initiatives aimed at addressing the core causes of health disparities and improving health outcomes for underserved populations that health plans support.

- **Biomarker testing coverage (A.1673/S.1196)** — Lawmakers struck a compromise on this proposal that mandates coverage of biomarker testing, addressing concerns health plans had raised with the broadness of the bill, with the final version ensuring individuals are able to access biomarker testing while emphasizing the importance of tests that are evidence-based.

- **Step therapy notices (A.463/S.2677)** — Requires written procedures for step therapy adverse determination notices.

- **Medicaid reserve sunset extension (S.7477/A.7393)** – extends the sunset on nonprofit reserve limits in Medicaid for an additional two years.

Several other health care bills did not receive final approval, including:

- **Step therapy (A.901/S.1267)** – would severely restrict health plans' ability to require step therapy programs for prescription drugs.

- **Transfer tax (S.3122/A.3885)** — Imposing a 9.63% tax on any out-of-state transfers health plans may make, including dividends, payments or loans.

- **"Gold carding" (S.2680/A.859)** — Requiring plans to institute "Gold Card" processes for providers meeting prior authorization thresholds.

- **Coverage expansion for undocumented residents (S.2237-A/A.3020-A)** — Directing the Commissioner of Health to amend the state's recent 1332 waiver request to allow undocumented New Yorkers who are currently excluded to enroll in the Essential Plan.

Regulatory

Health Plans Assisting in State's Redetermination Effort

New York has begun the process of redetermining eligibility of nearly nine million Medicaid, Child Health Plus and Essential Plan members that was paused during the COVID-19 Public Health Emergency. Last week, HPA issued a news release highlighting the critical role that plans – including Highmark Western and Northeastern New York -- are playing to help individuals and families renew their health insurance and ensure they have uninterrupted access to needed care and services. As detailed in the release, health plans are undertaking a broad range of efforts to assist throughout the redetermination period — from multi-faceted messaging to educate members about the process, to supporting providers with the resources they need to help patients, to deploying mobile units and taking part in local community events to provide enrollment assistance to consumers.

Postpartum Care Coverage Extended

DOH last week announced that CMS approved the expansion of New York's Medicaid and Child Health Plus postpartum coverage from 60 days to a full year following pregnancy. New York is the 35th state, along with the District of Columbia, to provide extended postpartum coverage.

State Issues

Pennsylvania

Legislative

House Committee Advances Preventive Services Legislation

On Monday, June 12, the House Insurance Committee unanimously advanced House Bill 1050 (Boyle, D – Philadelphia). House Bill 1050 seeks to preserve the ACA preventive service requirements in response to a recent federal district court decision in *Braidwood Management, Inc. v. Becerra*, which would prevent enforcement of certain preventive services required by the ACA.

House Bill 1050 now awaits consideration from the full House.

Why this matters: Highmark expressed support for advancing House 1050 and preserving the ACA preventive services requirements in Pennsylvania as preventive services provide a vital benefit our members and patients.

Governor Signs Cyber Security Legislation

On Wednesday, June 14, Governor Shapiro signed House Bill 739 (Boyle, D – Philadelphia) and is now Act 2 of 2023. Act 2 of 2023 requires licensed insurance entities to develop cybersecurity policies and report cybersecurity events to the Insurance Commissioner.

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/.**