Highmark's Weekly Capitol Hill Report

Issues for the week ending July 21, 2023

Federal Issues

Legislative

House Panel Takes Up Health Care Bills

On Wednesday, the House Energy and Commerce Committee marked up several pieces of health care legislation. All bills that were considered cleared the committee, some with bipartisan support, others on party-line votes. Of note, legislation that would allow employers to offer telehealth-only benefits to part time and seasonal workers without access to group coverage passed on a largely party-line vote.

Most Democrats opposed the measure, citing the lack of comprehensive benefits and consumer protections in the proposal.

Bills passed by the committee include:

- H.R. 824, the Telehealth Benefit Expansion for Workers Act (29-20)
- H.R. 3226, the Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Reauthorization Act (48-0)
- H.R. 3838, the Preventing Maternal Deaths Reauthorization Act (50-0)

In this Issue:

- H.R. 3843, the Action for Dental Health Act (50-0)
- H.R. 3884, the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act (50-0)
- H.R. 3821, the Firefighter Cancer Registry Reauthorization Act (51-0)
- H.R. 3391, the Gabriella Miller Kids First Research Act 2.0 (50-0)
- H.R. 3836, the Medicaid Primary Care Improvement Act (51-0)
- H.R. 4531, the Support for Patients and Communities Reauthorization Act (49-0)
- H.R. 4529, the Public Health Guidance Transparency and Accountability Act (25-21)
- H.R. 4381, the Public Health Emergency Congressional Review Act (28-21)
- H.R. 3813, the CDC Leadership Accountability Act (27-20)
- H.R. 4421, the Preparing for All Hazards and Pathogens Reauthorization Act (28-23)
- H.R. 4420, the Preparedness and Response Reauthorization Act (27-22)
- H.R. 3887, the Children's Hospital GME Support Reauthorization Act of 2023 (27-17)

Next steps: Some or all of the bills will be considered on the House floor in the fall, in conjunction with the work of other committees.

- **FTC/DOJ Release Draft Merger Guidelines for Comment**

State Issues

New York

Legislative

- **Single Payer Legislation Reintroduced**

Regulatory

- **Regulatory Updates**

Industry Trends

Policy / Market Trends

- **Coalition Highlights the Value of Telehealth Services in Medicare Advantage**

Federal Issues

Regulatory

Administration Pauses Some Procedural Disenrollments in Medicaid

The Centers for Medicare & Medicaid Services (CMS) indicated it has required 12 states to pause procedural disenrollments for some Medicaid populations or risk losing their enhanced federal matching funds (FMAP). CMS clarified no states have been required to pause procedural disenrollments across all populations, and some of the required pauses have already been lifted. Additionally, the pauses may be of short duration and for a small subset of a state's Medicaid population. CMS issued a factsheet highlighting examples of complaint actions.

At this time CMS does not plan to name the states involved unless the issues are not resolved and an FMAP penalty is imposed. However, the threat of a reduced FMAP is expected to ensure a rapid response by states.

There are three types of pauses on procedural disenrollments:

- **Type 1: States that adopted Mitigation Strategy 1 prior to April 1**: The summary of state mitigation strategies includes as the first strategy "holding procedural terminations." Nine states are listed as having adopted this strategy to address identified areas of noncompliance: DE, ID, IA, ME, MN, MS, NY, WV, and WY. The mitigation strategy only needs to be applied to impacted populations. Some of the areas of non-compliance have been addressed and states have retired use of some or all mitigations.

- **Type 2: States that have voluntarily adopted a CMS flexibility to pause procedural disenrollments for 1 month in order to conduct additional outreach**: CMS shared 11 states have self-identified their interest in voluntarily adopting a flexibility to pause disenrollments to allow for more time for additional outreach. This flexibility can be adopted for some or all populations and is the state's option. CMS is tracking the states that are adopting this flexibility and intends to post information about which states are using it.

- **Type 3: States where statutory or regulatory due process violations have been identified since April 1**: The type discussed in the news articles and factsheet above.

Medicaid Continuous Enrollment Unwinding Tri-Department Letter to Employers, Plan Sponsors, and Issuers

The Departments of Treasury, Labor, and Health and Human Services issued a joint letter encouraging employers and other plan sponsors to match the steps taken by HealthCare.gov.

Why this matters: The letter encourages employers and plan sponsors to amend their group health plans to extend the period for special enrollment under their plans beyond the minimum 60-day period required by statute for individuals losing Medicaid and CHIP. The Departments write individuals losing Medicaid and CHIP should instead be able to enroll anytime during this annual redetermination process, in recognition of the complicated transition and the importance of

maintaining life-saving coverage for employees and their families. There are no legal or regulatory barriers that would prevent group health plans from allowing longer special enrollment periods beyond the minimum 60 days.

Also in line with recent guidance from the Departments, the letter encourages employers and other plan sponsors to get the word out about Medicaid and CHIP renewals and encourages health plan administrators be prepared to assist with transitioning individuals from Medicaid to employment-based or Marketplace coverage. View the letter here.

CMS Releases Initial Technical Guidance on IRA Part D Cost-Share "Smoothing" Program

CMS released a technical memorandum to Part D plan sponsors that provides an important glimpse into how CMS plans to interpret a key provision in the IRA: the option for beneficiaries to pay cost-sharing through monthly installments through the coverage year, starting on January 1, 2025, instead of at the pharmacy counter.

Why this matters: If a member chooses this option, they will pay cost-sharing to the Part D plan which will bill them directly. This IRA is notable given that no other major federal health insurance program offers this feature.

The memo provides examples for how CMS will apply the statutory language addressing the billing calculation and procedures.

- Importantly, "the enrollee will not have any monthly bills to pay under this program until the enrollee elects into the program and incurs out-of-pocket drug costs."
- However, exactly how enrollees opt into the program, what role, if any, pharmacies will play to educate members about the program, whether the program will apply to all Part D drugs the members take or can apply to a subset, and the implications if an enrollee fails to pay their cost-sharing, are important aspects that are not addressed in this guidance.
- Additional guidance is expected.

OIG Releases Report on Prior Authorization Denials in Medicaid Managed Care

On Monday, the HHS Office of Inspector General released a report titled, "High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care." The report analyzed the prior authorization denials and related appeals data of the seven largest MCO parent companies.

The report found three primary concerns including:

(1) the high number and rates of denied prior authorization requests by some MCOs,

(2) the limited oversight of prior authorization denials in most states, and

(3) the limited access to external medical reviews.

OIG recommended CMS require states to review the appropriateness of a sample of MCO prior authorization denials regularly, require states to implement automatic independent reviews of upheld denial, to issue guidance to states on the use of MCO prior authorization data for oversight and work alongside states to identify and address MCOs that may be issuing inappropriate prior authorization denials.

CMS Issues Proposed National Coverage Determination Removing Current Limits for Amyloid PET Scans

The Centers for Medicare & Medicaid Services (CMS) issued a proposed National Coverage Determination (NCD) that would replace the current NCD limiting amyloid PET scans. The new NCD would permit Medicare beta amyloid imaging coverage determinations to be made by Medicare Administrative Contractors (MACs).

Why this matters: Since September 27, 2013, CMS has provided coverage for PET beta amyloid imaging under coverage with evidence development (CED). The current NCD permits coverage of one lifetime amyloid PET scan per patient under CED. Initiation of a new NCD analysis was internally generated by CMS based on stakeholder feedback received during the finalization of the NCD pertaining to Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease, given that those clinical study protocols may involve more than one PET beta amyloid scan per patient.

Comments on the proposed NCD are due to CMS by August 16.

FDA Approves RSV Vaccine for Infants & Young Children

The Food and Drug Administration approved a monoclonal antibody to protect infants and young children from severe illness caused by respiratory syncytial virus (RSV). RSV is the top cause of hospitalization of babies in the United States, with nearly 600,000 infants under 1 year requiring medical care.

Why this matters: AstraZeneca and Sanofi's Beyfortus (nirsevimab) was approved for use for the prevention of RSV lower respiratory tract disease (LRTD) in newborns and infants born during or entering their first RSV season, and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

The drug manufacturers have indicated that they will make Beyfortus available for the 2023-2024 RSV season.

The antibody treatment will still need to be recommended by the Advisory Committee on Immunization Practices (ACIP). ACIP has scheduled a meeting for August 3 to vote on recommending this product.

CMS Releases New Medicaid Redeterminations Resources

CMS released two new resources outlining actions that both states and CMS officials are taking to prevent avoidable coverage loss during the Medicaid unwinding period.

- The first resource, a fact sheet titled "Returning to Regular Medicaid Renewals: Monitoring, Oversight, and Requiring States to Meet Federal Requirements," describes the actions that CMS is taking to monitor states' redeterminations processes and ensure compliance with all federal requirements.
- The second resource, titled "Summary of State Mitigation Strategies for Complying with Medicaid Renewal Requirements Described in the Consolidated Appropriations Act, 2023," outlines the waiver flexibilities and other strategies states have used to support the redeterminations process and identifies areas in which each state has been found to be out of compliance with renewal requirements. The document reflects areas of non-compliance as of March 31, 2023, and CMS has noted that states have already begun taking steps to come into compliance with federal requirements.

Factsheet on Monitoring State Data and Information

- The first resource is a factsheet, "Returning to Regular Medicaid Renewals: Monitoring, Oversight, and Requiring States to Meet Federal Requirements," which describes CMS's efforts to monitor state data and information from stakeholders to identify problems, and to take action to ensure compliance. CMS says it will work with states to pause certain terminations, reinstate coverage for those impacted by systems issues, and implement systems changes; and notes that if states do not comply, they risk losing their enhanced federal funding.

State Mitigation Strategies

- The second resource is a summary of state mitigation strategies for complying with Medicaid renewal requirements, listing each state's areas of non-compliance with renewal requirements and the primary mitigations and other strategies that the state has adopted.

Read More

- Returning to Regular Medicaid Renewals: Monitoring, Oversight, and Requiring States to Meet Federal Requirements
- Summary of State Mitigation Strategies for Complying with Medicaid Renewal Requirements Described in the Consolidated Appropriations Act, 2023

FTC Votes to Withdraw Prior PBM Materials

The Federal Trade Commission (FTC) voted 3-0 at an Open Meeting to issue a statement "cautioning against reliance on prior advocacy statements and studies related to pharmacy benefit managers (PBM) that no longer reflect current market realities."

Why this matters: The vote comes as the Commission continues its investigation into PBMs and as Congress considers legislation related to PBMs. The Senate Finance Committee is scheduled to hold a markup on Wednesday, July 26, to advance PBM legislation.

The statement is a response to PBMs' continued reliance on older FTC advocacy materials that opposed mandatory PBM transparency and disclosure requirements, and it warns against reliance on the Commission's prior conclusions, particularly given the FTC's ongoing study of the PBM industry to update its understanding of the industry and its practices. The Commission's statement warns against relying on nine advocacy letters published or issued between 2004 and 2014 that advocated against proposals to increase regulatory oversight and transparency of PBMs. The statement also cautions against reliance on a 2004 joint report with the Department of Justice and a 2005 FTC study, as these reports may no longer accurately reflect the current PBM industry.

Until the FTC's current PBM study is complete and previously issued materials can be reevaluated, the Commission discourages reliance on these advocacy letters and reports.

CMS Releases Summary Report of 2021 RADV Adjustments to State Risk Adjustment Transfer

The Centers for Medicare and Medicaid Services (CMS) released the Summary Report of 2021 Benefit Year (BY) Risk Adjustment Data Validation Adjustments to Risk Adjustment State Transfers.

Why this matters: This report sets forth by HIOS ID and state market risk pool the applicable adjustments to 2021 benefit year risk adjustment state transfers based on the 2021 benefit year HHS-RADV results.

FTC/DOJ Release Draft Merger Guidelines for Comment

On July 19, the Federal Trade Commission and the Department of Justice released a draft update of the Merger Guidelines, which describe and guide the agencies' review of mergers and acquisitions to determine compliance with federal antitrust laws.

- The goal of this update is to better reflect how the agencies determine a merger's effect on competition in the modern economy and evaluate proposed mergers under the law. Both agencies encourage the public to review the draft and provide feedback through a public comment period that will last 60 days.

- The draft guidelines build upon, expand, and clarify frameworks set out in previous versions. At the outset, the guidelines give an overview of thirteen principles that the agencies may use when determining whether a merger is unlawfully anticompetitive under the antitrust laws. These guidelines are not mutually exclusive, and a given merger may implicate multiple guidelines. The document then describes in greater depth the frameworks and tools that may be used when analyzing a merger with respect to each guideline.

The proposed merger guidelines focus on 13 core principles:

1. Mergers should not significantly increase concentration in highly concentrated markets.

2. Mergers should not eliminate substantial competition between firms.
3. Mergers should not increase the risk of coordination.
4. Mergers should not eliminate a potential entrant in a concentrated market.
5. Mergers should not substantially lessen competition by creating a firm that controls products or services that its rivals may use to compete.
6. Vertical mergers should not create market structures that foreclose competition.
7. Mergers should not entrench or extend a dominant position.
8. Mergers should not further a trend toward concentration.
9. When a merger is part of a series of multiple acquisitions, the agencies may examine the whole series.
10. When a merger involves a multi-sided platform, the agencies examine competition between platforms, on a platform, or to displace a platform.
11. When a merger involves competing buyers, the agencies examine whether it may substantially lessen competition for workers or other sellers.
12. When an acquisition involves partial ownership or minority interests, the agencies examine its impact on competition.
13. Mergers should not otherwise substantially lessen competition or tend to create a monopoly.

Following a public comment period, which included a request for information, more than 5,000 members of the public—including consumers, workers, state attorneys general, academics, businesses, trade associations, practitioners, and entrepreneurs—contributed feedback. The agencies also conducted four listening sessions that highlighted the potential for mergers and acquisitions to undermine open, vibrant, and competitive markets in industries ranging from food and agriculture to health care.

The public can provide comments to the Draft Guidelines through September 18, 2023. The agencies will use the public comments to evaluate and update the draft before finalizing the guidelines.

A fact sheet on the draft merger guidelines is available online.

Why this matters: The FTC and DOJ protect competition through enforcement of the antitrust laws and other federal competition statutes. Since 1968, the agencies have issued and revised merger guidelines to enhance transparency and promote awareness of how the agencies carry out that charge with respect to mergers and acquisitions.

State Issues

New York

Legislative

Single Payer Legislation Reintroduced

The updated New York Health Act, a bill to create a government-run single payer health system for New York, has officially been introduced — S.7590 (Rivera)/A.7897 (Paulin). Assembly Health Committee chair Paulin was on Capitol Pressroom last week discussing the bill's reintroduction.

She said that the major change to the bill was language that attempts to address the concerns of public health employee unions that their existing health care plans would not be diminished. When asked if the changes will put to rest the concerns from organized labor, she said they haven't gotten any reaction yet, but noted that the perspective of organized labor is very important. Other elements of the bill discussed included how the program would be financed, provider reimbursement structure and the impact on the existing health care system, specifically the loss of jobs in the insurance industry.

Next steps: The bill could be considered in the next legislative session starting in January 2024, but there are no indications from leadership in the Senate or Assembly that this will be a priority for next session.

In other legislative news: Bills approved in the 2023 Legislative Session are beginning to be sent to the Governor for her consideration. A.7393/S.7477, extending provisions adopted in the FY2019 budget authorizing the Commissioner of Health to establish a reserve ceiling on nonprofit health plans, was signed by the Governor last week.

Regulatory

Regulatory Updates

- **Colorectal Cancer Screening Circular Letter** — The Department of Financial Services has posted the final colorectal cancer screening circular letter to the DFS website.

- **Travel Insurance Pre-proposed Regulation** — DFS also posted a pre-proposed draft amendment related to travel insurance. Pre-proposed regulations have a 10-day response window for comments.

- **Form Filing Tips** —The Department has updated its Guidance for Filing Accident and Health Insurance Policy Forms, which is intended to provide "tips" for successful form filings.

Industry Trends

Policy / Market Trends

Coalition Highlights the Value of Telehealth Services in MA

The Coalition for Medicare Choices (CMC) posted a new article highlighting the vital role of telehealth for seniors and individuals with disabilities who rely on Medicare Advantage (MA).

Why this matters: CMC points out how telehealth has become an increasingly popular and effective choice for millions of Americans, especially for seniors in rural areas or those with mobility issues. The article also details how telehealth provided support during COVID-19 and the importance of telehealth in mental health services.

In the article, CMC members share first-hand stories on how telehealth is an efficient and effective way to improve care outcomes, and reduce unnecessary and costly visits to the emergency department. For example, CMC member Freda shared her experience as a senior living in a rural area of Arizona, “Medicare Advantage offers convenient and accessible benefits despite where I live, ensuring I can connect with my doctors and maintain a peace of mind.”

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/.**