Highmark's Weekly Capitol Hill Report

Issues for the week ending February 10, 2023

Federal Issues

Legislative

President Biden Delivers State of the Union Address

On Tuesday night, President Biden delivered his State of the Union address to a joint session of Congress. Notably, the president foreshadowed the end of the public health emergency, saying that "COVID no longer controls our lives."

Why it matters: While it is largely a messaging opportunity, the address gives the President the opportunity to frame his position on important issues facing the nation. The speech also provides a preview of forthcoming budget proposals, which will mark his ideas for solving the nation's problems via legislation he will be asking Congress to advance.

The speech touched on several of his administration's health care priorities, including:

- Providing a $35 co-pay cap on insulin for all Americans
- Maintaining the Rx drug reforms in the Inflation Reduction Act
- Making enhanced ACA tax credits permanent
- Closing the Medicaid coverage gap
- Preventing cuts to Medicare

In this Issue:

- Improving access to mental health care and addressing the opioid epidemic
- Codifying Roe v. Wade

West Virginia
Legislative
- **Senate Committee Advances Dental Medical Loss Ratio Legislation**

Senate Judiciary Committee Advances Drug Pricing Bills

On Thursday, in its first legislative action of the 118th Congress, the Senate Judiciary Committee passed several bipartisan bills designed to enhance consumer access to lower cost prescription drugs. All bills were approved by voice vote.

Why it matters: Some of the bills passed were specifically endorsed by the BlueCross BlueShield Association in its Affordability Solutions for the Health of America white paper released in January. The bills passed by the committee include:

S. 142, The Preserve Access to Affordable Generics and Biosimilars Act
- This would prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market and prohibit biological product manufacturers from compensating biosimilar/interchangeable companies to delay the entry of biosimilar/interchangeable biological products.

S. 148, The Stop STALLING Act
- This would enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar.

S. 150, The Affordable Prescriptions for Patients Act
- This would amend the Federal Trade Commission Act to prohibit product hopping.

S. 79, The Interagency Patent Coordination and Improvement Act of 2023
- This would establish an interagency task force between the United States Patent and Trademark Office and the Food and Drug Administration to share information and provide technical assistance on patents.

S. 113, The Prescription Pricing for the People Act of 2023
- This would require the Federal Trade Commission to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations.

Federal Issues

Regulatory

HHS Releases Medicare Prescription Drug Inflation Rebate Program Guidance

The Biden Administration announced initial guidance for Medicare Prescription Drug Inflation Rebate Program as a part of the Inflation Reduction Act (IRA). The CMS release provides guidance for Part B and Part D rebates. Additional background can be found in the CMS Fact Sheet and Press Release.

As a part of the guidance, CMS seeks public feedback in the following areas:

- The process to determine the number of drug units for rebatable drugs
- The reduction of rebate amounts for certain rebatable drugs in shortage and in cases of severe supply chain disruptions
- The process to impose civil monetary penalties on manufacturers of Part D rebatable drugs that fail to pay rebates
- Assuring accuracy of the inflation rebate payments

Comments on the guidance must be submitted to CMS by Saturday, March 11, 2023. CMS anticipates issuing revised guidance later in 2023 for the Medicare Prescription Drug Inflation Rebate Program.

HHS Halts Federal No Surprises Act Dispute Determinations After Court Loss

A federal court in Texas granted health care providers' requests to set aside August 2022 final regulations governing the arbitration process under the *No Surprises Act.* At issue is the criteria used by independent dispute resolution entities tasked with picking an offer between a provider and health plan with respect to out-of-network claims that cannot be balance billed to a patient.

Why it matters: While the ruling was expected, it further undermines the importance of the qualifying payment amount (QPA) in independent dispute resolution (IDR), driving arbiters to focus on factors less central to how reimbursements are typically determined. This decision echoes last year's court decision disallowing the primacy of the QPA in IDR.

The details: This new ruling vacated provisions from last year's final rule, which was intended to address concerns raised by the court on a previous Texas Medical Association case. **The final rule required arbitrators to:**

- **Consider** the QPA first and "then consider" the other factors
- **Refrain** from "giv[ing] weight to" non-QPA factors unless certain prerequisites are met
- **Issue** a written explanation when giving weight to any non-QPA factor

Next Steps: The Depts. of HHS, Treasury and Labor's (Tri-agencies) will go back to the drawing board to presumably create more provider-friendly regulations or appeal the decision. In the meantime, HHS has directed a halt to issuing payment determinations, which will likely increase the backlog that already numbers 100,000+ cases.

Two additional lawsuits filed by the Texas Medical Association, one challenging the methodology used to calculate the QPA and another challenging a recent increase in IDR-related fees, are still pending in the same court. AHIP filed an amicus brief in support of the federal government's effort to defend the Final Rule.

The Coalition Against Surprise Medical Billing (CASMB) issued a new statement in response to the decision:

"We are disappointed in the ruling in the Texas Medical Association case following their continued efforts to disrupt the patient protections and increase costs. The latest TMA decision hurts patients by making health care more expensive and benefits private-equity and out-of-network providers, whose 16 court challenges demonstrate they care more about protecting their own profits."

CASMB will continue to encourage the Administration to protect patients from surprise medical bills, just as Congress intended when they passed the *No Surprises Act*. The full CASMB statement can be read here.

HHS Announces Funding to Address Disparities in Cancer Care

The Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced it would provide $11 million in funding to 22 HRSA-funded health centers in an effort to improve access to life-saving cancer screenings and early detection services for underserved communities.

Why it matters: The funding announcement coincides with the one-year anniversary of the White House's Cancer Moonshot Initiative, which seeks "to reduce the death rate from cancer by at least 50 percent over the next 25 years, and improve the experience of people and families living with and surviving cancer." The HRSA funding is a part of a series of new actions that the White House announced to build on the work of the Moonshot Initiative.

In 2022, HRSA also announced $5 million in funding for the Accelerating Cancer Screening Program, which focuses on leveraging outreach specialists and patient navigators to conduct patient outreach in underserved communities.

Click here to read more about the HRSA funding and read more from AHIP on why cancer drugs are so expensive.

CDC Adds COVID-19 Vaccines to Official Immunization Schedule

The Centers for Disease Control and Prevention (CDC) added the COVID-19 primary vaccine series and boosters to its routine immunization schedules recommended for children, adolescents, and adults. The 2- or 3-dose primary series and booster COVID-19 vaccine is recommended for children starting at 6 months and any age after for adolescents and adults.

State Issues

New York

Legislative

Committees Considering Health Care Bills

Several bills of interest are under consideration by various Assembly and Senate committees this week.

- **Ambulance direct reimbursement (S. 1466)** — Requires health plans to directly reimburse ambulance service providers regardless of whether they are in-network or out-of-network providers.

- **Provider termination process (S. 3282/ A.1777)** — Creates a new process for the termination of a contract between physician providers and health plans, which could unilaterally extend the contract.

- **Medicaid carve out (S. 2867)** — Permanently carves out individuals served by the nursing home transition diversion (NHTD) and traumatic brain injury (TBI) waivers from the Medicaid managed care program.

Regulatory

State to Submit Essential Plan Expansion Waiver Request to CMS

The New York State of Health and Department of Health last week announced their intention to submit a proposal to the Centers for Medicare & Medicaid Services for expansion of the Essential Plan. The long awaited 1332 waiver application reflects provisions in the FY23 budget to expand eligibility for the EP from 200% to 250% of the federal poverty level. The posting of the document triggers the required 30-day public comment period, which runs until March 11, 2023. The full public notice for the 1332 waiver application is available for review here and a draft of the application and actuarial analysis is available here. The State will host two virtual public hearings — February 22 and 23 — during which members of the public may provide verbal comments.

State Issues

West Virginia

Legislative

Senate Committee Advances Dental Medical Loss Ratio Legislation

The 2023 West Virginia Legislature has now officially passed the half-way point in its 60-day Regular Session and the level of activity around the State Capitol increased significantly last week and will only intensify further as important procedural deadlines approach for the final introduction of bills and to pass bills from their house of origin.

- On Wednesday, February 8, the Senate Health Committee advanced Senate Bill 290 (Takubo, R-Kanawha). Senate Bill 290 was rewritten this past week to require small group and individual dental plans to have a 70% medical loss ratio and for large group plans to have a 75% loss ratio. Senate Bill 290 now awaits full consideration from the Senate.

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/.**