Highmark's Weekly Capitol Hill Report

Issues for the week ending November 19, 2021

Federal Issues

Legislative

House Narrowly Passes Build Back Better Act

In a 220-213 vote, the U.S. House on Friday narrowly passed the budget reconciliation legislation carrying key components of President Biden's Build Back Better agenda. The move follows the release of cost estimates from the Congressional Budget Office (CBO) that several moderate Democrats insisted on seeing before voting. The $1.7 trillion package now moves to the Senate for consideration, where it will likely be amended.

As previously reported, key health care components of the House-passed legislation include:

- Hearing coverage as a benefit to original Medicare starting in 2023;
- Redesign of Medicare Part D, including a $2000 out-of-pocket cap;
- Allowing Medicare to negotiate the prices of certain prescription drugs;
- Full repeal of the Trump administration's rebate rule;
- Expanding home and community-based care services;
- Extending the Affordable Care Act (ACA) enhanced premium tax credits through 2025;

In this Issue:

- Expanding the ACA premium tax credits to below 100 percent of the federal poverty level to cover those in the “Medicaid gap” in non-expansion states through 2025;
- Provide mothers with postpartum Medicaid coverage for one year after they give birth.

CBO Analysis: According to the CBO, the health coverage provisions would decrease the number of uninsured by about 3.4 million on average through 2025. This includes an increase of 4.9 million people with non-group coverage, 100,000 more people with Medicaid and 1.6 million fewer people with employer-sponsored coverage. The enhanced ACA tax credits are estimated to cost $74 billion, and the cost of closing the Medicaid coverage gap is estimated at $57 billion. The drug pricing provisions collectively are estimated to save about $304 billion (which includes estimated savings of $75.8 billion for drug price negotiations, $83.6 billion for inflation rebates in Medicare Part B and Part D, $142.6 billion for rebate rule repeal, and $1.6 billion for Part D redesign).

What’s next: Senate Democrats are expected to move to quickly take up the package after the Thanksgiving holiday — with a goal of enactment by year’s end. The bill faces changes to ensure the votes of all 50 Senate Democrats and to satisfy the Senate Parliamentarian, who will order the removal of items that do not have a budgetary effect. With government funding scheduled to end Dec. 3, lawmakers will also likely pass a short-term continuing resolution to fund the government into next year and also suspend the debt-ceiling temporarily.

Federal Issues

Regulatory

Interim Final Rule on Health Care and Rx Reporting Released

The Department of Health and Human Services (HHS), together with the Department of Labor (DOL) and the Department of the Treasury, as well as the Office of Personnel Management (OPM), released an interim final rule with request for comments (IFC), entitled “Prescription Drug and Health Care Spending.” This IFC is required under Section 204 of the No Surprises Act and implements new requirements for health plans and health insurance issuers in the group and individual markets and FEHB carriers to submit to the Departments certain information about prescription drug and health care spending. More information is available in the CMS fact sheet and the Federal Register announcement.

Why this matters: Starting in late 2022, health plans are required to submit certain data to the Departments and provide updates annually thereafter. Reported information includes:

- Enrollment and premium information, including average monthly premiums paid by employees versus employers;

- Total health care spending, broken down by type of cost (hospital care; primary care; specialty care; prescription drugs; and other medical costs, including wellness services), including prescription drug spending by enrollees versus employers and issuers;
- The 50 most frequently dispensed brand prescription drugs;
- The 50 costliest prescription drugs by total annual spending;
- The 50 prescription drugs with the greatest increase in plan or coverage expenditures from the previous year;
- Prescription drug rebates, fees, and other remuneration paid by drug manufacturers to the plan or issuer in each therapeutic class of drugs, as well as for each of the 25 drugs that yielded the highest amount of rebates; and
- The impact of prescription drug rebates, fees, and other remuneration on premiums and out-of-pocket costs.

Plans and issuers are to begin submitting the required information to the Departments by December 27, 2021. Going forward this information will be required by June 1 of each year thereafter. The Departments have announced that they will exercise discretion to provide temporary deferral of enforcement regarding this year's December and the June 1, 2022 deadlines. Comments for this rule are due by January 22, 2022.

CMS Delays Best Price Provisions and Reporting for the Medicaid Drug Rebate Program

On November 17, the Centers for Medicare and Medicaid Services (CMS) announced a final rule that delays the effective date of the best price provisions related to Value-Based Purchasing arrangements and the reporting of multiple best prices to CMS for purposes of the Medicaid Drug Rebate (MDR) program until July 1, 2022, instead of January 1, 2022. The final rule also delays the effective date of inclusion of the five U.S. territories for purposes of participation in the MDR until January 1, 2023.

More information is available in the Federal Register here.

COVID-19 Updates

- The Department of Health and Human Services (HHS) withdrew a policy established during the previous administration that limited the Food and Drug Administration's (FDA) ability to require premarket reviews of laboratory developed tests for COVID-19. The policy, first announced on August 19, 2020, affected oversight of tests created and used within a single laboratory.
    - The FDA also updated its policies regarding COVID-19 tests currently being offered prior to or without authorization, as well as policies regarding the types of tests on which the FDA intends to focus its review. Moving forward, the agency "generally expects" new COVID-19 tests entering the market will obtain an emergency use or traditional marketing authorization.
    - For further details, please see the HHS press release and FDA press release.
- Pfizer is formally petitioning the Food and Drug Administration (FDA) for emergency use authorization (EUA) of its antiviral Covid-19 pill, two weeks after reporting trial results showing the treatment cuts the risk of hospitalization and death from the disease by 89%. The Phase II/III trials

focused on high-risk, infected adults who were treated with the drug or a placebo within three days of the onset of symptoms.

- The FDA is also considering an EUA application from Merck for an antiviral drug, Molnupiravir, creating the prospect of two at-home coronavirus treatments being available. FDA's independent advisers will meet on Nov. 30 to consider Merck's application.

- Moderna announced that the company has filed for Emergency Use Authorization of its COVID-19 booster shot for all adults 18 and older with the FDA. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) announced today that it would meet on Friday to discuss booster shot availability for all adults.

- The Occupational Safety and Health Administration (OSHA) announced it is suspended the enforcement of the COVID-19 vaccine mandate for large employers. A federal appeals court upheld a stay. OSHA said in a statement published on its website it is suspending activities related to the mandate due to the pending litigation.

State Issues

Pennsylvania

Legislative

House of Representatives Swears in New Member

On Wednesday, November 17, the House of Representatives swore in Thom Welby (D-Lackawanna). Representative Welby fills the seat previously held by Senator Marty Flynn (D-Lackawanna) who vacated the seat after winning a special election for State Senate in May 2021.

After Wednesday's swearing-in ceremony, the Republicans still lead the Democrats by 113-89.

Industry Trends

Policy / Market Trends

New ICER Report Identifies 2020 Drug Price Hikes Not Supported by Clinical Evidence

The Institute for Clinical and Economic Review (ICER) released a new report identifying the top drugs with price increases in 2020 and noting seven of the 10 lacked adequate new evidence to demonstrate a substantial clinical benefit justifying their price hikes. According to the report, the price increases on the seven treatments cost the U.S. health system an additional $1.67 billion with approximately $1.4 billion being attributed to a single drug alone—Humira.

The Campaign for Sustainable Rx Pricing (CSRxP) continues to post "Earnings Watch" articles on their website highlighting the hugely profitable price hikes major brand name drugmakers engage in each

quarter. Last week, CSRxP posted a new "Earnings Watch" article showcasing how brand name drugmaker AstraZeneca engaged in price-hikes and other tactics to undermine competition during the pandemic, and topping Wall Street expectations for Q3.

Please click here to view the ICER 2021 Unsupported Price Increase report.

More Than 100,000 Americans Died of Drug Overdoses in One Year

Data released on Wednesday, November 17, showed 100,000 lives were lost to the overdose epidemic from April 2020 to April 2021, a 28.5% jump from the previous 12 months, according to data from the U.S. Centers for Disease Control and Prevention. The U.S. states with the biggest percentage spike in overdose deaths were Vermont at 70%, followed by West Virginia (62.2%) and Kentucky (54.5%). California, the most populous state, saw its overdoses climb nearly 47.8%. Experts believe the top drivers are the growing prevalence of deadly fentanyl in the illicit drug supply and the COVID-19 pandemic, which left many drug users socially isolated and unable to receive treatment or other support. Drug overdoses now surpass deaths from car crashes, guns and even flu and pneumonia. The total is close to that for diabetes, the nation's No. 7 cause of death.

Eighth Circuit Decision Involving North Dakota PBM Law

The U.S. Court of Appeals for the Eighth Circuit issued a decision in PCMA v. Wehbi (formerly PCMA v. Wilke), a case involving ERISA and Medicare statute preemption challenges to a North Dakota law regulating certain pharmacy benefit manager (PBM) activities. It is the first significant appellate court case to consider ERISA preemption since last year's Supreme Court decision in Rutledge v. PCMA in the context of ERISA preemption. However, unlike in Rutledge, the case also examines the additional question of the scope of Part D preemption under the Medicare statute. In May 2021, AHIP filed an amicus brief supporting PCMA's effort to have the law struck down under both statutes' preemption provisions. Amicus briefs supporting North Dakota's defense of its law were filed by various pharmacy and pharmacist groups as well a brief filed by 33 states and the District of Columbia.

Why this matters: In last week's decision, the Eighth Circuit found that the state law was not preempted by ERISA but issued a mixed decision on Part D preemption. There, the court parsed each provision of the state's law and found that some provisions of the North Dakota law were preempted by the Medicare statute, including, for example, a requirement that PBMs with certain pharmacy ownership interests disclose the difference paid to a pharmacy and the amount charged to a plan; a provision prohibiting PBMs from charging pharmacies certain fees; and PBMs utilizing certain types of pharmacy performance measures and quality assurance standards. However, the court also found that other provisions were not preempted by the Medicare statute and could remain in place, including, for example, provisions related to the availability of and fees on pharmacy mail order services; prohibiting PBMs from requiring pharmacies meet certain accreditation or recertification requirements; and various PBM reporting requirements.

New 2022 Open Enrollment Period Report Shows Strong Enrollment Numbers

The Centers for Medicare & Medicaid Services (CMS) announced approximately 851,000 people selected individual market plans during the second week of the 2022 Open Enrollment Period. To date, more than 1,624,000 people have selected individual market plans in the 33 states that utilize the HealthCare.gov platform. Importantly, these numbers are on par with last year's 2021 Open Enrollment Period.

On a per-day basis, 2022 Open Enrollment selection has increased by 7.8% from last year. Moreover, when correcting for the three states that transitioned to state-based marketplaces this year, including Kentucky, Maine, and New Mexico, the per-day enrollment has actually increased by 10% from last year.

This year, the American Rescue Plan provides enhanced financial assistance, which can significantly reduce premiums for new and returning customers. Consumers generally need to choose a plan by December 15 for their coverage to start January 1.

To view this week's report, please click here.

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/.**