Highmark's Weekly Capitol Hill Report

Issues for the week ending Sept. 17, 2021

Federal Issues

Legislative

Budget Reconciliation Process Continues in U.S. House

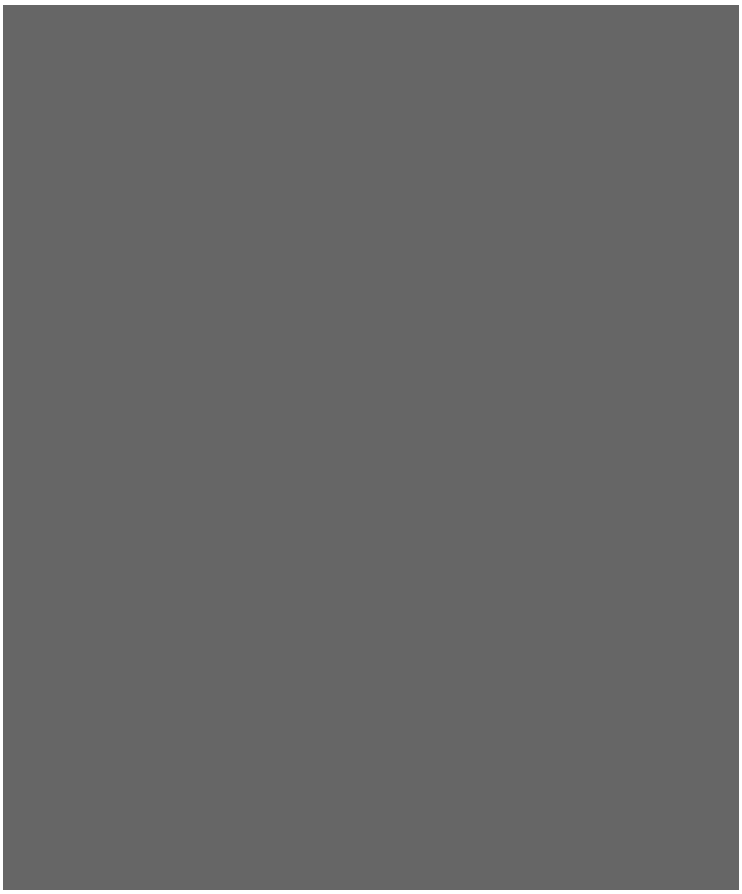
Over the last week, key U.S. House committees of jurisdiction finalized and approved their respective provisions of the "Build Back Better" budget reconciliation package. The health care components of the package moved largely through the Energy and Commerce (E&C) and Ways and Means (W&M) committees.

Key health components advanced by the committees include:

- A permanent extension of enhanced ACA subsidies
- Establishment of a new $10 billion per year federal health insurance affordability fund beginning for plan year 2023 to allow states to establish a reinsurance program or lower cost-sharing.
- The addition of dental, vision, and hearing benefits to Medicare Part B
- Medicare Part D restructuring, including a $2,000 maximum out-of-pocket cap
- Repeal of the Part D rebate rule

In this Issue:

- Government price negotiation of up to 250 drugs based on an international price index and mandatory rebates on the price of Medicare drugs that increase above inflation, available to Medicare and commercial markets
- A 7% FMAP increase for states that implement a home-and-community-based improvement program to strengthen and expand HCBS.
- Establishment of a federal Medicaid program for individuals who reside in states that have not expanded Medicaid. The benefits would come via expanded ACA subsidies from 2022-2024, followed by a new federal Medicaid program in 2025. A maintenance of effort requirement is included to prevent disruption in states that have already expanded their Medicaid programs.
- Permanent extension of the Children's Health Insurance Program (CHIP)
- Significant new investments in maternal health



Drug difficulties: While the committees were largely able to pass their components of the package on party-line votes, the E&C Committee failed to advance its drug pricing provisions due to objections several Democratic members raised over a provision allowing the federal government to negotiate the prices of certain drugs. As a result, that title was approved by the W&M committee, which shares jurisdiction. The move suggests Democrats may need to modify the drug pricing proposals to ensure passage by the full House. Any reduction in savings generated by the drug pricing provisions would result in a further search for offsets from either additional revenue increases or cuts to programmatic spending.

Next steps:

- With committee markups completed, the House Budget Committee will work to consolidate the language into a single legislative package.
- The package will then move to the House Rules Committee, which will enact further changes to the proposals via a manager's amendment that reflects ongoing, behind-the-scenes "pre-conference" discussions between the White House and House and Senate leadership.
- The goal is to bring the package to a vote on the House floor the week of Sept. 27, although this timing could easily slip given the need to pass a continuing resolution to avoid a government shutdown on Oct. 1 as well as a promised vote on the Senate-passed infrastructure bill.

In the Senate, there are no plans for committee markups. The Senate will call up the House-passed bill and initiate its own reconciliation process via a substitute or manager's amendment. While the timing is unclear, Majority Leader Chuck Schumer (D-NY) is holding floor time for early October to begin Senate

consideration. This timing could easily slip depending on how quickly the House moves, as well as progress during ongoing pre-conference conversations to find a compromise that balances the wishes of progressives for a $3.5 trillion package with ongoing demands from moderates to significantly scale back the overall package.

Federal Issues

Regulatory

New No Surprises Act Rule Focuses on Air Ambulances, Enforcement, and Broker Compensation

The Biden Administration released a proposed rule, the second in what is expected to be a three-rule installment of rules to implement the core provisions of the No Surprises Act, passed last year as part of the Consolidated Appropriations Act of 2021. **The proposed rule addresses three separate policies:**

- Requires group health plans and health insurance issuers in the group and individual markets, and health insurers contracting with the Federal Employee Health Benefits program, to report certain information about air ambulance services to the Departments. Air ambulance companies would also report information to the Departments of HHS and Transportation or risk civil monetary penalties for failure to report.

- Provides the initial framework and process by which HHS would investigate complaints and potential violations of the No Surprises Act provisions and, if warranted, take enforcement action, including the imposition of civil money penalties, against providers (including air ambulances) and facilities, including providers of air ambulance services. HHS is currently assessing the authority of states to enforce the No Surprises Act on providers and facilities; a federal fallback process will be established if states lack the authority to enforce or a hybrid federal-state collaborative agreement will be in place if a state is unable to achieve voluntary compliance.

- Requires health insurance issuers offering individual health insurance coverage or short-term limited duration insurance to disclose direct and indirect compensation information (e.g., commission schedules and bonus structures) to all potential or new policyholders as well as upon renewal of a policy. Disclosures would be required before a consumer finalizes their plan selection and on a document that confirms initial enrollment in coverage, such as an enrollment packet or alongside a summary of benefits and coverage document. Insurers would also need to report compensation information to HHS annually on a retrospective basis.

Comments to the proposed rule are due by October 18, 2021.

Note: This is not the second Interim Final Rule on requirements related to surprise billing, which is expected imminently.

You can read more about the rule in the HHS fact sheet and press release. Concurrently, HHS also released a new report on air ambulance surprise billing.

CMS Finalizes Payment Parameters for 2022 and Beyond Rule

The Centers for Medicare and Medicaid Services (CMS) issued a pre-publication version of the "Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond" final rule that applies to the individual health insurance market.

Why this matters: In the final rule, CMS adopts an extended open enrollment period and special enrollment period (SEP) for low-income individuals beginning plan year 2022 which will run from November 1 through January 15 (extended from December 15) in states using Healthcare.gov. State-based Marketplaces will retain flexibility to set their own enrollment deadlines.

Also beginning in 2022, CMS finalized a new monthly SEP for individuals eligible for advance payments of premium tax credit (APTC) with a projected household income of less than 150 percent of the federal poverty level (FPL) as proposed. The SEP will be available while enhanced APTC benefits—as under the American Rescue Plan Act or subsequent statute or rule—are available.

CMS also made available a press release and fact sheet.

CMS Proposes Repeal of Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (R&N) Final Rule

In January 2021, CMS finalized a rule that established a new Medicare coverage pathway for FDA-approved breakthrough devices under which national Medicare coverage (both traditional fee-for-service Medicare and Medicare Advantage) would begin on the same day a breakthrough device receives FDA approval and last up to four years. The rule also codified regulatory standards Medicare uses to make "reasonable and necessary" determinations for items and services furnished under Parts A and B.

Why this matters: After multiple effective date delays, CMS has issued a notice of proposed rulemaking (NPRM) to fully repeal the rule, which would otherwise go into effect on December 15, 2021. CMS also intends to pursue future rulemaking on an expedited coverage pathway for innovative technologies and a regulatory definition of the "reasonable and necessary" standard for Medicare coverage. In the NPRM, CMS states the agency believes the finalized MCIT/R&N rule "is not in the best interest of Medicare beneficiaries because the rule may provide coverage without adequate evidence that the Breakthrough Device would be reasonable and necessary treatment for the Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose."

The NPRM includes a public comment period with comments due on October 15th.

CMS Will Not Enforce Payer to Payer Data Exchange Requirements Until Future Rulemaking

The Centers for Medicare & Medicaid Services (CMS) updated its Frequently Asked Questions (FAQs) on the May 2020 Interoperability and Patient Access final rule. The agency will be exercising its enforcement discretion for the payer-to-payer data exchange provision. It will not take action to enforce compliance with these specific provisions until future rulemaking is finalized. This provision was set to take effect January 1, 2022.

Why this matters: The decision comes in response to advocacy regarding implementation of the payer-to-payer data exchange requirement. Ultimately, CMS recognized that the lack of technical specifications for

the payer-to-payer data exchange requirement may lead to differences in implementation across the industry, poor data quality, operational challenges, and increased administrative burden.

For more information on this decision, please click here.

CMS Report Shows 2.8 Million Americans Gain Health Coverage During Special Enrollment Period

The Centers for Medicare and Medicaid Services (CMS) announced 2.8 million people newly signed up for coverage through Healthcare.gov and state-based marketplaces (SBMs) during the 2021 Marketplace special enrollment period (SEP), which ran from February 15 to August 15. In the final detailed SEP report, CMS reported 2.1 million Americans newly signed up for coverage through Healthcare.gov and 738,000 Americans signed up for coverage in the 15 SBMs as of their most recent reporting periods. This brings total Marketplace effectuated enrollment to 12.2 million as of August 2021.

CMS also released a related infographic alongside the final report, which details demographic and geographic trends in SEP enrollments and savings consumers realized as a result of the American Rescue Plan Act (ARPA) enhanced subsidies. According to CMS, over 90 percent of SEP enrollees received reduced premiums as a result of the ARPA tax credits and existing enrollees who updated or changed plans during the SEP saw a premium savings of, on average, $67 (or 50 percent) per month.

HHS Releases $25.5 Billion in COVID-19 Provider Funding

The Health Resources and Services Administration (HRSA) is making $25.5 billion in new funding available for health care providers affected by the COVID-19 pandemic. This funding includes $8.5 billion in American Rescue Plan (ARP) resources for providers who serve rural Medicaid, Children's Health Insurance Program (CHIP), or Medicare patients, and an additional $17 billion for Provider Relief Fund (PRF) Phase 4 for a broad range of providers who can document revenue loss and expenses associated with the pandemic.

Key highlights from the announcement include:

- PRF Phase 4 payments will be based on lost revenues and expenditures between July 1, 2020, and March 31, 2021.
    - PRF Phase 4 will also include bonus payments for providers who serve Medicaid, CHIP, and/or Medicare patients, who tend to be lower income and have greater and more complex medical needs.
- The application process will allow for providers to apply for both programs in a single application. The application portal will open on September 29, 2021.
- Phase 3 payment calculation methodology was released. This will allow providers who believe their Phase 3 payment was incorrect to request a reconsideration. Details on the reconsideration process are forthcoming.
- A final 60-day grace period to come into compliance with the PRF reporting requirements that are due September 30 for the first reporting time period. Enforcement actions for noncompliance will be on hold during this grace period.

COVID-19 Updates

- The Department of Labor's Occupational Safety and Health Administration (OSHA) has indicated it will release the Emergency Temporary Standard (ETS) requiring all businesses over 100 people to have a vaccination requirement or weekly testing of their employees in the coming weeks. It will be effective upon release but will undergo a public comment period. A separate Executive Order provides more details around the vaccination requirements for Federal Contractors.

- The Centers for Disease Control and Prevention (CDC) released findings from a study that showed full vaccination reduced the risk of COVID-19 infection by five times, reduced risk of hospitalization by over ten times, and reduced risk of death by over ten times, when compared to unvaccinated individuals.

- The Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee voted 16-2 against approval for a booster dose of Pfizer-BioNTech's COVID-19 vaccine in individuals 16 years of age and older. The panel, which was charged with reviewing the company's supplemental Biologics License Application (BLA) for the 3rd dose or booster reviewed presentations from Pfizer on the results of their post-hoc clinical trials and from representatives from the Israeli Ministry of Health and Weizmann Institute on Israel's experiences with waning vaccine effectiveness and booster doses. The panel's vote reflected concerns about the amount and quality of data available to weigh the booster's long-term effectiveness and its safety, especially in young people.
    - The panel, however, voted unanimously to approve an Emergency Use Authorization (EUA) for a Pfizer-BioNTech COVID-19 vaccine booster dose administered at least 6 months after completion of the primary series for individuals aged 65 years of age and older, individuals for whom the vaccine is authorized who are at high risk of severe COVID-19, and health care workers or others at high risk.
    - The recommendations will go to the FDA for approval. It is important to note that the FDA is not bound to the recommendations from the Advisory Committee.

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/.**