Highmark's Weekly Capitol Hill Report

Issues for the week ending October 8, 2021

Federal Issues

Legislative

Congress Reaches Deal to Temporarily Lift Debt Ceiling

Senate Majority Leader Chuck Schumer (D-NY) and Minority Leader Mitch McConnell (R-KY) reached a deal last week to raise the debt ceiling by $480 billion as a temporary solution to the ongoing impasse. While there is no specific date attached to the increase, the agreement is expected to provide debt ceiling relief through at least Dec. 3, when the current continuing resolution expires – setting up another fiscal cliff battle before the end of the year.

Why it matters: The deal temporarily takes the issue off the table and buys time for Democrats to come to agreement on the Build Back Better reconciliation package. Discussions continue regarding a topline spending number for the package, which likely shrink substantially from the $3.5 trillion passed by House committees.

This means intensifying debates around which provisions to include, which to scale back or limit and which to cut outright. Major health care topics in the mix include the scope of expanding Medicare dental, vision and hearing benefits, policies to enable expansion of Medicaid in states that have not

In this Issue:

expanded the program, drug pricing reforms, expansion of home and community-based (HCBS) services and increases to ACA market subsidies.

Lawmakers Continue to Haggle Over Surprise Billing

Last week, House Ways and Means Chair Richard Neal (D-MA) and Ranking Member Kevin Brady (R-TX) sent a joint letter to Secretaries Becerra, Yellen, and Walsh stating the Administration strayed from Congressional intent in developing the process for resolving payment disputes between providers and insurers. The letter complains about the median contracted rate being considered the default in the independent dispute resolution process and requests a detailed follow-up "explaining how the regulation issued… comports with the law Congress enacted." The letter also expresses concern about the delay in implementation of the Advance Explanation of Benefits.

The move comes after House Energy and Commerce Committee Chair Frank Pallone (D-NJ) and Senate Health, Education, Labor, and Pensions Committee Chair Patty Murray (D-WA) released a joint statement on September 30th applauding the Administration's rule, stating the rule "implements the No Surprises Act just as we intended and is a significant new protection for families across the country that will save countless patients from being forced to foot the bill for care they thought was covered by their insurance. It establishes a fair payment resolution process between providers and insurers while finally taking patients out of the middle."

The opposing comments highlight the ongoing differences of opinion between committees of jurisdiction over the best way to resolve payment disputes between payers and providers in surprise billing scenarios.

Federal Issues

Regulatory

New Agency Guidance Clarifies Vaccine Coverage and Permits Health Plan Vaccine Incentives

The Departments of Labor, Health and Human Services (HHS), and the Treasury issued joint Frequently Asked Questions (FAQs) guidance to address insurance coverage regarding the COVID-19 vaccine

Why this matters:

- The FAQ first confirms health plans must cover COVID-19 vaccines and their administration without cost sharing once the vaccine is authorized or approved.

  Coverage must be provided consistent with the scope of the EUA or BLA for the vaccine, including any EUA or BLA amendment, such as to allow for the administration of an additional dose to certain

individuals, administration of booster doses, or the expansion of the age demographic for whom the vaccine is authorized or approved.

- Second, the guidance confirms that employer-sponsored coverage, specifically a group health plan (or health insurance issuer offering coverage in connection with a group health plan), may offer participants a premium discount for receiving a COVID-19 vaccination. Under existing law, the discount must not exceed 30 percent of the total cost of employee-only coverage, and there must be an opportunity for individuals to qualify for a reward under the program at least once per year.

- Further, consistent with existing law, individuals must be offered a reasonable alternative standard (e.g., masking) to qualify for the discount to accommodate those with medical conditions for which obtaining the vaccine is not advisable. Please see the FAQs at this link for further details.

The guidance comes as employers await forthcoming emergency regulations from the Department of Labor that are expected to require certain larger employers to mandate vaccines (or testing).

CMS announced Medicare Advantage Plans Must Pay for Vaccines (Including Boosters) Starting Jan. 1, 2022

During a CMS and CDC Town Hall event, CMS announced Medicare Fee-for-Service (FFS) will no longer pay for the vaccine product and administration fee. Starting on Jan. 1, 2022, MA plans will be responsible for paying for the vaccine product and administration fee for all COVID-19 vaccine shots (initial series or booster) for their members.

As a reminder, CMS previously released an HPMS memo stating COVID-19 vaccines met the significant cost threshold for 2020 and 2021 and FFS would pay for the vaccine product and administration in those years. CMS has also been prepping MA plans to consider the costs for future payment. CMS included in the 2022 MA/Part D Rate Announcement that plans should incorporate costs for the vaccine product and administration for 2022. The announcement that MA plans will be responsible for both the vaccine product and administration and previous application of the significant cost threshold suggests CMS has likely considered the additional costs of boosters and is unlikely to trigger the significant cost threshold again. Further guidance is expected, but no specific timeframe was provided. Medicare FFS will continue to be liable for vaccine product and administration for MA beneficiaries who receive their first dose in 2021.

CMS Releases 2022 Medicare Advantage and Part D Star Ratings, With Improved Measures for Plans from 2021

The Centers for Medicare & Medicaid Services (CMS) issued a press release and fact sheet providing information about Medicare Advantage (MA) and Medicare Prescription Drug plan (Part D) Calendar Year (CY) 2022 Star Ratings.

CMS estimates that approximately 90 percent of MA enrollees with drug coverage will be in plans with four or more stars in 2022, up from 77 percent in 2021. For stand-alone drug plans, CMS reports that approximately 68 percent of MA plans that offer prescription drug coverage will have an overall rating of four stars or higher in 2022, up from 49 percent in 2021.

In addition, the average Star Rating for MA plans that include prescription drug coverage is now 4.37, an improvement from the 4.06 average last year. CMS indicates that "while adjustments were made for the 2022 Star Ratings due to the possible impact of the COVID-19 pandemic," the increase to the average Star Ratings also "reflects improvements in sponsors' scores on several measures."

More detailed information is displayed in Star Ratings tables and related technical notes available on the CMS website.

COVID-19 Updates

- Pfizer and BioNTech announced that they had submitted a request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of their COVID-19 vaccine in children ages 5 to 11. The FDA has tentatively scheduled a meeting on October 26 to consider the EUA request.

- The Biden Administration announced this week that they would purchase $1 billion worth of rapid at-home COVID-19 tests. The announcement came from White House COVID-19 coordinator Jeffrey Zients. Zients did not mention at the briefing any details about testing costs, but he did state that free testing options still exist because health insurance providers cover testing without cost-sharing for patients.

- Johnson & Johnson requested Food and Drug Administration (FDA) emergency use authorization of its COVID-19 vaccine booster for people 18 and older. The submission includes recent results from a Phase 3 study that found a second dose two months after the first increased protection against symptomatic moderate to severe COVID-19 to 94%, with 100% protection against severe illness. The company did not specify how long after initial vaccination the second, booster dose should be given.

- AstraZeneca requested FDA emergency use authorization for its long-acting antibody combination to prevent symptomatic COVID-19. Phase 3 data demonstrated a statistically significant reduction in the risk of developing symptomatic COVID-19. The treatment could provide an additional tool to protect vulnerable groups such as the immunocompromised, who may not mount a sufficient immune response to the virus after vaccination, as well as people with underlying conditions that put them at greater risk for severe disease.

- FDA issued an emergency use authorization (EUA) for the ACON Laboratories Flowflex COVID-19 Home Test, an over-the-counter COVID-19 antigen test, which adds to the growing list of tests that can be used at home without a prescription. The company plans to scale manufacturing of the home test — which can be used by individuals who have no symptoms without repeat testing — to 100 million units a month by the end of the year, according to FDA.

- Drugmaker Merck released preliminary findings on an experimental antiviral pill that appears to cut the risk of hospitalization or death from COVID-19 by half. The drug, molnupiravir, performed well enough in a late-stage clinical trial of adults at high risk of severe COVID-19 that Merck will seek FDA authorization "as soon as possible." The U.S. government agreed earlier this year to purchase 1.7 million treatment courses of the drug pending FDA authorization.

State Issues

New York

Regulatory

Administrative Simplification Report Issued

The Department of Financial Services, in conjunction with the Department of Health, last week delivered the report of the Administrative Simplification Workgroup to the New York State Legislature. The report included numerous recommendations to reduce health care costs and complexities for the benefit of consumers, providers, and health insurers, including credentialing, preauthorization processes and insurance eligibility verification. In addition to the recommendations, the report noted areas where consensus could not be reached. The report is the culmination of 10 months of discussion by the Administrative Simplification Workgroup, comprised of stakeholders from the hospital industry, health plans and consumer groups.

Marketplace Enrollment Hits 6.3 Million

As the state prepares for the start of the 2022 open enrollment period, the NY State of Health last week reported that more than 6.3 million New Yorkers are now enrolled through the state marketplace (Medicaid 4.7 million; Essential Plan 914,000; QHPs 230,000). Data on the impact of federal and state health policy changes on individuals across the New York state is provided in the NYSOH's "Health Insurance Coverage Update." Open enrollment for coverage in a 2022 Qualified Health Plan for new and returning consumers starts November 16, 2021 and ends on January 31, 2022.

On a related note, the NYSOH last week announced that Danielle Holahan has been named Executive Director. Danielle had been serving as Acting Director since the retirement earlier this year of Donna Frescatore who was NYSOH Executive Director and NYS Medicaid Director.

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/.**