Highmark's Weekly Capitol Hill Report

Issues for the week ending June 2, 2023

Federal Issues

Legislative

President Biden Signs Debt Ceiling Deal

On Saturday, President Biden signed into law the agreement he negotiated with House Speaker Kevin McCarthy (R-CA) to lift the debt ceiling, just ahead of the Treasury Department's projected default date.

On Friday, the Senate voted 63-36 to approve the deal, which suspends the debt ceiling until 2025. Forty-six Senate Democrats and 17 Senate Republicans supported the bill's final passage, a day after the bill passed the House by a vote of 314-117 with 149 Republicans joining 165 Democrats in advancing the agreement.

Why this matters: Beyond avoiding catastrophic default, the agreement takes the issue off the table until after the November 2024 elections.

In addition to suspending the debt ceiling, the bill will apply new caps on federal spending, among other provisions. It will also establish new work requirements for some categories of adults without dependents receiving assistance through the Supplemental Nutrition Assistance Program (SNAP) and Temporary Assistance for Needy Families (TANF)--but not to Medicaid enrollees.

In this Issue:

Key provisions of the legislation include:

- Suspending the debt ceiling until 2025
- Funding non-defense discretionary spending at FY22 levels and limiting topline federal spending to 1% annual growth for the next 6 years
- New work requirements for some adult recipients of Supplemental Nutrition Assistance Program (SNAP) and Temporary Assistance for Needy Families (TANF) benefits but new exemptions to work requirements for veterans, people experiencing homelessness, and people ages 18 to 24 who were in foster care when they turned 18
- A modest increase in defense spending, and clawbacks of unspent COVID aid and IRS funding
- **No cuts to mandatory health care programs, tax increases and other revenue-raisers**

Medicaid work requirements that had been passed by the House were not included in the final package.

- **DFS Posts 2024 Proposed Rate Increases**

Federal Issues

Regulatory

CMS Announces Plan to Expand Availability of New Alzheimer's Drugs Granted Full FDA Approval

The Centers for Medicare & Medicaid Services (CMS) issued additional information on Medicare coverage of costly drugs that may slow the progression of Alzheimer's disease. According to CMS, "if the Food and Drug Administration (FDA) grants traditional approval, then Medicare will cover it in appropriate settings that also support the collection of real-world information to study the usefulness of these drugs for people with Medicare."

The FDA has granted accelerated approval for 2 drugs that slow the progression of Alzheimer's: Biogen's Aduhelm and Eisai's Leqembi. CMS indicated possible traditional approval for Leqembi could come "within weeks."

Why this matters: If Leqembi or future treatments receive traditional approval, Medicare will provide coverage only if the prescribing physician and clinical care team participate in a registry that collects evidence on treatment efficacy for ongoing coverage evaluations and prospective research.

CMS Issues Final Rule Lifting COVID-19 Vaccine Mandate

On Wednesday, the Centers for Medicare & Medicaid Services (CMS) issued a final rule formally rescinding the Omnibus COVID-19 Health Care Staff Vaccination interim final rule (IFR) (originally issued in November 21). The IFR's withdrawal comes after a May 1 announcement from the White House that it would lift all remaining COVID-19 vaccine requirements.

Why this matters: It means that Medicare- and Medicaid-certified healthcare facilities will no longer be required to enforce COVID-19 vaccination among staff and contractors. CMS commented that its rescission of the IFR reflects its belief that "the risks targeted by the staff vaccination IFR have been largely addressed." However, the final rule makes permanent policies requiring long-term care providers to offer COVID-19 vaccines and related education to staff and residents.

What's next? The final rule will become affected 60 days after the date of publication in the Federal Register (expected June 5). However, CMS will exercise enforcement discretion prior to this date, and will no longer enforce the vaccine requirement during the 60 days.

CMS Announces Reorganization Related to Managed Care Delivery System

CMS announced the Center for Medicaid and Children's Health Insurance Program (CHIP) Services (CMCS) was establishing a new group called the Managed Care Group (MCG). Two existing divisions, the Division of Managed Care Policy within the Disabled and Elderly Health Programs Group and the Division of Managed Care Operations in the Medicaid and CHIP operations group will move into MCG. CMS notes these changes are intended to create an organization structure best positioned to meet the needs of the people it serves.

Supreme Court Issues Opinion in False Claims Act Case; Revives Cases Charging Safeway and SuperValu

The U.S. Supreme Court issued an opinion in a case considering the criteria surrounding a defense (the *Safeco* defense) used in certain False Claims Act (FCA) cases. The case, *United States ex rel. Schutte v. SuperValu Inc.*, was considered and decided together with *United States ex rel. Proctor v. Safeway, Inc.*. The Court's decision rejects the argued-for application of the Safeco defense to FCA cases. Instead, the decision holds that the existence of some "other, objectively reasonable interpretation" of a legal requirement does not matter if the FCA defendant "correctly understood" the relevant standard and still submitted claims that did not meet that standard.

Background: The whistleblower cases allege Safeway and SuperValu knowingly overcharged Medicare and Medicaid by $200 million for prescription drugs by overstating what "their usual and customary" prices are.

- The 7th Circuit Court of Appeals had ruled that the pharmacies didn't knowingly violate the False Claims Act, which the Supreme Court unanimously overturned.

The decision notes an FCA violation has two essential elements: (1) the falsity of a claim and (2) the defendant's knowledge of a claim's falsity. In this case, the Seventh Circuit held the defendants were entitled to summary judgment, even if they thought they were not meeting their legal requirement, because their actions were consistent with an objectively reasonable interpretation of the relevant legal requirement someone could have believed. In rejecting this decision by the Seventh's Circuit, the Court first looks at the definition of "knowingly" in the text of the FCA. Noting the FCA tracks common law fraud requirements, the Court concludes the FCA's standards for knowledge focus on what defendants knew and believed. The Court adds the focus of both the FCA's text and the common law is on what the defendant thought when submitting the claim, not "*post hoc* interpretations that might have rendered their claims accurate."

The Court next examines the specific statutory obligation in the case, which focuses on "usual and customary" amounts. It concedes the phrase is not clear on its face but notes the Seventh Circuit did not hold the defendants made an honest mistake on their interpretation of the phrase. Instead, the Court notes, the Seventh Circuit held, if others might make an honest mistake, the defendants could not have the knowledge necessary to violate the FCA. In rejecting the Seventh Circuit's holding, the Court notes it is possible to learn the correct meaning of ambiguous terms, or at least become aware of a substantial likelihood of the terms' correct meaning. It also indicates Safeco does not dictate a result here because it involved a different statute and does not set forth the objective safe harbor asserted by defendants. Finally, the Court rejects the argument that the issue in the case is a misrepresentation of law (as opposed to a misrepresentation of fact) and therefore is not actionable.

Why this matters: As a result of the Supreme Court's decision, the whistleblowers will have another chance to challenge Safeway and SuperValu. Legal experts believe the ruling could result in more false claims cases and impact companies that currently have government contracts.

AHIP and the American Hospital Association (AHA) filed a joint amicus brief in the case. In the brief, the organizations argue the federal government's "erroneous construction and expansion of the FCA threatens the legitimate business activities of every government contractor, hospital, healthcare provider, health insurance provider, and grant recipient in the nation," and would "ultimately divert resources away from the primary missions of AHA's and AHIP's members: caring for patients, reducing the cost of care, and ensuring a healthy citizenry." Unfortunately, the Court did not reach the policy issues raised, noting it did not need to address policy arguments given the presence of clear statutory text.

HHS Releases Report to Increase Language Access for Persons with Limited English Proficiency

On May 24, the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) released a report summarizing the progress the Department has made on improving the provision of meaningful access to language assistance services to persons with limited English proficiency (LEP). This includes OCR's collection and analysis of 25 HHS agency and component-level Language Access Plans,

and a review of work by the HHS Language Access Steering Committee to assess needed improvements and to share best practices.

The report discusses how work will continue in 2023 and beyond, including, for example, the creation of a new HHS Language Access Coordinator position and the setting up of a centralized language access center hub for HHS. The report was issued in response to President Biden's Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, which seeks to increase access to government services to address barriers in federal programs and services.

White House Seeks Comment on National Priorities for Artificial Intelligence

The U.S. Government and European Union leaders announced plans to draft a combined non-binding AI code of conduct in the next several weeks. The announcement follows a Request for Information issued by the White House's Office of Science and Technology Policy (OSTP) on May 23 on the Biden administration's ongoing development of a National AI Strategy. The intent of the strategy is to provide a "whole-of-society approach to AI." Input specifically requested addresses the following topics: (1) Protecting rights, safety, and national security; (2) Advancing equity and strengthening civil rights; (3) Bolstering democracy and civic participation; (4) Promoting economic growth and good jobs; and (5) Innovating in public services.

Why this matters: The RFI specifically seeks feedback on issues of interest to health care stakeholders such as the principal benefits of AI in the health domain and how AI can be harnessed "to improve consumer access to and reduce costs associated with products and services." Other areas of interest is the unique considerations for understanding the impacts of AI systems on underserved communities and particular groups, such as minors and people with disabilities and "what additional considerations or measures are needed to assure that AI mitigates algorithmic discrimination, advances equal opportunity, and promotes positive outcomes for all, especially when developed and used in specific domains (e.g., in health and human services, in hiring and employment practices, in transportation)?"

Comments to the RFI are requested by July 7, 2023.

State Issues

New York

Legislative

Priority Bills in Last Week of Session

This week is scheduled to be the last week of the 2023 Legislative Session, and lawmakers are expected to consider a blizzard of bills in the final days, including:

- **Biomarker testing coverage (S.1196/A.1673) --** requires health insurance policies and Medicaid to cover biomarker testing). Highmark medical directors have met with the sponsor to successfully narrow the scope and it is likely to pass.

- **Step therapy (A.901/S.1267)** – would severely restrict health plans' ability to require step therapy programs for prescription drugs. Highmark pharmacy staff have met with both the Assembly sponsor and Insurance Committee chair to explain the negative effects it would have on patient and employer costs.

- **Ambulance direct reimbursement (A.250/S.1466-A)** -- requires health plans to directly reimburse ambulance service providers regardless of whether they are in-network or out-of-network providers.

- **Essential Plan coverage for undocumented residents (S.2237-A (Rivera)/A.3020-A) --** directs the Commissioner of Health to amend the state's recent 1332 waiver request in order to allow undocumented New Yorkers who are currently excluded to enroll in the Essential Plan.

- **Transfer tax (S.3122/A.3885)** -- would impose a 9.63% tax on any out-of-state transfers health plans may make, including dividends, payments or loans. After claiming it was not a priority, the bill's sponsors held a press conference to push for its passage, claiming the measure is necessary to provide funding for financially distressed hospitals.

Regulatory

DFS Posts 2024 Proposed Rate Increases

The Department of Financial Services last week posted plans' premium rate applications for the 2024 plan year, with a proposed average rate increase of 20.9% for the individual market and 15.3% for small group policies. This posting started the 30-day public comment period and triggered the requirement for plans to send out notices to policy holders.

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/.**