Holland & Knight

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A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

This Week: House Passes Debt Limit Deal

Over the weekend, President Joe Biden and Speaker of the House Kevin McCarthy (R-Calif.) reached a deal to raise the debt limit for two years (until 2025) as the U.S. Department of the Treasury is projected to run out of cash reserves on June 5. The deal, titled the Fiscal Responsibility Act, includes government spending cuts; addresses the speed of permitting for energy projects; redirects $20 billion from the IRS to other agencies; makes modest reforms to the student loan program, the Temporary Assistance for Needy Families (TANF) program and the Supplemental Nutrition Assistance Program (SNAP); and rescinds $28 billion in unspent COVID-19 funding.

The deal was crafted by Office of Management and Budget (OMB) Director Shalanda Young, White House Senior Adviser Steve Ricchetti, White House Legislative Affairs Director Louisa Terrell, Rep. Garret Graves (R-La.), Rep. Patrick McHenry (R-N.C.) and the Speaker's Chief of Staff Dan Meyer. The House Committee on Rules advanced the bill on May 30, 2023, and was approved by the House on May 31, 2023. The package now goes to the Senate; the chamber could vote on the bill as early as June 3, 2023, unless members agree to advance the measure via unanimous consent.

House Committee on Energy and Commerce Advances Multiple Healthcare Bills

The full House Committee on Energy and Commerce held a markup hearing on May 24, 2023, that included six healthcare bills related to competition, transparency and access to care:

- H.R. 1418, the Animal Drug User Fee Amendments of 2023 (ADUFA), would amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to reauthorize user fee programs related to new animal drugs and generic new animal drugs.
- H.R. 2544, the Securing the U.S. Organ Procurement and Transplantation Network Act, would provide the U.S. Department of Health and Human Services (HHS) authority to expand competition for contracts related to the network's operation.
- H.R. 2666, the Medicaid VBPs for Patients (MVP) Act, would amend Title XIX of the Social Security Act to codify value-based purchasing arrangements under the Medicaid program and reforms related to price reporting under such arrangements.
- H.R. 3284, the Providers and Payers COMPETE Act, would require the HHS secretary to submit an annual report on the impact of certain Medicare regulations on provider and payer consolidation.
- H.R. 3290 would amend Title III of the Public Health Service Act to ensure transparency and oversight of the 340B Drug Pricing Program.
- H.R. 3561, the Promoting Access to Treatments and Increasing Extremely Needed Transparency (PATIENT) Act of 2023, was considered in the markup as a package of bipartisan bills that would increase price and ownership transparency, reduce healthcare costs and strengthen the health workforce.

Having been reported from the Energy and Commerce Committee, these bills could advance to the House floor. The House Committee on Ways and Means shares jurisdiction on some provisions, however, which could impact both the timeline and contours of the bills before they advance to the House floor.

House Committee on Oversight and Accountability Holds Hearing on Role of PBMs

The House Committee on Oversight and Accountability met on May 23, 2023, to discuss pharmacy benefit manager (PBM) oversight, focusing on PBMs' impact on patient health, independent pharmacies and access to care. The committee discussed PBM practices that may negatively impact patients and independent pharmacies as well as the problems of transparency and high drug costs. There was significant discussion between the committee members and witnesses on how the vertical integration of PBMs can cause issues in the prescription drug market.

CDC Director to Testify Before Select Subcommittee on the Coronavirus Pandemic

The Centers for Disease Control and Prevention (CDC) Outgoing Director Rochelle Walensky will testify on June 13, 2023. The GOP-led Select Subcommittee on the Coronavirus Pandemic and its chairman, Rep. Brad Wenstrup (R-Ohio), invited Walensky last week to testify on June 13, 2023, about the CDC's handling of the COVID-19 pandemic. The HHS has agreed to allow Walensky to appear in a hearing that will likely see the director scrutinized over school reopening guidance issued in February 2021.

REGULATORY UPDATES

CMS Releases Updated FAQ on PHE Unwinding

The Centers for Medicare and Medicaid Services (CMS) released an updated frequently asked questions document last week on the end of the COVID-19 public health emergency (PHE), indicating that the Medicare program will no longer cover telehealth services provided by hospital-based physical and occupational therapists and speech-language pathologists beyond 2023. CMS states that it will exercise discretion through the end of this year to continue paying for outpatient therapy provided via telehealth billed from institutional providers. CMS continues to update the COVID-19 resource page, which includes fact sheets on various issues related to the end of the PHE.

CMS Proposes Changes to the Medicaid Drug Rebate Program

CMS released a proposed rule, "Medicaid Program: Misclassification of Drugs, Program Administration and Program Integrity Updates under the Medicaid Drug Rebate Program," on May 23, 2023. This proposed rule seeks to implement policies in the Medicaid Drug Rebate Program (MDRP) related to the new legislative requirements in the Medicaid Services Investment and Accountability Act of 2019 (MSIAA).

The proposed regulation would give CMS and individual states additional tools such as a drug price verification survey of manufacturers and wholesalers that would require the Inflation Reduction Act (IRA)-like disclosures of manufacturer cost and pricing data. To begin, CMS would conduct a mandatory survey of drug manufacturers for three to 10 high-cost drugs each year. There would be a multi-step process in selecting the drugs subject to the survey. CMS would identify high-cost outpatient prescription drugs based on the highest drug spending per claim, highest total Medicaid drug spending, highest one-year price increase or highest launch price. CMS would then exclude drugs for which a manufacturer currently participates in CMS drug pricing programs or initiatives, including Medicare negotiation and the Center for Medicare and Medicaid Innovation (CMMI) Cell and Gene Therapy (CGT) Access Model. It would also exclude drugs for which at least half of states have negotiated supplemental rebates that result in greater-than-average total rebates.

CMS would further narrow the list by considering state input regarding manufacturer efforts to work with states to lower drug prices (including negotiating subscription models) and which of the remaining drugs have the highest costs. The survey intends to help state Medicaid programs better understand manufacturer pricing, which could increase states' leverage in negotiating more significant supplemental rebates for this limited number of high-cost drugs.

The rule, if finalized, would also result in greater transparency between Medicaid-managed care plans and PBMs as to prices PBMs pay pharmacies. It would also require modification of numerous Medicaid Drug Rebate Program (MDRP) requirements that could have significant implications for manufacturers. The rule also proposes to rescind the changes to the exclusions from average manufacturer's price (AMP) and best price finalized in a December 31, 2020, final rule, which required manufacturers to "ensure" that price concessions were, in fact, passed through to patients for such price concessions to be excluded from the AMP and best price calculations. CMS is proposing this change in light of a ruling by the U.S. District Court for the District of Columbia mainly vacating these regulatory changes. Comments on the proposed rule are due by July 25, 2023. The CMS press release and the proposed rule can be found online.

CBO Releases Latest Health Coverage Projections

The Congressional Budget Office (CBO) released updated projections last week of health insurance coverage for people under age 65 over the next decade. The share of Americans under age 65 who are uninsured is currently at a historic low of 8.3 percent, which CBO attributes to temporary policies instituted in response to the COVID-19 pandemic, including continuous coverage provisions in state Medicaid programs and enhanced premium subsidies in the Affordable Care Act's individual marketplace. CBO's analysis indicates that more than 6 million people will lose their health insurance coverage following the end of these COVID-era policies. While the nation's uninsured rate will remain below pre-pandemic levels, it is expected to rise from 8.3 percent to 10.1 percent in 2033.