



H&K Health Dose July 12, 2022 A weekly dose of healthcare policy news

Legislative Updates

Congress This Week: A Packed Summer Agenda

Congress returned this week for a three-week congressional work period before its August recess and the beginning of election season. Senate Majority Leader Chuck Schumer (D-N.Y.) and Sen. Joe Manchin (D-W.Va.) continue to work together on a reconciliation package that could include drug pricing and an Affordable Care Act (ACA) tax credit extension. Last week, Sen. Schumer [submitted the text of an agreement](#) reached among Democrats to enable the Medicare program to directly establish the price of certain prescription drugs. The revived language is similar to the drug pricing proposal debated last November. The legislation would allow Medicare to negotiate the prices of 10 drugs starting in 2026, with the number increasing to 15 in 2027 and increasing by an additional 20 in 2029 and every year thereafter. The drugs subject to negotiation will be chosen by the U.S. Department of Health and Human Services (HHS) based on their total Medicare Parts B and D spending. In addition, the legislation would also repeal the Part D rebate rule sought to eliminate the safe harbor for Part D drug rebates. The text also includes a proposal to allow a delay in biologic drug negotiation if a biosimilar treatment is likely to come to market within two years. The agreement is being reviewed by the Senate parliamentarian to ensure that it complies with the Senate's rules for reconciliation. Democrats have also reached a deal to extend the solvency of the Medicare program by closing a tax loophole for pass-through businesses. A deal has not yet been reached on the broader reconciliation package, which Democrats hope to move before the midterm elections in November.

Meanwhile, this week, the House votes on two bills to protect abortion access post the U.S. Supreme Court's decision to overturn *Roe v. Wade*. Last week, President Joe Biden [signed an executive order](#) that directs HHS to expand access to medication abortion, and increase education and outreach efforts for abortion services.

The House also plans to vote on six appropriations bills next week. The minibus includes fiscal year (FY) 2023 programs under the Transportation-Housing and Urban Development, Agriculture-Rural Development, Energy-Water Development, Financial Services-General Government, Interior-Environment and Military Construction-Veterans Affairs sections of the appropriations legislation.

Regulatory Updates

Biden Administration to Extend the Public Health Emergency (PHE)

The declared [Public Health Emergency \(PHE\) under the Public Health Service Act](#) is rumored to be renewed at least one additional time beyond its current July 15, 2022, expiration, as the U.S. Department of Health and Human Services (HHS) has repeatedly committed to providing 60-day notice before the termination or expiration of the PHE. The extension should run through Oct. 13, 2022.

CMS Releases CY 2023 Medicare Physician Fee Schedule (MPFS) Proposed Rule

As reported last week, CMS [released](#) the Calendar Year (CY) 2023 Medicare Physician Fee Schedule Proposed Rule, which included a number of telehealth and behavioral health flexibilities and major tweaks to the Medicare Shared Savings Program (MSSP), among other changes. The main takeaway is a 4.42 percent overall decrease in the Medicare conversion factor because of a combination of an expiring 3 percent pay bump to mitigate the impact of E/M coding changes, a zero percent payment update under the Medicare Children's Health Insurance Program (CHIP) and



Reauthorization Act, and a statutorily required budget neutrality adjustment. The proposed cut to Medicare physician pay prompted strong push-back from a number of physician groups calling for various possible solutions, including extending the 3 percent bump, ending the budget neutrality adjustment and implementing an annual inflation-based update. However, these would require a congressional fix that is not expected until end of year.

Comments on the rule are due Sept. 6, 2022, and can be submitted on the [Regulations.gov website](https://www.regulations.gov). Holland & Knight is reviewing the rule and will be providing a detailed analysis. Note the CY 2023 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule has not yet been released by the agency. We will also provide an update and summary upon its release.

PRF Reporting Period 3 Portal Opens

The Provider Relief Fund (PRF) [reporting portal](#) is open for reporting Period 3. Providers who received one or more PRF payments exceeding \$10,000, in the aggregate, from Jan. 1, 2021, to June 30, 2021, must report on their use of funds no later than Sept. 30, 2022. Reporting Period 4 will open on Jan. 1, 2023, and reporting Period 5 will open on July 1, 2023.

National Stakeholder Call on July 19 with the CMS Administrator

The Centers for Medicare & Medicaid Services (CMS) Administrator Chiquita Brooks-LaSure, and her leadership team, are holding a National Stakeholder Call on July 19, 2022, at 1 p.m. ET to discuss the CMS Strategic Plan and key initiatives. Interested participants can [register online](#) for the webinar.

New CMS Report Reveals Implicit Bias in Value-Based Models

The Centers for Medicare & Medicaid Services (CMS) Innovation Center has conducted [new analyses](#) on several value-based payment models, which revealed implicit biases toward people of color, as well as lower-income individuals in at least three models, including the Kidney Care Choices (KCC) Model, Comprehensive Care for Joint Replacement (CJR) Model and Million Hearts Cardiovascular Risk Reduction Model (MHM). Both the KCC and MHM use biased metrics that can wrongly overestimate kidney and heart health for certain racial and ethnic groups, which can exclude them from participation in the models. "The number of Black beneficiaries who may have been excluded from the model cannot be reliably estimated," the report states. Concerns were also raised about the CJR Model because of the fact that its bundled payment mechanism may dissuade integration of patients who require more institutional post-acute care, which can disproportionately impact Black and low-income patient populations. The Innovation Center says it will apply lessons learned to its development of future models, for which health equity will be a primary focus.

Payer Price Transparency Requirements in Effect as of July 1

Under new price transparency requirements effective July 1, 2022, payers must publish machine-readable files that contain negotiated rates with participating providers for all covered services and items, and allowed and billed amounts for out-of-network providers. In addition, payers must create an internet-based price comparison tool that allows individuals to receive an estimate of their cost-sharing responsibility for 500 common items and services, and make a request for their estimated out-of-pocket cost for any specific item or service not listed. In response to reports that hospitals are having difficulty complying with their requirements which became effective Jan. 1, 2022, U.S. Department of Health and Human Services (HHS) has also issued new [guidance](#), including FAQs, 8 steps to a machine-readable file and 10 steps to a consumer-friendly display. Last month, CMS announced their [first penalties assessed](#) to hospitals under the program. For more information on hospital and payer requirements, visit CMS' price transparency [website](#).



FDA Seeks to Expand Accelerated Approval Pathway to New Uses

The U.S. Food and Drug Administration (FDA) wants to leverage the accelerated approval pathway for cell and gene therapies and expand the pathway in general, says Peter Marks, director of the FDA Center for Biologics Evaluation and Research. Marks added that the post-market studies enhance the ability to collect data on rare side effects and long-term durability, which can be difficult to collect from smaller pre-market trials. The FDA is simultaneously working to reform the accelerated approval pathway following backlash over the controversial approval of the Alzheimer's drug Aduhelm.

CMS Soliciting Feedback on Social Risk Factor Readmissions Measures

The Centers for Medicare & Medicaid Services (CMS) privately issued hospitals performance feedback designed to illuminate differences in readmission rates for patients with social risk factors. The agency used two distinct methods and is now soliciting feedback and questions, which can be submitted to cmsdisparitymethods@yale.edu.

2023 Rate Hikes Expected Next Year, Though Impact Depends on Congressional Action

According to a new [issue brief](#) by the American Academy of Actuaries, 2023 health insurance premium rates will spike next year. However, this will vary state-to-state and depends on several factors that may not come to bear, such as enhanced premium subsidies included in the American Rescue Plan Act not being extended. Other reasons for the anticipated hike include upcoming Medicaid redeterminations following the end of the COVID-19 Public Health Emergency, inflation, and increased demand for mental health and telehealth services.

COVID-19 Update

The Biden Administration is considering recommending a second booster shot this fall for all adult Americans amid a surge largely due to the Omicron BA.5 variant, which is now the dominant strain in the U.S. and may be resistant to earlier strains of the virus, including other Omicron strains. The administration will purchase 105 million doses of Pfizer's Omicron-resistant COVID-19 vaccine with the option to purchase up to 300 million more doses. Moderna also announced July 11, 2022, that it is advancing two Omicron vaccines, one targeted for the BA.1 variant and another for variants BA.4 and BA.5. The administration also purchased 3.2 billion doses of Novavax's protein-based vaccine, which it hopes individuals who avoided earlier vaccines made with new mRNA technology will consider. A Massachusetts-based startup says it can use artificial intelligence to predict future variants, which could be crucial to rapidly developing targeted vaccines to stay ahead of evolving variants. An experimental cancer drug was also found to reduce the risk of death for people hospitalized with COVID-19 by half, though experts caveat that the trial was relatively small.