



H&K Health Dose: September 21, 2022

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

Congress This Week: Continuing Budget Resolution Talks Continue

Congress' priority for the next two weeks is to fund the government past Sept. 30, 2022, through a continuing resolution (CR). While passage is expected before the deadline, a few key items are stalling progress. On the healthcare front, the administration has requested additional COVID-19 funding, but this request is being met with Republican opposition. Additionally, Senate Republicans hope to add a five-year reauthorization of the U.S. Food and Drug Administration's (FDA) user fee to the CR this week. Other policy riders – such as an overhaul of the FDA's diagnostic, dietary supplement and cosmetic regulations – are still on the table for the moment, but may be pushed to an end-of-the-year omnibus package. Debates over Federal Emergency Management Agency (FEMA) funding and Ukraine aid are adding complication, as are an agreement between Senate Majority Leader Chuck Schumer (D-N.Y.) and Sen. Joe Manchin (D-W.Va.) on major energy provisions, which dozens of House Democrats and at least two Democratic senators have formally opposed. The Senate will most likely move first given that bipartisan cooperation is necessary to secure the 60 votes required for passage in the 50-50 Senate.

House Passes Medicare Advantage Prior Authorization Legislation

The House of Representatives on Sept. 14, 2022, passed the Improving Seniors' Timely Access to Care Act ([H.R. 3173](#)). The bill would establish an electronic prior authorization process, establish decision timeframes for payers including "real time" decisions for common services, require plans to report data and encourage plans to adhere to evidence-based guidelines. The Congressional Budget Office [estimates](#) that the bill will cost more than \$16 billion over the next decade. Companion legislation ([S. 3018](#)) has been introduced in the Senate by Sen. Roger Marshall (R-Kan.) and currently has 43 bipartisan cosponsors.

Reps. Bera, Bucshon Introduce Bill to Thwart Proposed Conversion Factor Cuts

Reps. Ami Bera, M.D. (D-Calif.) and Larry Bucshon, M.D. (R-Ind.) [introduced](#) the Supporting Medicare Providers Act ([H.R. 8800](#)) on Sept. 14, 2022. The bill seeks to reverse the impending 4.42 percent cut to the 2023 Medicare Physician Fee Schedule conversion factor that resulted from budget neutrality requirements. Notably, the bill also directs policymakers to "commit to taking administrative and legislative actions to—(1) ensure financial stability and predictability in the Medicare physician payment system; (2) promote and reward value-based care innovation; and (3) safeguard timely access to high-quality care by advancing health equity and reducing disparities." Companion legislation has yet to be introduced in the Senate. Providers are hoping that the bill will be taken up as part of a larger budget or healthcare package later in the year before cuts are scheduled to go into effect Jan. 1, 2023.



Telehealth Action Calls

On Sept. 13, 2022, a total of 375 stakeholders sent a letter to Senate leadership on the importance of finding a permanent solution to Medicare telehealth coverage. The letter urges the Senate to approve the House-passed extension of telehealth services through 2024 (H.R. 4040). Notably, the letter urges the Senate to also address prescriptions for clinically appropriate controlled substances without in-person visit requirements and preeductible coverage for telehealth services under high-deductible health plans (HDHPs). Currently, telehealth service waivers would expire roughly five months after the COVID-19 Public Health Emergency (PHE) ends, per the 2022 omnibus passed in March 2022.

In a separate letter, Reps Ann McLane Kuster (D-N.H.), Lori Trahan (D-Mass.), and Peter Welch (D-Vt.) [urged](#) the Centers for Medicare & Medicaid Services (CMS) to reconsider its proposal to eliminate coverage for audio-only telehealth visits after the COVID-19 PHE ends. In response to the 2023 Medicare Physician Fee Schedule proposed rule, the members wrote, "In many rural communities where internet is unreliable, audio-only telehealth services are an essential part of care delivery." They also noted that telehealth visits with video require internet access, which not all Medicare beneficiaries have. The group urged CMS to consider how ending coverage for audio-only telehealth would "compromise the provider-patient relationship and disproportionately impact populations who face barriers to accessing care."

House Republicans Press Biden Administration to Take Action on 42 CFR Part 2

Seven House Republicans sent [a letter](#) to the U.S. Health and Human Services (HHS) Secretary Xavier Becerra urging him to release long overdue 42 Code of Federal Regulations (CFR) Part 2 regulations to modernize substance use disorder privacy regulations as required by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The rule was originally directed to be released in March 2021. The updates are intended to align the laws that govern substance use records with existing Health Insurance Portability and Accountability (HIPAA) laws that regulate the exchange of medical records between providers with informed patient consent.

House Ways and Means Committee Addresses Healthcare System's Preparation for Climate Crisis

The House Ways and Means Committee on Sept. 15, 2022, held a [hearing](#) to discuss preparing the nation's healthcare infrastructure for the climate crisis. The committee also [released an accompanying five-part report](#) that summarized stakeholder responses to a request for information issued on the topic earlier this year. A majority of respondents reported having experienced an extreme weather event within the last five years.

REGULATORY UPDATES

Surprise Billing Action Picks Back Up

A [request for information](#) (RFI) was released on Sept. 14, 2022, regarding advanced explanation of benefits (AEOB) requirements and good faith estimates (GFEs) for insured patients. AEOB and GFE requirements were finalized late last year for uninsured/self-pay patients, but deferred for insured patients to allow more time for implementation. The release of this RFI suggests that HHS and other agencies are likely not in a position to implement these provisions by next year. The RFI covers a broad range of topics primarily related to establishing data transfer standards, including what information should be required in estimates, provider/payer burden and data privacy. [Comments](#) are due Nov. 15, 2022.



The RFI follows an Aug. 19, 2022, [final rule](#) that clarified important provisions concerning the qualifying payment amount (QPA) and independent dispute resolution (IDR) process. The rule chiefly clarifies that the QPA will no longer be the "presumptive amount" over other factors included in the law and introduces new considerations for counting additional criteria and new requirements intended to boost transparency. Additional information can be found in Holland & Knight's [summary](#) of the rule.

Conflicting Remarks Cause Confusion Over Official End of COVID-19 Public Health Emergency

Over the weekend, President Joe Biden caused a stir as he said during a "60 Minutes" interview that "The pandemic is over. We still have a problem with COVID, we're still doing a lot of work on it. But the pandemic is over." On Sept. 19, 2022, National Institute of Allergy and Infectious Diseases Director Anthony Fauci struck a different chord by saying the United States is "not where we need to be" in our COVID-19 response and we must do what we can to prepare for future variants and possible new outbreaks in the upcoming fall and winter months. Meanwhile, the administration is still pressing lawmakers to approve \$22 billion in emergency funding for priorities, including COVID-19 as a new report funded by the American Hospital Association found that more than half (53 percent) of U.S. hospitals expect to lose money this year because of costs associated with treating COVID-19 patients coupled with increased staffing and supply costs. According to a [summary](#) of the report, "optimistic" projections indicate margins will continue to be down 37 percent relative to pre-pandemic levels.

Administration officials have also taken steps to clarify that the president's statements are not indicative of plans to officially end the COVID-19 PHE, which is currently set to expire in mid-October. The PHE must be renewed in 90-day increments. The administration had previously indicated that they would provide at least 60 days' notice, so most expect the PHE to be extended at least one additional time through mid-January 2023.

Period 3 Provider Relief Funding Reporting Deadline is Sept. 30

A Sept. 30, 2022, deadline is nearing by which providers must report how funds were used if they received \$10,000 or more in provider relief funding during the first half of 2021. The Health Resources and Services Administration (HRSA) indicates that they will soon announce opportunities to request to report late due to extenuating circumstances. Additional information can be found on the HRSA [website](#).

White House Releases New Roadmap for Behavioral Health Integration

HHS on Sept. 14, 2022, released a new [roadmap](#) for behavioral health integration with other healthcare services. The roadmap centers around three core pillars: strengthening system capacity; bridging care caps; and supporting community-based efforts. It also acknowledges the importance of integrating behavioral health beyond the primary care setting, as well as advancing health equity. The report calls out the Biden Administration's historic investments in mental health and outlines major challenges to integration, including care silos, coverage limitations, workforce challenges, insufficient investments in preventive care and unequal access for underserved populations.

White House Issues Executive Order; Outlines Spending For New Biotech, Biomanufacturing Initiative

The Biden Administration issued an executive order ([EO 14081](#)) to establish a new biotechnology and biomanufacturing initiative across multiple sectors of the economy, including within the healthcare realm. A key policy goal set forth by the White House seeks to harness biotechnology and biomanufacturing research and development (R&D), particularly through applied biosafety and biosecurity innovation. This [fact sheet](#) from the White House provides additional details. In conjunction with the new initiative, the White House held a Summit where various agencies announced details for investments and resources to implement the EO.



Notably, the \$2 billion funding tranche includes \$40 million for the HHS to expand the role of biomanufacturing for active pharmaceutical ingredients, antibiotics, and more. The president also provided an [update on progress](#) and next steps for the Cancer Moonshot initiative and the administration's "Cancer Cabinet."

Hurricane Fiona Tests Puerto Rico Health Infrastructure Resiliency

Nearly five years after Hurricane Maria, the FDA and health industry remain on high alert to see whether Hurricane Fiona delivers a similar devastating blow to the island's healthcare infrastructure, including several national healthcare suppliers and distributors with a major presence on the island. Power has been knocked out across the island, but early reports seem to indicate that at least some companies are prepared to resume operations shortly with generator power. The next several days will provide a more accurate indicator of whether additional interventions may be needed. The FDA says it is "actively monitoring" the situation and in close contact with key facilities.

New Reports Indicate Record Levels of Enrollment; Certain Advantages for MA Plans

Two new reports by the Kaiser Family Foundation are offering insights into the Medicare Advantage market. The [first report](#) indicates that enrollment in Medicare Advantage (MA) plans are at a record high with slightly less than half (48 percent) of the Medicare eligible population now enrolled in MA plans. Additionally, the average Medicare beneficiary now has access to 39 MA plans, the largest in the past decade. The [second report](#) looked at how MA plans compared to traditional Medicare in terms of patient satisfaction, affordability, quality and utilization. It found similar rates of satisfaction and access, but that MA beneficiaries tended to report fewer cost-related problems and access preventive care services more frequently than those with traditional Medicare coverage alone.