



H&K Health Dose September 21, 2021 A weekly dose of healthcare policy news

Legislative Updates

Congress this Week

This week, the House joined the Senate back in Washington facing a challenging few weeks ahead. Earlier tonight, the House passed a continuing resolution (CR) along a party-line vote that would avert a Sept. 30 spending cliff and fund the federal government through December 3 to provide more time hammer out the details of the Democrat's massive \$3.5 trillion reconciliation package. The CR also contains \$28.6 billion in disaster relief funding, \$6.3 billion in support resettlement efforts for Afghan evacuees, and would suspend the debt ceiling to Dec. 16, 2022 to avoid severe economic consequences. 10 Republican votes are required in the Senate to pass the measure under regular order. Senate Minority Leader Mitch McConnell has indicated that Republicans will not support a debt ceiling increase and has instructed Democratic leadership to include in the budget reconciliation package, which Democrats intend to pass without Republican support.

Meanwhile, various house committees of jurisdiction will continue to work out the details of their budget blueprint reconciliation package. Many moderate Democrats have tied their support for the package to the bipartisan infrastructure bill, which House Speaker Nancy Pelosi has signaled she intends to hold a vote on Sept. 27 as promised, but most expect it to fail until the final details of the reconciliation are ironed out, which is likely to stretch into October. The main holdup is the total cost and scope of the package. Pelosi hasn't totally given up all hope on the topline figure of \$3.5 trillion, but moderates are signaling they'd like to see a smaller number, which could entail some tough decisions in the coming weeks. The current drug pricing plan is facing some intense Democratic opposition despite being popular amongst voters and ability to help pay for the package. Democrats also have to make sure whatever is included passes the "Byrd rule," which requires that provisions are primarily budgetary in nature, as opposed to broader policy changes. Already, Senate Parliamentarian Elizabeth MacDonough dashed Democrat's hopes of including broader immigration reform in the package.

The House and Senate have been pre-conferencing much of the budget reconciliation package in an attempt to minimize changes on the backstretch. That said, Senate Democrats are reportedly discussing some changes, such as making Medicare vision, dental, and hearing benefits more expansive. Any changes to resolve disagreements between the House and Senate versions or trim spending so that the package does not add to the federal deficit would have to worked out by the House Rules Committee. Senate Democrats postponed markups for individual appropriations bills this week after Republicans said they want to have the larger budget blueprint in-hand first. Buckle up for a whirlwind fall.

More than 70 House Members Call on CMS to Rethink Medicare Specialty Cuts

In a [letter](#) to CMS, more than 70 bipartisan House members called on the agency to reverse sections of a proposed rule that would cut redistribute payments in such a way that would cut payments for some specialists by up to 20% next year after a temporary 3.75% boost is set to expire at the end of this year. The letter encourages CMS to "work with Congress on fundamental reform to the physician fee schedule."

Administrative/Regulatory Updates



CMS delays enforcement of payer-to-payer data exchange provision of 2020 interoperability rule

CMS issued new [FAQs](#) explaining its intention to exercise enforcement action against payers for the payer-to-payer data exchange provision of the May 2020 Interoperability [final rule](#) pending future rulemaking on the technical specifications and format of the data being exchanged to ensure consistency and avoid operational delays. The agency notes that the decision will not affect any other regulatory requirements and implementation timelines finalized in the 2020 rule.

FDA Releases Guidance on Approvals for Biosimilars and Interchangeable Products

The FDA released new [draft](#) and [final](#) guidance that aims to make approvals for biosimilars and interchangeable products more transparent. The draft guidance states that generic injectable products must have an equivalent amount of the drug substance in content and concentration. The final guidance explains how close a biosimilar product's formulation and delivery device must be to a reference product and addresses licensure issues.

Biden Administration Extends ACA Enrollment Period, Makes Other Changes for 2022 and Future Years

CMS [released](#) updated payment parameters and other changes for the 2022 and future years for the ACA marketplace, including permanently extending the annual enrollment period from November 1 of the prior year through January 15 of the benefit year, extending it from a total of 45 to 75 days. The guidance will also allow a monthly special enrollment period for families making a combined income below 150% of the federal poverty level and amends previous guidance concerning section 1332 waivers.

CMS Rescinds Next Phase of ET3 Program

According to new [FAQs](#), CMS will not move forward with the medical triage line component of the Emergency Triage, Treat, and Transport Model citing an insufficient number of applications received.

FTC Releases New Policy Obliging Health App Manufacturers to Protect Patient Data

The FTC issued a policy [statement](#) clarifying that mobile health app makers have an obligation to notify consumers if their data is exposed or shared without their permission. The policy is intended to fill a "gap" in regulations for breaches of health apps, which aren't covered by HIPAA.

CMS Distributes \$452 million in Reinsurance Funds to States

CMS last week distributed an additional \$452 million in American Rescue Plan funding to shore up reinsurance pools in 13 states. The amounts range from \$2.5 million to \$139 million per state depending on factors like the size of the reinsurance program. The House Energy & Commerce and Ways & Means committees separately debated federal funding for state reinsurance programs moving forward, including for states that don't have their own reinsurance programs yet, as part of the Democrat's budget reconciliation package.

COVID Update

The Biden administration is negotiating with Pfizer to buy an additional 500 million vaccines to donate globally. Despite distributing the most vaccines of any other country, the U.S. is facing international scrutiny for trying to move forward with booster shots before much of the rest of the world is vaccinated. Aside from equity concerns- many experts are saying the best way to protect Americans and prevent further spread of the disease is to vaccinate as much of the global population as possible. Aside from supply and shipping constraints, the U.S. is running into regulatory red tape that is



slowing approvals in certain countries and an inability to provide the necessary cold storage in others. President Biden called on other wealthy nations to step up their donation efforts.

The FDA will formally consider boosters after its Center for Biologics Evaluation and Research voted to recommend boosters of the Pfizer vaccine for elderly and at-risk individuals. Dr. Anthony Fauci says approval for the Moderna and J&J shots are “a few weeks behind.”

Pfizer said Monday that its COVID-19 vaccine works for children ages 5 to 11 and that it will seek U.S. authorization for this age group soon. The vaccine is already available for those 12 and older.

According to new CDC data, Moderna’s vaccine was still 92% effective against hospitalization after four months, with Pfizer’s at 77% and J&J at 68%.

The U.S. will begin allowing fully vaccinated foreign nationals to enter the country beginning in early November