



H&K Health Dose September 14, 2021 A weekly dose of healthcare policy news

Legislative Updates

Congress this Week

Yesterday, the Senate returned from August recess. However, all eyes are on the House, which is technically out until next Monday, but committees are working at a feverish pace to mark up their portion of Democrat's massive spending package. The Sept. 15 deadline originally listed in the reconciliation instructions as the deadline for committees to report out their various pieces appears to be slipping. Adding fuel to the frenzy, Sens. Joe Manchin (D-WV) and Kyrsten Sinema (D-AZ) both indicated they will not support a \$3.5 trillion package, leading Democrats to duke it out over which priorities will make it into a final package that may get slimmed down closer to \$1-2 trillion. Both chambers are operating with very narrow margins, with three votes to spare in the House and a narrow 50-50 margin in the Senate that requires all Democrats to be supportive of the package.

Yesterday and today, the House Energy and Commerce Committee [marked up](#) various healthcare provisions, including Medicare drug price negotiation, Part D out-of-pocket caps, \$190 billion in funding for home- and community-based services, a permanent extension of the Children's Health Insurance Program (CHIP), adding dental, vision and hearing benefits to Medicare; \$35 billion investment in the public health infrastructure, filling the Medicaid coverage gap in non-expansion states, and requiring 12 months of Medicaid coverage for postpartum women. At least two committee Democrats indicated that they would vote against the draft drug pricing proposal, countering with a scaled down proposal of their own, further complicating the path forward for the drug pricing proposal, and possibly, the larger reconciliation package itself.

Last week, the House Ways and Means Committee approved expanding Medicare benefits, requiring employer-based retirement plans, childcare, and universal paid family and medical leave. The committee will continue [markups](#) today and tomorrow to consider drug pricing measures, extending Medicaid and enhanced ACA subsidies, and funding for home health services. A proposal to lower the Medicare eligibility age was not included in draft legislation, though House progressives are reportedly "still pushing very hard" on lowering the Medicare eligibility age to 62. Over the weekend, Ways and Means Committee Chairman Richard Neal (D-Mass.) also circulated a draft [document](#) detailing plans to raise \$2.9 trillion in new taxes to help pay for the package. Though not considered final, changes include increasing the top tax rate from 37 to 39.6 percent, hiking the corporate tax rate from 21 to 26.5 percent, and raising the capital gains tax rate from 20 to 25 percent.

At this point, it is more likely that the Senate will not engage in a significant or lengthy committee process on reconciliation, with much of that work occurring now in the House. Ultimately, the House will have to consider the reconciliation package prior to the end of September under a previously agreed upon rule.

In addition to the budget resolution, Speaker Pelosi promised moderates a vote on the bipartisan infrastructure bill by Sept. 27, which also makes that the defacto deadline for the Democrat's spending package since progressives are threatening to withhold their support of the infrastructure bill without it.

Separately, Congress must also take action to continue funding for the federal government beyond the close of the current fiscal year (FY 2021) on Sept. 30. House Majority Leader Steny Hoyer (D-MD) has indicated his goal to bring up a stopgap spending bill, known as a Continuing Resolution (CR), next week. While the length of the CR is up for debate, it is likely to persist into the fall or early winter. The CR would also likely need to include several other measures, including \$14 billion for natural disasters, \$6.4 billion for the relocation of Afghan refugees, and \$10 billion for Hurricane Ida relief, as well as raising the debt ceiling, which Treasury Secretary Janet Yellen said will likely expire at some point next month.



During the CR period, Congress will continue to take action on regular appropriations for fiscal year 2022. So far, the House has passed nine of the 12 regular appropriations bill, with the Defense, Homeland Security, and Commerce-Justice-Science bills outstanding. The Senate Appropriations Committee has considered and passed three of the 12 regular appropriations bills, with no consideration of any bills by the full Senate and without a topline spending figure having been set. The House is currently pegged at approximately \$1.5 trillion for a topline figure.

In Other Hill News... Prescription Drug Pricing Transparency Bill Introduced

U.S. Senators Susan Collins (R-ME) and Bob Casey (D-PA) introduced the [Prescription Drug Pricing Dashboard Act](#), which would make pricing information for prescription drugs readily available through a CMS website.

Administrative/Regulatory Updates

COVID Relief Funds

Last week, HHS [announced](#) \$25.5 billion in additional provider relief funds, which includes \$8.5 billion from the American Rescue Plan for rural providers. Providers may apply for both through a single application beginning on September 29. Phase 4 payments will be based on providers' lost revenues and expenditures between July 1, 2020, and March 31, 2021. HRSA will focus more funds on smaller providers, those who serve vulnerable and isolated communities, those who service high Medicaid, CHIP, and/or Medicare patient populations, and those operating on "thin margins." The agency also announced plans for a 60-day grace period for the September 30, 2021 deadline for the first PRF Reporting Time Period, citing recent natural disasters and the Delta variant.

CMS Proposes to Nix Trump-Era Expedited Medicare Payments for Breakthrough Devices

The Biden administration is [proposing](#) to repeal a Trump-era rule that would allow Medicare to start reimbursing certain devices immediately after FDA approval, as opposed to having to wait 9-12 months, citing inadequate evidence that the treatment would be reasonable and necessary. CMS said in a separate [blog post](#) that it intends to explore a new expedited coverage pathway for innovative technologies. Comments on the rule are due Oct. 15.

White House's Prescription Drug Pricing Plan Lays Out Broad Plans; Details Limited

HHS released a prescription drug pricing [plan](#) that backs Democratic legislative proposals to block "unreasonable" price increases, support drug price negotiation, and cap Part D out of pocket expenses. The plan also outlines an administrative strategy that includes promoting industry competition and fostering research and innovation. Notably, the plan did not include "march in rights" i.e. the federal government exercising authority to revoke patents for drugs deemed too expensive, though the report did say it would be given "due consideration."

In the Courts

The Justice Department [sued Texas](#) over its restrictive new abortion law, saying the near-total ban on abortions is "clearly unconstitutional."

COVID Update

President Biden announced sweeping new COVID-19 vaccination rules mandating that private employers with more than 100 workers require vaccination or weekly testing and requiring that all health care workers, federal employees and federal contractors get vaccinated without the ability to opt out with regular testing, with limited exceptions.



Two departing top FDA vaccine experts said that there was no evidence to support boosters, adding more fuel to rising tensions between the White House and FDA and CDC when it comes to boosters, which the White House has called for as soon as Sept. 20 for the immunocompromised but so far no guidance has been released.

President Biden will deliver his first speech to the United Nations General Assembly on Sept. 21 and is expected to address international vaccine strategy. WHO-backed Covax cut its COVID-19 vaccination forecast to 1.4 billion doses this year, down from its target of 2 billion citing manufacturing challenges and regulatory delays in the U.S. and elsewhere.