



H&K Health Dose September 28, 2021

A weekly dose of healthcare policy news

Legislative Updates

Congress this Week: A Hollywood Worthy Cliffhanger

Congress faces arguably its biggest week for this 117th Congress as it continues to slog through a bipartisan infrastructure bill, Democratic budget reconciliation package, and most immediately, a continuing resolution that would starve off an impending government shutdown if Congress fails to act before current funding expires on Sept. 30.

As expected, last night Republicans blocked a motion to proceed on a House-passed continuing resolution that would fund the federal government through Dec. 3 because it also included a provision that would also suspend the debt ceiling to Dec. 16, 2022, instead calling on Democrats to extend the debt limit via Democratic votes only by including it as part of their budget reconciliation package. For now, the Senate will proceed with negotiating a continuing resolution sans debt limit, which House Speaker Nancy Pelosi has indicated her willingness to consider.

U.S. Treasury Sec. Janet Yellen announced today that the Treasury is likely to exhaust its so-called “extraordinary measures” by October 18, creating a new deadline by which Democrats must race to pass their reconciliation package if they tie in the debt limit. The package took a major step forward over the weekend when the House Budget Committee [reported out](#) an overall economic package marrying the work of over a dozen committees. However, the provisions of the package, as well as the topline spending figure, are still subject to negotiation as Democratic leadership looks to strike a difficult balance between making strategic cuts to reign in the topline figure to appease moderates like Senators Joe Manchin and Krysten Sinema while not losing the support of progressives. A topline figure of \$1-2 trillion is being discussed, which means some difficult choices ahead given the current \$3.5 trillion figure. It is said it is more likely that provisions will be scaled back across the board, as opposed to certain provisions being gutted altogether from the bill. Healthcare priorities that are reportedly up for negotiation include prescription drug spending reform, making CHIP permanent, and proposed hearing, dental, and vision Medicare benefits. A final package could still be weeks away.

Amidst all of this, House Speaker Nancy Pelosi is all but forced to bring a separate, Senate-passed \$1.1 trillion bipartisan infrastructure package that has been waiting on ice to a vote by Thursday given that funding authorization for surface transportation programs expires Thursday at midnight plus earlier promises she made to moderates that she would bring it to a vote this week. Today, for the first time, Speaker Pelosi began signaling to progressives that they may need to be prepared to vote for the bipartisan infrastructure package as the details of the larger budget reconciliation package get worked out in the coming weeks, despite progressives adamantly insisting up to this point that they would withhold support for the infrastructure package without it being linked to a vote for the broader budget reconciliation package. Grab your popcorn! This is shaping up to be a rollercoaster finish.

Abortion Rights Bill Passes House; Faces Uphill Battle in the Senate

In separate news, the House passed by a vote of 218-211 the Women’s Health Protection Act, which would codify abortion rights. The bill was introduced in response to state measures that would significantly limit access to abortion services, including a Texas law that took effect on Sept. 1, but faces a significant uphill battle in the Senate.

Grassley to have Another Go

Iowa Republican Senator Chuck Grassley confirmed he will seek an eighth term next year, which boost the Republican’s chances of retaking the Senate majority next year.



Administrative/Regulatory Updates

CMS Awards State Medicaid Agencies Grants for Community-Based Mobile Crisis Intervention Services

CMS awarded \$15 million in planning grants to 20 State Medicaid Agencies for providing community-based mobile crisis intervention services. More information can be found in the CMS [announcement](#).

Provider Relief Fund Portal for Phase 4 Distributions Opens Tomorrow

The [portal](#) to apply for the fourth tranche of Provider Relief Funding totaling \$25.5 billion, which includes \$8.5 billion in relief for rural providers from the American Rescue Plan Act, is set to open tomorrow and will remain open until 11:59 p.m. ET on Oct. 26. The payments are meant to cover lost revenue and higher spending due to the COVID-19 pandemic that occurred between July 1, 2020, and March 31, 2021. CMS will prioritize funding for smaller providers and those serving vulnerable or isolated communities, but will make determinations about how to divide up the funding after all applications are collected. More information is available [here](#).

The deadline for the first Provider Relief reporting period is Sept. 30, though CMS recently announced a 60-day grace period. This reporting period covers payments received between April 10, 2020, and June 30, 2020.

CMS also released a [detailed methodology](#) for calculating Phase 3 payments. Providers who believe their payments were not calculated correctly according to this methodology may request a reconsideration. More details are forthcoming.

CMS Reevaluating Exceptions From Off Campus Outpatient Facility Payment Cuts

CMS is [rescinding](#) previous denials for mid-build exceptions and giving hospitals another opportunity to submit additional documentation by Oct. 10 to justify that off campus outpatient facilities were already under construction when the Bipartisan Budget Act of 2015 passed, which would protect them from 40% payment cuts under new site neutral payment policies included in the law. During this time, entities will no longer have to return overpayments.

Drug Makers Could Face Steep Fines for Potential 340B Violations

In the latest development in the ongoing saga over contract pharmacies, HRSA sent letters to six drug manufacturers (Eli Lilly, AstraZeneca, Novartis, Novo Nordisk, Sanofi and United Therapeutics) last week informing them that it has referred them to the HHS' Office of the Inspector General for possible penalties after failing to comply with advisory guidance by extending 340B discounts to contract pharmacies. Potential fines could exceed \$5,000 per instance. This past summer, a federal judge refused HHS' attempt to dismiss a case that AstraZeneca had brought forward on the issue stating the law is vague and HHS' advisory opinion is a departure from previous policy, allowing the case to proceed.

New OIG Report Finds Possible Upcoding by Medicare Advantage Plans Consolidated

In a new [report](#), HHS' Office of Inspector General recommended increased oversight and targeted audits after it found that 20 Medicare Advantage plans received over half (54%) of \$9.2 billion in risk-based payment enhancements despite comprising less than a third of beneficiaries, signaling possible upcoding.

In the Courts

Centene and Humana are suing Merck & Co. over deploying so-called "pay-for-delay" tactics to prevent lower-cost generic drugs from entering the market, which the insurers argue caused them to overpay by hundreds of millions of dollars for cholesterol medications Vytorin and Zetia. Kaiser filed a similar suit against Merck a few months earlier.



COVID Update

Following FDA and CDC approval last week, Pfizer booster shots began Friday for adults aged 65 and older, immunocompromised, and healthcare or other frontline workers at high risk for exposure who are at least six months out from their last dose. According to a CMS [press release](#), shots will continue to be available to Medicare beneficiaries without cost sharing. The White House also added during a press briefing that they will rely on “self-attestation.” In other words, those seeking the shot will not need to show proof of identification or insurance or prove they are one of the eligible at-risk groups. Approval of a booster shot of Moderna and J&J is anticipated in the coming weeks. President Biden said booster shots will probably open up more widely in the near future and encouraged people to wait their turn.

Meanwhile, Moderna's chief executive said this week that it was possible to gear up production to produce enough vaccines for "everyone on this earth" within the next year.

Dr. Anthony Fauci said he is hopeful the FDA will approve the Pfizer vaccine in children ages 5 to 12 by the end of October. Pfizer also says it is ready to manufacture the vaccine, which is a smaller dosage than the adult shot, immediately pending authorization. The U.S. has reported nearly 1 million cases among children under 18 in the last month amidst the return to in-person school.

At least three types of daily antiviral pills for COVID are being tested by Pfizer, Merck, and Roche in clinical trials and are said to be showing promising results so far, with full results expected as soon as late fall or winter.

Federal contractor employees must be fully vaccinated by Dec. 8 unless they're granted a legal accommodation, according to new [guidance](#) released Friday. The penalties for noncompliance are not abundantly clear. In response, federal workers and contractors are suing the U.S. government.

Vice President Kamala Harris announced that the U.S. will contribute at least \$250 million to a new international health fund to combat future pandemics and biological threats and asked Congress for another \$850 million.