



H&K Health Dose November 30th, 2021

A weekly dose of healthcare policy news

Legislative Update

Congress This Week - Brace for a Bumpy Ride

Continuing Resolution Efforts

The current Continuing Resolution (CR) funding the federal government expires on December 3. Leadership is expected to draft a CR by tomorrow. However, they have not yet said how long the stopgap measure will last. A temporary stopgap CR is considered all but certain; however, the timeframe is unclear. There have been divisions among Democrats and between the chambers over the length of the stopgap funding bill. Some seek a short-term CR that doesn't go beyond December; however, a mid-to-late January or even possibly February CR is more likely.

The CR is one of the best opportunities for Congress to attach legislation addressing items such as the looming payment comprised of a 4% Medicare cut due to Pay-As-You-Go (PAYGO) spending, a return of the automatic 2% Medicare sequester cuts, and a 3.75% reduction to the Medicare conversion factor due to changes to evaluation and management (E/M) codes that were offset in 2020 due to the pandemic. If this vehicle is not used, these provisions become more challenging to pass this year. However, bipartisan concern over these issues remains. If not done in this CR, it is possible they could be addressed in January instead.

Debt Limit & Appropriations

Meanwhile, Congress is only a couple of weeks away from hitting the December 15 target to raise the federal debt limit. The debt limit—commonly called the debt ceiling—is the maximum amount of debt that the Department of the Treasury can issue to the public or to other federal agencies. The amount is set by law and has been increased over the years to finance the government's operations. CBO projects that if the debt limit remained unchanged and if the Treasury transferred \$118 billion to the Highway Trust Fund on December 15, as currently planned, the Treasury would most likely run out of cash before the end of December.

House Budget Chair John Yarmuth (D-Ky.) has said House plans to defer to the Senate on debt limit strategy, which Senate Majority Leader Chuck Schumer (D-N.Y.) and Minority Leader Mitch McConnell (R-Ky.) met on November 18 to discuss; however, they don't appear to be close to a deal. While neither party wants to see the impacts of inaction would have on the economy — particularly the stock market — Republicans stand firm that it is something Democrats should address because of the contribution that recent high price tagged legislation has had on the debt limit.

Not surprisingly, appropriations work seems to have stalled; the House passed nine of its 12 total fiscal year (FY) 2022 appropriations bills, including the Education-Labor-HHS bill, over the summer. So far, three Senate appropriations bills have advanced out of committee, but none have passed the full chamber. Republicans panned Democratic bills and have identified several points of contention but have yet to offer a written counter-proposal.

Defense Bill Update

Lastly, the Senate is hoping to wrap up a massive defense policy bill, known as the National Defense Authorization Act (NDAA), this week. Senators left town before the Thanksgiving recess after they failed to get a deal for votes on 18 amendments to the sweeping bill, including votes on whether to require women to register for the selective service and to repeal the 2002 Iraq War authorization. Last night, the Senate took an initial vote to start winding down the bill, with 60 votes needed to overcome the first hurdle. The vote failed as several Senators' amendments were not included in the



Manager's Substitute Amendment. Therefore, the process will be delayed for the next day or so, and it appears there will be very few if any amendments allowed. The plan is still for the Senate to finish up consideration of the NDAA this week so they can start what looks like an abbreviated conference before passing the final bill in mid-to-late December.

Status of the Build Back Better Act

So, what does this all mean for the Build Back Better (BBB) Act? All eyes remain on Sens. Joe Manchin (D-WV). We anticipate some significant maneuvering in the days and weeks ahead. Additionally, congressional staff is beginning to meet with the Senate Parliamentarian's office to determine what may have to come out of the House-passed version due to Byrd Rule requirements. We still expect the Senate to begin consideration of the BBB Act next week. Byrd rule considerations will continue, and a "vote-a-rama" with several amendments is likely. If the BBB Act passes the Senate, then it is back to the House for a possible final passage if the House accepts the changes made by the Senate. Otherwise, the back-and-forth continues, so stay tuned.

Administrative Updates

Rural Provider Relief Funds Released; Remainder Expected Next Month

HHS [distributed](#) \$7.5 billion in COVID-19 relief to \$40,000 rural providers and will release the remaining approximately \$9.5 billion of the phase 4 provider relief funds in the next few weeks. The exact amount remaining is unclear but is believed to be between \$22 and \$26 billion after this latest disbursement. The funds are also used to reimburse the cost of vaccine administration for uninsured patients. Four House members [introduced](#) bipartisan legislation that would require HHS to distribute all remaining funds by March 31.

New Reporting Requirements to Identify Prescription Drug and Medical Costs.

The Biden Administration implemented new requirements that require health insurers, employer-based health plans, and other group health plans to report on prescription drug and health coverage costs. The requirements, which were issued through an HHS, Labor, and Treasury [interim final rule](#), are President Biden's most recent attempt to provide additional transparency and oversight to prescription drug and health coverage prices. Payors will be required to submit key data to the departments, which will publish a report on the prescription drug price trends and rebates and their impact on out-of-pocket costs for patients.

Nominations

President Joe Biden last week formally nominated Shalanda Young as the chief of the Office of Management and Budget, an agency charged with overseeing federal agencies and administering the federal budget. Young has served in an acting capacity for the same role for most of the last year and previously staffed the House Appropriations Committee.

Carole Johnson is in line to become the director of HHS' Health Resources and Services Administration. Johnson has been serving on President Biden's COVID-19 response team since last December.

After a paperwork delay, FDA nominee Robert Califf will likely not get a committee nomination hearing before the Senate Health, Education, Labor, and Pensions (HELP) Committee until mid-December at the earliest, effectively pushing a Senate floor vote until next year. Notably, HELP Committee Chair Patty Murray (D-Wash.) has already endorsed the nominee.



Surprise Billing Updates: New Drug Price Reporting Rule and HHS Issue Brief; Comments on 2nd IFR Due Dec. 6

A new [interim final rule](#) with a comment period will require insurers to report cost data on frequently prescribed drugs, including premiums, rebates, and total spending by patients, employers, and insurers. HHS will use this information to publish a report on drug pricing trends as required under the No Surprises Act. A fact sheet is available [here](#). The regulations are generally applicable starting Dec. 27, 2021. [Comments](#) are due Jan. 24, 2022.

HHS also released a new 10-page [issue brief](#) defending the No Surprises Act and its accompanying regulations. It faces two impending lawsuits, one from the Texas Medical Association and another from the Association of Air Medical Services. [Comments](#) on the [second interim final rule](#), which details elements of the payer-provider independent dispute resolution process and good faith estimates for self-pay/uninsured patients, are due Monday, Dec. 6.

HHS Delays Rule Allowing Drug Prices to Vary by State Medicaid Agency

The HHS [delayed](#) until July 1 provisions of a Trump-era rule that lets manufacturers give state Medicaid agencies different prices for the same drugs. HHS said it wants to take the extra time “to assure that stakeholders can implement the new policy in a way that ensures patient access and quality of care.”

HHS Directs \$1.5 Billion in Funding to Address Healthcare Shortage in Underserved Communities

The Biden administration [will direct](#) \$1.5 billion to address the shortage of health care workers in underserved communities by supporting the National Health Service Corps, Nurse Corps, and Substance Use Disorder Treatment and Recovery programs in the form of scholarship and loan repayment funding for health care students and professionals in exchange for a service commitment in hard-hit and high-risk communities.

Nominations for New Ground Ambulance Surprise Billing Committee due Dec. 13

CMS is [soliciting](#) nominations for a new Ground Ambulance and Patient Billing Advisory Committee. Nominations can be sent to GAPBAdvisoryCommittee@cms.hhs.gov and are due Dec. 13. The committee is charged with finding ways to protect consumers from ground ambulance surprise medical bills, which were excluded from the No Surprises Act. The committee will make recommendations to help inform future policy changes at the state and federal levels.

[In the Courts](#)

Federal Court Temporarily Blocks CMS Vaccine Mandate Rule in 10 States

On Monday, a federal judge [temporarily blocked](#) the vaccination mandate for staff at all health facilities that receive federal funding from taking effect in 10 states, saying the mandate was “arbitrary and capricious,” would disrupt the health care sector, and should only move forward with clear authorization from Congress. The injunction covers Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming.

Supreme Court Hears Oral Arguments on DSH Payments and 340B Contract Pharmacies

On Monday, the Supreme Court heard oral arguments in *Becerra v. Empire Health Foundation* -- a case focused on whether CMS must include patients who have exhausted their Medicare Part A benefits when calculating hospital Disproportionate Share payments. It’s an incredibly wonky case and, as we best understand, hinges on the definitions of what patients are “entitled to” versus “eligible for.” Today, the court is hearing arguments on *AHA v. Becerra*, a case concerning CMS’ 2018 policy that cuts Medicare pays for outpatient 340B drugs from 106% of ASP to ASP minus 22.5%.



COVID Update

News of the global spread of the latest Covid-19 variant called Omicron spread rapidly over the weekend. Despite no confirmed U.S. cases, most experts believe it is likely here already, prompting New York Governor Kathy Hochul to declare a state of emergency. It will be a few weeks until more is known about current vaccines' severity, transmissibility, and effectiveness. Still, NIH Director Francis Collins warned Omicron is believed to spread rapidly and be highly contagious. It also has many more mutations than the Delta variant. It is unclear at this point whether a new shot is needed but BioNTech/Pfizer and Moderna are already adjusting their COVID-19 vaccines to fight the new variant, which BioNTech says it should have within 100 days. The Omicron variant can be detected on a PCR test.

A WHO-backed South African Lab is reportedly nearing replication of Moderna's vaccine. While they can take it up to the clinical trial stage to avoid legal troubles, they say they ideally want to reach a license agreement with Moderna, which has been unwilling to license its product to other manufacturers. The South African company aims to improve the formula by creating a freeze-dried version that wouldn't require cold storage and improve access to the vaccine in poorer nations. Less than 5% of the continent of Africa is currently vaccinated.

Today, an FDA advisory committee met to discuss an antiviral pill made by Merck and Ridgeback Biotherapeutics. The Biden administration plans to buy 10 million courses of Pfizer's COVID-19 antiviral drug called Paxlovid, which is awaiting FDA emergency authorization. The White House will also partner with private companies in a multi-billion dollar effort to shore up domestic vaccine manufacturing to produce one billion doses annually by July 2022.

On Monday, the White House told federal agencies they could delay penalizing federal workers who failed to comply with the November 22 COVID-19 vaccination deadline. 92% of federal employees have at least one shot, and 96.5% are compliant.

Four senators teamed up to [introduce](#) bipartisan legislation to create a 9-11-style commission to investigate the COVID-19 outbreak and identify lessons learned regarding U.S. preparedness, response, and recovery to better prepare the nation to respond to future outbreaks.