



H&K Health Dose October 5, 2021 A weekly dose of healthcare policy news

Legislative Updates

Congress this Week:

This week, the central focus will be addressing the looming debt ceiling, which Treasury Secretary Janet Yellen has said will hit on/around Oct. 18. Senate Majority Leader Chuck Schumer (D-NY) advanced another bill that would suspend the debt limit through Dec. 16, 2022 and noted action must be taken by the end of this week to stave off potential economic consequences. However, Republicans have already blocked two previous attempts and have shown no indications of backing down and Democrats don't have the votes to overcome a filibuster.

Democrats have a few options. They could amend the current reconciliation instructions to suspend the debt limit, which would only require 50 Democratic votes. However, they are hoping to avoid going that route should changes be needed to the social spending bill that is currently being debated. Reconciliation instructions typically require weeks to draft, giving Democrats just days to make a decision. Other options include raising the debt limit to a specific target, which could peel off enough Republican support, or creating an exception to the filibuster which would allow Democrats to take a simple majority vote on the debt ceiling. However, the latter would require all 50 Democratic Senators and Sen. Joe Manchin (D-WV) has already come out against it. The next few days will be very telling in terms of strategy.

Meanwhile, Congress approved a 30-day extension for expiring surface transportation program funding and set a new deadline of Oct. 31 to get both the \$550 billion Bipartisan Infrastructure Framework and separate budget reconciliation package over the finish line. Progressives have threatened to withhold their support on the bipartisan infrastructure package without the separate reconciliation package of Democratic social priorities. However, those negotiations have stalled as Democratic Senators Joe Manchin (D-WV) and Kysten Sinema (D-AZ) have come out against the \$3.5 trillion price tag. Discussions are now ongoing between progressive and moderate Democrats in both chambers about how to lower the total cost to the \$1.7 to \$2.2 trillion range, including means-testing and time-limiting certain provisions such as expanded Medicare benefits. Pay-fors are also a subject of intense debate- particularly proposals to raise corporate taxes and negotiate drug prices.

Amidst all the drama, the annual appropriations process is chugging along. On Sept. 30, President Biden signed a continuing resolution that funds the federal government through Dec. 3, plus allocates \$28.6 billion for states recovering from hurricanes and wildfires and \$6.3 billion to resettle Afghan refugees. The Senate Appropriations Committee so far has only considered three FY 2022 appropriations bills, but could be releasing the rest in the next few weeks.

Administrative/Regulatory Updates

New Provider Relief Funding (PRF) Guidance Offers Insightful Details into Tranche 4 Funding

HRSA released new [guidance](#) pertaining to the fourth tranche of provider relief funding. The application portal is now open and closes Oct. 26. Notably, eligibility for \$8.5 billion set aside in rural funding will be based on whether the patients are rural, not the providers. In addition, rural health clinics, critical access hospitals and in-home health, hospice or long-term service providers are also categorically eligible. Stay tuned for additional Holland & Knight insights.

Second Surprise Billing Rule Details Independent Dispute Resolution (IDR) Process

On Sept. 30, HHS and DOL jointly [released](#) a second interim final rule implementing provisions of the No Surprises Act. The rule largely centers on the IDR process under which parties can submit their offers for payment along with an administrative fee (\$50 for 2022). Within 30 days, the IDR entity will select one as the binding payment amount and the



non-prevailing party would owe an additional fee. Generally, insurers and patient groups came out in support of the rule while provider groups are concerned that the process is too deferential to payers, given that IDR entities must begin with the presumption that a plan's median in-network contracted payment for a service is the appropriate amount, leaving it to the facility or provider to provide credible and relevant information to prove otherwise. In addition, the rule outlines requirements for “good faith” cost estimates for uninsured/self-pay individuals, expands circumstances to dispute payment denials, and establishes the process for applying to become a certified IDR entity (which will be accepted starting Nov. 1), as well as monthly reporting requirements. The policies in these rules are generally effective Jan. 1, 2022 and comments will be accepted for 60 days following publication in the Federal Register.

340B Contract Pharmacy Drama Continues to Unfold

HHS sent a letter ordering drug maker Boehringer Ingelheim to resume 340B drug discounts to contract pharmacies threatening that failure to do so could result in penalties up to \$5,000 per overcharge. On Sept. 30, PhRMA filed a new suit over a potentially game-changing Arkansas law that requires drug companies to give 340B discounts to all pharmacies contracted by 340B entities. On Oct. 1, HHS rescinded a Trump-era regulation that required health centers to pass 340B discounts for insulin and injectable epinephrine onto patients saying it would have unduly burdened health centers, especially during the pandemic. These are the latest in an ongoing saga which includes HHS reporting several drug companies to HHS’ Office of Inspector General last month as well as several pending lawsuits on the issue.

2022 Medicare Part C and D Premiums Released:

CMS [announced](#) 2022 payment rates for Medicare Advantage (MA) and Part D prescription drug plans. Average MA premiums will decrease slightly from \$21.22 to \$19. Meanwhile, projected enrollment continues to increase. Approximately 40% of Medicare beneficiaries are currently enrolled in an MA plan. Average 2022 Part D monthly premiums will be \$33, a small increase from \$31.47. Medicare Open Enrollment begins Oct. 15 and ends Dec. 7.

HHS Reverses Trump-Era Title X Funding Restrictions

HHS issued a [final rule](#) reversing Trump-era regulations that barred clinics who offer abortion referrals from receiving Title X funding. The new policy is set to take effect Nov. 8. The number of patients served by Title X grants fell by 2.4 million from 2018 to 2020, nearly two-thirds of which was estimated to be caused by the funding restrictions.

FDA Issues Multiple Changes to Approval Criteria

A new [final rule](#) clears an easier and faster pathway to market approval for certain new medical devices under the De Novo Process by giving them a special low-risk classification. The rule becomes effective in roughly 90 days.

The FDA also released new [draft guidance](#) to help ensure complete and accurate EHR data when demonstrating “real world evidence” about a drug’s risks and benefits and to satisfy post-approval study requirements. The guidance is subject to a 60-day comment period before being finalized.

New GAO Study Identifies Shortcomings of Medicare MIPS Quality Program

A new GAO [report](#) based on interviews with provider stakeholder groups concluded that the program is administratively burdensome, has too small a financial stake, and may not help to meaningfully improve the quality of care. MedPAC had previously [recommended](#) to repeal MIPS and start over with a new program.



Senior CMS Official Sheds Light on Future Direction of CMS Payment Models

CMS Chief Operating Officer Jon Blum reiterated that the CMS Innovation Center is looking for a “more simplified set” of Alternative Payment Model options and will not promote higher risk models “just for the sake of having more risk,” citing downsides and possible selection bias. More focus will be placed on risk adjustment, including more accurately accounting for race and ethnicity.

American Rescue Plan (ARP) Funding Stalled As Millions in Mental Health Funding Distributed

According to an Associated Press analysis of financial disclosure reports, states had spent just 2.5% and large cities 8.5% of their initial allotment of ARP funding. The law gives until the end of 2024 to make spending commitments and to the end of 2026 to actually spend the money. States spent the most money shoring up unemployment trust funds while cities primarily used funds to help close revenue shortfalls and fund government services.

Meanwhile, SAMHSA is doling out \$825 million of Consolidated Appropriations Act funding to 231 community mental health centers to help address mental illness, \$1.65 billion of which goes to substance abuse prevention and treatment.

Administration Shake Ups

Lisa Pino, an Obama alum who was most recently executive deputy commissioner of New York State’s Department of Health, was nominated for director of HHS’ Office of Civil Rights, which is responsible for enforcing federal civil rights laws as they apply to health care and patient privacy laws.

Dr. Francis Collins announced his impending retirement from serving as NIH Director after a 12-year run, the only to ever serve for three separate administrations. President Biden intends to pick a replacement before Collins steps down.

CDC veteran Henry Walke will also step aside as head of the CDC’s pandemic response team and will be replaced by Barbara Mahon, who is deputy chief of the enteric-disease branch.

In the Courts

Federal Court Rejects Medicare Co-Pay Assistance for Expensive Specialty Pfizer Drug

A Federal Court rejected Pfizer’s proposal to cover Medicare co-pays for a \$225,000 per year heart medication over concerns that it would violate the Anti-Kickback Statute. Tafamidis is the only FDA-approved treatment for a rare progressive heart disease affecting between 100,000 and 150,000 Americans that leads to heart failure and death.

Opioid Trial to Test Culpability of Major Pharmacy Chains

The first trial over national pharmacy giants' culpability for the national opioid crisis is officially underway, which includes CVS Health Corp, Walgreens, Giant Eagle, and Walmart. None have admitted any wrongdoing.

COVID Update

U.S. COVID-19 deaths have officially passed the 700,000 mark. The number of cases varies significantly by state.

After promising data showing their antiviral drug could cut the risk of hospitalization and death due to COVID in half, Merck announced it plans to seek emergency use authorization soon.



The FDA is expected to extend the expiration date for millions of unused doses of Moderna's vaccine by two months. The agency also [authorized](#) a new rapid, at-home COVID-19 test that is expected to double availability of such tests in the coming weeks.

An FDA advisory committee will meet Oct. 14 and 15 to discuss booster doses of Moderna and Johnson & Johnson's Covid-19 vaccines, including mixing and matching vaccines. On Oct. 26, the same committee will discuss emergency use authorization of the Pfizer vaccine in children ages 5-11.

California Governor Gavin Newsom announced the nation's first vaccine mandate for schoolchildren, requiring that all elementary through high school students get vaccinated pending federal approval for each age group.

A new CDC report found that side effects from a third vaccine dose are similar to those from the second. The Center also [doubled down](#) on its recommendation that it is safe and encouraged for pregnant women to get vaccinated.

U.S. officials are preparing for what could be the biggest surge at the southern border in decades if a COVID-based migrant travel restriction is lifted later this week.