H&K Health Dose June 15, 2021

A weekly dose of healthcare policy news

Legislative Update

Congress This Week

House lawmakers began their floor activity for June this week. On the Senate side, floor activity will focus primarily on confirming President Joe Biden's pending nominations. Regarding healthcare-related nominations, Dawn O'Connell is seeking confirmation to be the Health and Human Services (HHS) Department's Assistant Secretary for Preparedness and Response (ASPR). She testified Tuesday before the Senate Health, Education, Labor, and Pensions (HELP) Committee.

As we enter the busy days before August recess, several deadlines will likely impact what can reasonably get done between now and the fall.

Items that are possible for action over the coming months include:

- Government funding (expires Sept. 30); The House Appropriations Committee is holding markups over the next several weeks. The Senate is off to a slower start, with markups unlikely until at least July, and floor time is uncertain. The only thing that appears certain at this point is, as is typical, the appropriations process won't be complete by Sept. 30, so Congress will likely need to pass a continuing resolution. Then appropriations work will continue into the fall (see more below under the budget section).

- Highway Trust Fund and federal surface transportation programs (expires Sept. 30);

- Debt limit (suspended through July 31, and Treasury will have some flexibility after that date, but to what extent is uncertain. Last month, Secretary Yellen indicated that congressional action could be needed this summer); and;

- Infrastructure (no firm deadline, see more detail below)

Infrastructure Talks Prove A Lot Can Change in a Week

This is considered by many to be make-it or break-it week for bipartisan infrastructure negotiations after President Biden broke off infrastructure negotiations with Sen. Shelley Moore Capito (R-WV) last week and has chosen Sen. Bill Cassidy (R-LA) as her replacement, who brings with him a bipartisan coalition of moderates including lynchpin Democratic vote Joe Manchin of W.V. The groups appear to be closer on final numbers to the tune of half a trillion dollars in new, spending provided Biden can beef up flood resiliency and energy provisions. Pay-fors remains a point of contention, with an infrastructure financing authority repurposing unused COVID-19 relief funds and taxing drivers of electric vehicles at the top of the list, according to Sen. Susan Collins (R-ME), who is involved in the negotiations. Details are still very much in flux as both sides whip support this week.

Suppose a deal cannot be made by the end of the week. In that case, infrastructure provisions will be incorporated into a larger reconciliation bill next month that is expected to tackle more progressive priorities like climate change, expanded social welfare programs, corporate tax reform, and possibly, prescription drug pricing reform. However, it's unclear Democrats will be able to rally the support they need internally for such a strategy, with Sens Joe Manchin of W.V. and Krysten Sinema of Arizona not committing to supporting a second and Sen. Bernie Sanders (I-VT) coming out in opposition to the bipartisan deal that's currently in the works, which Democrats worry may lead to other progressives in the House following suit.

House Budget Committee Chairman John Yarmuth (D-KY) is not overtly optimistic the bipartisan infrastructure talks will pan out and is allowing room for Biden's infrastructure proposals in budget reconciliation instructions that are currently being crafted, setting the stage for a potentially massive omnibus package that could pass without Republican support.

Budget

The House voted 216-206 yesterday to "deem" a $1.5 trillion top-line spending figure for fiscal 2022 funding bills, which will allow appropriators to start work on their bills without voting on a full budget resolution. The total generally reflects the President Biden's proposed budget request. The move also strategically avoids using reconciliation, preserving it for a larger omnibus package later this year. House markups will start next week and continue through mid-July.

Senate Passes the United States Innovation and Competition Act

The Senate passed the United States Innovation and Competition Act (S. 1260) last week. The bill would provide $120 million for programs at the National Science Foundation, the Department of Commerce, the Department of Energy, and the National Aeronautics and Space Administration (NASA). It would also create a directorate of technology and innovation at the National Science Foundation. The Act also establishes a new Supply Chain Resiliency and Crisis Response Program with the national security mission of strengthening critical technology supply chains in the U.S. and with global allies and partners. Additionally, the bill invests in U.S. manufacturing innovation and competitiveness with more than $2.4 billion in funding to enhance and expand the Manufacturing USA network. Despite Senate passage, the bill has a long road ahead as the House process is very much in its infancy. House leadership has not yet decided exactly how to handle the package, and they are still considering options to package or handle committee pieces standalone. Finally, any House product(s) will have to be conferenced with the Senate.

Senate Democrats Continue to Draft a New Drug Pricing Bill

Senate Democrats are crafting an alternative to H.R. 3 amid doubts over whether it can garner enough support amongst Democrats. Senate Finance Committee Chairman Ron Wyden is taking the lead with Senate Majority Leader Chuck Schumer, also engaged on the issue. The details are still in flux, but it's expected to be primarily modeled after the 2019 Grassley-Wyden legislation with some form of negotiation added on, which will likely mean no Republican support. The scaled-down bill would also not achieve the same half a trillion in savings to fund other Democratic healthcare priorities, such as expanding Medicare. The legislative vehicle for the bill remains under consideration, but budget reconciliation is likely. With increased attention to drug pricing after the approval of ADUHELM (aducanumab), we can expect to see draft legislation soon.

Democrats Resume Universal Coverage Push

25 Democrats reintroduced legislation that would create a waiver giving states access to federal funding and regulatory flexibility to implement universal health care coverage. Proposals must cover 95% of residents within five years with equal or greater benefits and be subject to review by an independent panel of experts and HHS approval.

Regulatory Update

Long-Awaited PRF Guidance: More Time & Flexibility; No New Money

HHS released the long-awaited provider relief funding (PRF) guidance on Friday, which includes more time to use funds (for some), reduced reporting burden, and enhanced flexibility to calculate losses. First, there are now four separate deadlines for when providers must spend or return PRF grants, depending on when payments were dispensed. Funds received before June 30, 2020, will still have a June 30 deadline. Providers now have 90 days after deadlines to meet reporting requirements instead of the original 30 days, and the portal is set to open July 1. Reporting will only apply to

providers whose aid totaled $10,000 or more during one of the four payment periods. Finally, providers can calculate lost revenue against actual, budgeted, or “any reasonable method,” though the latter methods come with more robust reporting requirements.

The guidance notably did not address the nearly $24 billion unspent PRF or $8.5 billion for rural providers. HHS Secretary Xavier Becerra told House Ways & Means Committee members last week that a “deadline has not yet been determined” for the tranche of money that has not yet been allocated. He also echoed previous sentiments about wanting more transparency about how those funds are spent and target funds to institutions that need it, such as those mainly serving Medicaid and other low-income patients.

Highly Anticipated Surprise Billing Rule at OMB

The first part of the highly anticipated rulemaking on the No Surprises Act is now under review by OMB, the last stage before being released in the proposed form for public comment. Under the Act, providers can no longer exceed in-network rates. Unresolved claims will be decided by an independent dispute resolution process set to go into effect Jan. 1. Several key decision points must be made in the regulation, including the methodology for determining the qualified payment amount, which is generally the median in-network rate but has several other factors for consideration, including providers’ level of training, patient outcomes, market share, patient acuity, and prior contracted rates. HHS must also craft guidance on the provision that allows out-of-network providers to balance bill a patient who has given consent to non-emergency care.

UnitedHealth Walks Back Highly Controversial New Policy

UnitedHealthcare announced Thursday it would delay implementing its new policy that would retroactively deny patients' E.D. visits that are deemed non-emergencies until "at least the end of the national public health emergency period" after facing a wave of harsh pushback from several provider organizations and medical societies. Anthem rolled out a similar controversial policy in certain states starting in 2017. Critics argue both violate the prudent layperson standard.

HHS Releases Spring Regulatory Agenda

HHS released its spring regulatory agenda, which includes several rules including a highly anticipated and controversial FDA rule with guidelines to consider when determining a product’s intended use, due out in July, and an unexpected move, advancing another controversial Trump-era regulation that would limit the government's ability to use “march in rights” to control prices on drugs developed from federally funded research.

Centene to Repay Billions in Drug Overpayments to State Medicaid Programs

Centene Corp. said it would pay about $143 million to settle claims with Ohio and Mississippi over its pharmacy-benefit billing practices for state Medicaid programs. It will set aside $1.1 billion to resolve similar issues with other states. Ohio Attorney General Dave Yost had accused the managed care company of misleading the state about its pharmacy-related costs, causing its Medicaid program to overpay for services. However, Centene admitted no wrongdoing in the settlements.

MACPAC & MEDPAC Release Annual Reports to Congress

The Medicaid and CHIP Payment and Access Commission (MACPAC) released its June 2021 Report to Congress on Medicaid and CHIP. The report recommended that Congress address high-cost specialty drugs, improve access to mental and behavioral health services, strengthen clinical integration through EHRs, and better integrate care for dual eligibles.

The Medicare Payment Advisory Commission (MEDPAC) also released it's June 2021 Report to Congress. Each June, as part of its mandate from Congress, MedPAC reports on issues affecting the Medicare program and broader healthcare delivery changes.

Fallout Continues After Controversial FDA Approval of Alzheimer's Drug

Three FDA advisory committee members resigned after the agency's controversial decision to approve Biogen's Alzheimer's drug Aduhelm with inconclusive evidence. Today, FDA drug chief Patrizia Cavazzoni said that the FDA's external scientific advisers need to remove emotional overtones from deliberations and focus on scientific decisions. However, she didn't mention the incident specifically. Some experts fear this will also open the door to approving other expensive therapies with inconclusive evidence. The next steps for Aduhelm will be a Medicare National Coverage Determination which will determine the Medicare price, mainly choosing how accessible the drug will be to Medicare beneficiaries.

Private Sector Moves

Humana will acquire One Homecare Solutions, in an effort to grow its value-based home healthcare offerings. The deal is expected to be inked by month's end.

New Studies Indicate Physician Shortfall Closing; Widespread Noncompliance with Price Transparency Rules

A new AAMC study predicts a shortage of up to 48,000 primary care physicians and 77,000 specialists by 2034, down from 55,000 and 86,700 respectively a year ago. They attribute the change to an increased number of GME slots and a growing number of advanced practice practitioners.

A new JAMA study found that only 17% of 100 randomly selected hospitals were fully compliant with the new federal price transparency rule.

COVID Update

COVID-19 cases in the U.S. stopped declining and began to plateau around June 8, according to CDC data. The highly contagious and more dangerous delta variant, first identified in India, now accounts for about 10 percent of U.S. cases and doubles every two weeks. However, vaccines have proven effective against it.

However, U.S. vaccination rates have slowed. Nearly a third of Americans are vaccine-hesitant and more highly concentrated in certain geographic areas, making it easier for variants to take hold and spread. To increase vaccinations in underserved areas, more than 4,200 rural health clinics will receive $100,000 each in federal funds for COVID-19 testing and mitigation, and 14 nonprofit organizations were awarded $125 million for community-based efforts to bolster vaccinations in underserved communities. To better serve Americans with mobility issues, Medicare will also pay an additional $35 per dose for COVID-19 vaccines administered in a beneficiary's home, nearly double.

Employers must track infections among workers and notify the government of deaths and hospitalizations according to new OSHA COVID reporting requirements.

Last week, the FDA failed to reach a consensus on whether vaccines should be authorized for emergency use in pediatric populations or go through the full licensure process. Pfizer so far is the only manufacturer with a vaccine approved in children younger than 16 and will launch a late-stage trial testing its vaccine in children younger than 12 within a few weeks. In addition, Moderna has requested emergency use of FDA authorization for its COVID vaccine in adolescents aged 12 to 17. Pfizer will also examine cases of fully vaccinated people who contracted COVID to assess the need for booster shots.

Biden and other G-7 leaders announced a plan to end the pandemic by 2023, including a combined minimum of 1 billion extra doses of vaccines over the next year with the intent to cover 80% of the world's adult population. The U.S. will give 500 million doses of Pfizer's vaccine to a WHO-backed initiative by mid-2022.

G7 leaders also called for a thorough WHO-led investigation into the origins of the COVID-19 pandemic in China, following U.S. investigations that started a few weeks ago. Two House Republicans are introducing a bill to sanction top Chinese health officials until China complies with foreign investigations.

Novavax's COVID-19 shot was found to be 90% effective and safe in a late-stage study. The drug is easy to store and transport and is expected to be a key component of boosting global vaccine rates, particularly in low and middle-income countries. The U.S. government also plans to buy about 1.7 million courses of Merck & Co's experimental treatment for COVID-19 patients who have not been hospitalized, which is pending FDA authorization. As a result, Merck expects to have more than 10 million doses available by year's end.