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H&K Health Dose– April 20, 2021

A weekly dose of healthcare policy news

Will Biden Compromise on Infrastructure?

The Biden administration is hammering out the details for Part 2 of its infrastructure package dubbed "the American Families Plan," which is expected to focus on healthcare and other "human infrastructure" provisions. Biden reportedly plans to release the package by April 28, when he will address a joint session of Congress. The speech will fall right before the President's 100th day in office.

The package could amount to $1 trillion in additional spending plus $500 billion in new tax credits, though details are still very much in flux. The second package is expected to be paid partially through a combination of prescription drug pricing reforms and a tax increase on upper-income Americans and investment income, a tough sell for Republicans. However, there is still no legislative text on the infrastructure proposal, and it is not clear when or how Congress will act on healthcare measures. What is possible remains unclear and depends on whether Biden compromises and pursues a bipartisan approach or attempts to advance a package with solely Democratic support.

Biden did meet yesterday (4/19) with a bipartisan group of lawmakers during which he reportedly instructed Republicans to offer their proposal on infrastructure by next month. Sen. Roy Blunt (R-Mo.), a senior appropriator and member of Senate Republican leadership, said an infrastructure package of about $600 billion to $700 billion that focuses on traditional items like roads and bridges "could be acceptable." Senator Joe Manchin's (D-WV) proposed alternative to increase the corporate tax by 4% instead of 7% is also reportedly gaining traction among moderate Democrats.

Round 2 of FCC COVID Telehealth Program Funding Portal Opens April 29 Closes May 6

The FCC will accept applications for Round 2 of its COVID-19 Telehealth Program from 12 pm E.T. on April 29 until 12 pm E.T. on May 6. This differs from Round 1, in which applications were reviewed and awarded on a rolling basis. Round 2 funding totals just under $250 million and supports reimbursement for telecommunications services, information services, and connected devices necessary to enable telehealth during the pandemic. Notably, Round 1 applicants who did not receive funding will receive preference in Round 2 applications and can update their prior application. The FCC has also now created clear metrics with a scorning mechanism to evaluate Round 2 applications. Applicants who demonstrate the following metrics are prioritized: 1) Hardest-Hit Area; 2) Low-Income Area; 3) Round 1 Unfunded Applicant; 4) Tribal Community; 5) Critical Access Hospital; 6) Federally Qualified Health Center (FQHC)/FQHC look-alikes or a Disproportionate Share Hospital; 7) Round 2 New Applicant; and 8) Rural Country. For additional information, review the Application Process Guidance. Questions should be directed to Round2TelehealthApplicationSupport@usac.org.

$150 Million in Grant Funding for Health Center Look-alikes

Health and Human Services (HHS) announced the availability of $150 million in grant funding to community-based health care providers to support approximately 100 Health Center Program look-alikes to respond to and mitigate the spread of COVID-19; strengthen vaccination efforts; and enhance health care services and infrastructure. The funding will be distributed through the Health Resources and Services Administration (HRSA) and was made available through the American Rescue Plan. Grant applications are due by 11:59 pm E.T. on May 14, 2021.

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E&C Leaders Encourage Enforcement of Hospital Transparency Rule

Bipartisan leadership of the House Energy and Commerce Committee sent a letter to the Health and Human Services (HHS) expressing concerns about implementing the Trump administration's Hospital Price Transparency Final Rule. The letter cites reports of hospitals failing to comply with the new regulation, which went into effect on Jan. 1, 2021, and urge HHS "to revisit its enforcement tools, including the amount of the civil penalty, and to conduct regular audits of hospitals for compliance." Under the regulation, hospitals are required to make public a machine-readable file listing all standard charges for items and services and to publish charges for the hospital's 300 most shoppable services in a consumer-friendly format. The letter was signed by Chair Frank Pallone (D-N.J.), Ranking Member Cathy McMorris Rodgers (R-Wash.), Health Subcommittee Chair Anna Eshoo (D-Calif.), and Health Subcommittee Ranking Member Brett Guthrie (R-KY.).

Legislation on Tax Treatment of Provider Relief Funds Introduced

H.R. 2079, the Eliminating the Provider Relief Fund Tax Penalties Act of 2021 was recently introduced by Rep. Cindy Axne (D-IA) and Rep. Neal Dunn (R-FL). The intent of this bill is to clarify that providers who received funding from the Public Health and Social Services Emergency Fund (PHSSEF) would not have to count it as gross income. This bill would ensure that all providers who received these funds, regardless of their tax status, are not subject to taxation on these funds. This proposal also guarantees that any expense attributed to the provider relief fund are tax deductible.

Social Determinants Accelerator Act Introduced

On April 14, Rep. Cheri Bustos (D-IL),Tom Cole (R-OK), Jim McGovern (D-MA), and Markwayne Mullin (R-OK) re-introduced H.R. 2503, the Social Determinants Accelerator Act. The legislation would assist states and communities in devising strategies to leverage existing programs and authorities in addressing all aspects of health, including food, housing, transportation, and workforce. This legislation provides funding for states and local entities to devise innovative approaches to coordinate services and improve outcomes.

[Medicaid] Times are a Changin'

HHS overturned a last-minute Trump-era approval that extended Texas's Medicaid 1115 waiver for ten years. The wavier included federal funding for the state's uncompensated care funding pool that reimburses hospitals for caring for the uninsured and is now set to expire Sept. 30, 2022. CMS cited a lack of notice and comment, though CMS said it is willing to work with Texas and review an extension application. It is unclear if Texas plans to submit one. This change could pressure the state to expand Medicaid, particularly given enhanced federal matching rates under the recently passed American Rescue Plan. In addition to the Texas waiver, the Trump Administration approved a 10-year uncompensated care pool 1115 waiver in Florida, and a 10-year 1115 waiver to implement an aggregate cap on federal Medicaid spending in Tennessee, two other non-expansion states. CMS under the Biden Administration has yet to issue any letters to revoke these waivers; however, we will be watching closely for any action in these two states as the Biden Administration continues to make its Medicaid priorities known.

Regarding postpartum coverage, HHS approved a handful of Medicaid waivers. Georgia's extends postpartum coverage from 60 days to six months for women earning up to 220% of the federal poverty level (FPL). Missouri's extends postpartum coverage to one year after beneficiaries diagnosed with a substance use disorder who have incomes up to 196% of the FPL. Illinois' extends coverage to one year for beneficiaries with incomes up to 208% of the FPL. Several other states are in the queue, including New Jersey, Indiana, Virginia, and Massachusetts. The American Rescue Plan allowed states to extend Medicaid postpartum coverage for up to one year without asking CMS. The Medicaid and CHIP

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Payment and Access Commission (MACPAC) has previously recommended the program be made permanent and mandatory.

COVID This Week

According to new CDC estimates, over half of all adult Americans have received at least one vaccine dose. About one-third are fully vaccinated, and anyone 16 and older in every U.S. state is now eligible for the shot. Simultaneously, global cases hit an all-time high, with 5.2 million new cases reported in one week. CDC Director Dr. Rochelle Walensky said the country remains in a "complicated stage," drawing attention to the rise in cases among younger, unvaccinated Americans. Vaccine demand is starting to decline in some regions, and experts worry they may not be able to reach the remaining Americans who do not want to get vaccinated and fall short of herd immunity.

The Biden administration announced the availability of nearly $150 million of American Rescue funds to community-based health care providers to aid their response to COVID-19. These funds will support approximately 100 Health Center Program "look-alikes" to mitigate the spread of COVID-19, strengthen vaccination efforts, and enhance healthcare infrastructure. Biden will also allocate $1.7 billion to track the spread of Covid-19 variants. This week, several HHS agencies also published several new resources to help states, vaccination providers, and others leading COVID-19 response activities improve access to vaccines for people with disabilities and older adults with mobility issues.

After a temporary pause, Anthony Fauci said the government would likely move to resume the use of Johnson & Johnson's vaccine later this week, and J&J reported that no additional cases of severe blood clots had been reported. Moderna announced its vaccine remains more than 90% effective against illness and more than 95% effective against severe disease after six months, results that are similar to Pfizer. Pfizer said people would likely need a third COVID-19 vaccine within a year and that annual booster shots may also be necessary. No-prescription, rapid COVID-19 home tests are set to become available at nationwide retailers beginning this week.

175 global leaders and a group of 10 U.S. Senate Democrats have called on President Biden to issue a temporary patent waiver for other countries to produce their vaccines. No response from Biden as of yet.

The U.S. will recommend against traveling to 80% of countries. A WHO panel came out against any requirements that travelers show proof of their COVID-19 vaccination to enter certain countries, citing concerns over inequalities.

News on the NIH/FDA Front

A final rule released Friday will exclude software that stores, transfers, or displays clinical lab tests or other medical data from FDA regulations governing medical devices. The new rule clarifies that software intended to encourage a healthy lifestyle unrelated to the diagnosis or treatment of a disease or condition isn't required to undergo FDA review. The law also clarifies that health facilities' administrative support systems that track billing and claims information or appointment schedules are outside this scope.

The HHS is reversing a Trump-era policy that effectively stopped the NIH from funding research using tissue from aborted fetuses. The National Institutes of Health will provide $155 million in funding for a Phase 3 clinical trial that tests up to 7 existing prescription and over-the-counter medications to be repurposed to treat mild to moderate symptoms of COVID-19.

The Mayo Clinic announced this week that it co-founded two new companies focused on the use of remote patient monitoring devices and predictive algorithms using artificial intelligence technology, one of which is expected to seek FDA authorization for an algorithm that would aim to predict and prevent heart failure later this year.

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Biden Officially Reverses Gag Rule

The administration formally announced its intention to roll back Trump-era changes to the Title X program with a notice of proposed rulemaking that would revert back to 2000 policies with a few minor changes. A Biden HHS analysis found that the 2019 changes that kept Title X grantees from talking about or referring patients for abortion services reduced the number of Title X grantees by 1,000 and left several states with limited or zero access to Title X services. The changes also disproportionately impacted access to family planning services for low-income, uninsured, and minority populations. President Biden's "skinny" budget would increase the Title X program's funding by 18.7%, though this budget is intended to serve as more of a blueprint for Congress.

Provider Community Seeks Clarification on Information Blocking Rules

Information blocking rules that went into effect on April 5 are causing confusion among providers due to a lack of guidance from the Office of the National Coordinator (ONC). According to one industry survey, 70% of respondents knew about the rules, but nearly half hadn't made any changes to comply or didn't know how to comply. The changes stem from the 2016 21st Century Cures Act, which prohibits stakeholders from blocking access to, exchanging, or using health information.

CBO Analysis of Drug Negotiation

The Congressional Budget Office (CBO) analyzed H.R. 3, introduced in the 116th Congress, to determine the impact of reduced revenues on the pharmaceutical industry's productivity. H.R. 3 would have required the HHS Secretary to negotiate prices for drugs and to subject manufacturers who did not participate in negotiations to an excise tax.

In its analysis, CBO concluded that H.R. 3 would reduce manufacturers' expectations about future revenues because of the new negotiating leverage of the Secretary. In turn, the prospect of such lower revenues would make investments in R&D less attractive to pharmaceutical companies. CBO estimated that, under the bill, approximately eight fewer drugs would be introduced to the U.S. market over the 2020–2029 period and about 30 fewer drugs over the subsequent years.

Pressure Mounts to Select an FDA Commissioner

Last Monday, Acting Food and Drug Administration Commissioner Janet Woodcock named Patricia Cavazzoni as her successor to be the permanent Director of the FDA Center for Drug Evaluation and Research. The decision has left many to speculate whether Acting Commissioner Woodcock expects to be named as the permanent FDA Chief, or if she wanted to secure long-term leadership of the drug center before ultimately retiring. Pressure is mounting for Biden to make a pick amid the ongoing COVID-19 pandemic. Woodcock remains in the running for the permanent job; however, some politicians and advocacy groups have pushed back on her potential nomination over concerns about past opioid approvals under her watch. Accordingly, the shortlist of candidates to lead the FDA continues to expand. The most recent name added to the list is Michelle McMurry-Heath, President and CEO of Biotechnology Innovation Organization (BIO).

Key HHS Nominations Hearing and Recent Hold

The Senate Finance Committee held a hearing last week on Chiquita Brooks-LaSure's nomination to lead CMS and Andrea Palm to serve as HHS Deputy Secretary. Both are Obama administration alums. The hearing was widely described as non-contentious, and both are expected to be confirmed. However, earlier this evening, Senator John Cornyn (R-TX) placed a hold on the confirmation of Brooks-LaSure due to the aforementioned administration's recent rejection of Texas' request to extend its Medicaid waiver, which the Trump administration had previously approved.

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Senate Majority Leader Chuck Schumer (D-NY) can decide how long to honor Cornyn's hold. It's highly unlikely he'd allow Cornyn's objection to derail the confirmation.

Republicans Down Another Heavy Hitter

Rep. Kevin Brady (R-TX) announced last week that we won't seek re-election in 2022. Brady is in his 13th term and currently serves as The Ranking Member of the House Ways & Means Committee, which he formerly chaired. The seat is expected to remain in Republican hands, but Brady's exit underscores a recent drain of senior GOP leadership.

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