



H&K Health Dose June 1, 2021 *A weekly dose of healthcare policy news*

Legislative News

Congress this Week

Congress returns from Memorial Day recess on June 7. Notably, Congress has missed many of the arbitrarily set deadlines for Memorial Day, including infrastructure that may set the stage for a long congressional summer.

Infrastructure Package Update

The White House has now pushed out its deadline for infrastructure as it continues to negotiate with the GOP. Last week, Senate Republicans unveiled a \$928 billion infrastructure counteroffer that includes over a quarter trillion in new spending but sticks to more traditional physical infrastructure items such as roads, bridges, airports, water, rail, and broadband and still falls well short of Biden's latest \$1.7 trillion offer. Tomorrow, President Biden will meet with Senator Capito, lead Republican negotiator on infrastructure, to find a compromise. Among the sticking points between the two parties: the definition of infrastructure—which Biden wants to broaden to include "human infrastructure" priorities like child care and senior care—the final price tag- and how to pay for it. Republicans are drawing a hard line on tax increases, which remains a primary component of Democrats' plan to pay for it. Meanwhile, Republicans' counter of siphoning already sanctioned CARES Act pandemic-related spending is considered DOA to Democrats. Democrats are increasingly considering turning once again to the reconciliation process where they would not need Republican support.

Biden Administration FY 2022 Full Budget - Health Proposals

President Biden [released](#) his full FY 2022 budget last Friday. Find the White House fact sheet [here](#), and the HHS Budget in Brief [here](#).

The \$6 trillion proposal calls for \$1.7 trillion in discretionary spending and \$4.0 trillion in mandatory spending. Historically, the President's budget request kicks off the congressional budget process, serving as a starting point for lawmakers to determine funding levels and national spending priorities. Congress is under no obligation to adopt all or any of the President's budget.

Under the budget, health spending would increase by almost a quarter of its current funding level, which reflects \$6.5 billion to build a new health research agency (Advanced Research Projects Agency for Health), plus boosts to most healthcare agencies' bottom lines to tackle priorities like addressing health equity, enhancing the nation's public health preparedness, and addressing the ongoing opioid crisis.

Of note, the budget specifically requests \$25 million for CMS to advance health equity directives, \$400 billion for an expansion of home and community-based healthcare services, \$2.2 billion in increased funding for the Indian Health Service, and \$3 billion on programs to reduce minority maternal mortality. The budget also calls for \$163 billion to permanently expand ACA premium tax credits to those making at or above 400 percent of the federal poverty line (FPL), building on the *American Rescue Plan Act* extension of these credits for 2021- 2022.

The plan also reiterates President Biden's campaign calls to expand Medicare benefits to include dental, hearing, and vision, Medicare prescription drug pricing reform, and close the Medicaid coverage gap in non-expansion states. However, it stopped short of providing specifics or including budgetary requests for these priorities, instead directing Congress to take the lead on passing legislation in these areas, despite calls from House Democrats to include them.



House Ways and Means Committee Chairman Richard E. Neal (D-MA) announced today that the committee would hold a hearing on the President's Proposed FY 2022 Budget with the Department of Health and Human Services Secretary Xavier Becerra on Tuesday, June 8, 2021, at 10:00 a.m. Members of the public may view the hearing via a live webcast accessible at the [Ways and Means committee's website](#).

The House Appropriations Committee plans to do subcommittee markups of their FY 2022 spending bills in June, with floor passage expected in July. It is currently unknown when the Senate Appropriations Committee plans to markup their bills, but it will most likely lag behind the House. Current funding is scheduled to run out by September 30.

Democratic Lawmakers Revive the Push for a Public Option.

Senator Patty Murray (D-WA) and Representative Frank Pallone, Jr. (D-NJ)—the respective chairs of Senate Committee on Health, Education, Labor and Pensions and the House Committee on Energy and Commerce—jointly [issued](#) a request for information (RFI) last week. The RFI solicits broad input on designing a public option, including eligibility, benefits packages, reimbursement rates, prices, premium support, and interaction with other programs. Legislative action on a public option is unlikely in the near term; responses will likely shape conversations around the 2022 midterm elections. Responses to the RFI are due by July 31.

Senate Health Committee Advances Two Maternal Health Bills

The Senate health committee approved two additional maternal health-focused bills last week to add to the several that have already advanced. The bipartisan *Maternal Health Quality Improvement Act* would establish grants to fund racial and ethnic bias training for health care providers, encourage integrated health care services for pregnant and postpartum women, and fund improved maternal health data collection and quality improvement initiatives. A second bill targeted towards improving health in rural areas would create grants for rural providers to develop obstetric networks, improve data collection, and expand telehealth.

Bill Introduced to Increase Foreign Medical Residents to Address Physician Shortage

Legislation was reintroduced last week that would potentially increase the cap on the number of international physician candidates allowed to attend US residency slots and remain in the country after training if they work in underserved areas. The legislation is intended to address anticipated physician shortages that would hit rural areas especially hard. The bipartisan bill has the support of the American Hospital and Medical Associations and was originally introduced by Sen. Amy Klobuchar (D-MN) in 2019 but did not advance out of committee. The version introduced last week includes several tweaks to draw more support, including reauthorizing the program for another three years.

Regulatory News

CMS reweights 2020 MIPS cost scores

CMS announced that all Merit-based Incentive Payment System (MIPS) eligible clinicians will see their 15 percent cost performance category zeroed out and redistributed to other performance categories. The agency reports that the volume of data available to calculate the scores for the cost measures significantly decreased overall compared to the prior years' data. As a result, CMS indicates it cannot reliably calculate scores for the cost measures to capture and reflect MIPS participants' performance adequately. Eligible professionals do not need to act on this announcement as cost category performance relies on administrative claims data.



Biden Administration Hands Down Key Delays/Decisions Impacting Drug and Device Manufacturers and Experimental Therapies

In new [enforcement guidance](#), the FDA pushed back by another two years the deadline by which medical device manufacturers must start using unique device identifiers, citing the COVID-19 pandemic. Manufacturers now have until Sept. 23, 2023, to become compliant.

HHS and FDA officials [announced](#) last week they would reinstate the FDA's Unapproved Drugs Initiative, an initiative dating back to 2006 that requires older drugs marketed without FDA approval to demonstrate safety and effectiveness to remain on the market. The announcement reverses a decision by Trump's HHS to eliminate the program in November and promises new forthcoming guidance. In the interim, the FDA will continue to exercise its existing general risk-based approach to prioritizing regulatory and enforcement action.

The Biden administration also issued a [proposed rule](#) that would delay by six months another Trump-era rule that requires drugmakers to include the patient discounted price when reporting the "best price" for drugs under Medicaid's drug rebate program. The new requirement that manufacturers participating in a value-based purchasing arrangement must report multiple best prices for Medicaid-covered drugs was supposed to begin Jan. 1, 2022, but is now delayed until July 1, 2022. The agency cited additional time to address stakeholder input and concerns.

The FDA also [announced](#) last week that it would also be cracking down on permit requirements and oversight for stem cell experimental therapies.

One Key Health Post Filled; Another Still Vacant as Pressure Mounts

Last week, the Senate voted 55-44 to confirm Chiquita Brooks-LaSure to lead the Centers for Medicare & Medicaid Services, with five Republicans joining Democrats to support her nomination. The delayed nomination comes just in time for peak rulemaking season.

Meanwhile, the clock is ticking on Acting FDA Commissioner Janet Woodcock. There is a 210-day statutory limit for how long an acting commissioner can work in a Senate-confirmed role, which means President Biden must nominate her or someone else on a permanent basis before the end of August. Many are saying not having a permanent person in place is holding the agency back at a critical point with the pandemic recovery because acting commissioners cannot start any new initiatives or change the overall structural direction.

Private Sector

Google has teamed up with national hospital chain HCA Healthcare Inc. to develop healthcare algorithms using patient records to improve operating efficiency, monitor patients, and inform clinical decision making. This move is the latest in what has been a recent trend of collaborations between provider organizations and technology firms.

COVID Update

According to [new federal guidance](#), employers can require employees to be vaccinated against COVID-19.

After weeks of declining demand, the latest data shows a bump in the doses administered per day. According to the latest CDC data, in 25 states, DC, and Guam, more than half of adults are fully vaccinated. The states with the lowest rates of fully vaccinated adults continue to be in the South. New findings from a Kaiser Family Foundation study show that financial incentives and paid time off have proven the most effective strategies to inoculate more Americans. Free transportation was also found to be popular among Black and Hispanic Americans.



Federal health officials are ramping up surveillance of a highly transmissible COVID-19 variant first identified in India. The Pfizer vaccine has proven "highly effective" against it, but experts warn that under-vaccinated areas in the US could become hot spots for the mutation.

The WHO announced an ambitious new goal to vaccinate at least 10% of every country's population by September, focusing on low- and middle-income countries, including all healthcare workers. The organization hopes to then immunize 30% of each country's population by the end of the year. The WHO President urged member states and wealthier nations to immediately share doses with the UN-backed Covax program, which seeks to distribute vaccines equitably worldwide.

Meanwhile, Biden is ramping up pressure on the WHO for a more aggressive investigation into the pandemic's origins after Chinese officials were reportedly dismissive of investigations during a recent WHO summit. But it has few powers to investigate on its own. WHO emergencies chief Mike Ryan said Friday that the organization was still determining how to proceed with their investigation and noted that "all hypotheses remain open."