



## H&K Health Dose January 18, 2022

A weekly dose of healthcare policy news

### Legislative Updates

#### **Congress This Week**

This week, the House and Senate are in session, following the Martin Luther King holiday. Progress on the *Build Back Better Act* (BBBA) continues to be on hold in the Senate. However, the White House seeks to "reset" talks on BBBA, aiming to salvage climate change measures but pare down items like the child tax credit and paid family leave to appeal to Senator Joe Manchin (D-WV) as soon as this week.

Meanwhile, Majority Leader Chuck Schumer (D-NY) announced last week that the Senate would vote on voting rights legislation in the coming days. This evening, the Senate began debate on the *John Lewis Voting Rights Act* and the *Freedom to Vote Act*. The *Freedom to Vote Act* would establish national election standards. The *John Lewis Voting Rights Advancement Act* would reinstate a core provision of the *Voting Rights Act* that required states with a history of racial discrimination in voting to get approval from the Justice Department before changing their election policies. As expected, if Republicans block the measure, the chamber will vote on changing the Senate's rules.

While there is a great deal of uncertainty around several policy issues like the BBBA, additional details and formal funding requests regarding a supplemental COVID relief package should come into focus soon. The Democratic and Republican leaders of the House and Senate Appropriations Committees held an initial meeting to discuss whether a bipartisan package could come together. These efforts would be in addition to more military personnel for hospitals and a new [website](#) and delivery program for free at-home tests that starts on Wednesday, January 19.

Possible priorities include more resources for testing and funding and addressing the global vaccine gap. Additionally, a great deal of the focus in Congress has been on non-health-related establishments that have been impacted by the pandemic, such as restaurants and gyms. There has also been discussion of the inclusion of disaster relief funding to provide relief for tornado-ravaged parts of the South and Midwest and the fires that impacted Colorado.

The government's current continuing resolution (CR) funding expires on February 18. The next appropriations bill, either an Omnibus for the remainder of Fiscal Year (FY) 2022 or another short-term CR, provides a vehicle for addressing COVID relief measures. However, congressional leaders could decide to move more quickly.

#### **Quick Legislative Takes:**

- The [Republican Healthy Future Task Force Subcommittee](#) on Treatments has issued a request for information (RFI) from health care stakeholders regarding medical innovation to inform legislation to speed the development and availability of treatments, devices, and diagnostics to address increasing patient costs. Those interested in responding to the RFI should fill out this [form](#) by March 11, 2022.
- Seven Democrats led by Sen. Elizabeth Warren (D-MA) and Rep. Jan Schakowsky (D-IL) sent a [letter](#) encouraging the President to immediately mandate the transfer of mRNA vaccine technology and create publicly owned manufacturing facilities to accelerate global production of COVID-19 vaccines.
- Healthcare CEO Sheila Cherfilus-McCormick (D) will be sworn in today to fill the South Florida District 20 seat of the late Rep. Alcee Hastings (D), having defeated Republican challenger Jason Mariner.
- The Senate Health, Education, Labor, and Pensions (HELP) Committee advanced the nomination of Dr. Robert Califf to serve as commissioner of the Food and Drug Administration (FDA) in a 13-8 vote. This nomination now goes to the Senate floor for the Senate's full confirmation vote.



## Administrative/Regulatory Updates

### **COVID-19 Public Health Emergency Extended; With It Key Telehealth and Other Flexibilities**

On Jan. 14, HHS Secretary Becerra extended the COVID-19 Public Health Emergency (PHE) an additional 90 days, which carries important flexibilities for telehealth, emergency use authorization for drugs and devices, patient cost-sharing, and certain oversight and enforcement activities. By law, the PHE must be renewed in 90-day increments.

### **New White House Task Force to Focus on New Variants and Other Threats**

The White House is reportedly planning to launch a new New Pandemic Innovation Task Force to focus on countermeasures to protect against future Covid-19 variants and other pandemic threats. The group will be housed within the White House Office of Science and Technology Policy (OSTP) and will focus on interagency solutions, including vaccines, diagnostic tests, and other treatment solutions.

### **CMS Takes Middle Ground Approach to Medicare Coverage of Controversial Alzheimer's Drug**

CMS announced a preliminary National Coverage Determination (NCD) for the new Alzheimer's drug, Aduhelm, limited in scope to patients participating in a CMS or NIH clinical trial. The agency hopes this approach will help generate the necessary evidence to address questions related to the drug's level of necessity to help inform future coverage determinations. The drug has been mired in controversy over the last several months due to its high price tag, which contributed to a subsequent hike in Medicare premiums, coupled with what many describe as inconclusive evidence of its effectiveness.

### **MedPAC Advances Controversial Recommendations for Physician Payments**

During its January [meeting](#) last week, MedPAC advanced several draft recommendations, including one to freeze Medicare Physician Fee Schedule (MPFS) rates in 2023 which the American Medical Association (AMA) immediately opposed and a new potential Alternative Payment Model (APM) strategy that would entail a single population-based shared savings model with multiple tracks including a no-risk option for safety net, rural and independent practice providers.

### **ONC Publishes Details for Highly-Anticipated Health Information Exchange Framework**

HHS' Office of the National Coordinator for Health Information Technology (ONC) published its long-anticipated Trusted Exchange Framework and the Common Agreement (TEFCA). Entities will soon be able to apply and be designated as Qualified Health Information Networks (QHINs), connecting to one another and enabling participants to engage in communal health information exchange. The TEFCA Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) Roadmap was also published the same day, which outlines how TEFCA will accelerate the adoption of FHIR-based exchange across the industry.

## Judicial Updates

### **Supreme Court Rules on Federal Vaccine Mandates**

On January 13, 2022, the Supreme Court of the United States (SCOTUS) released two emergency opinions regarding federal vaccine rules. The SCOTUS ruling 5-4 stayed the injunctions that barred enforcement of the CMS COVID-19 vaccine mandate in 24 states. The Court emphasized that one of HHS' functions is to ensure that health care providers



protect their Medicare and Medicaid patients' health and safety and [found](#) that these "unprecedented circumstances provide no grounds for limiting the exercise of authorities the agency has long been recognized to have." Justices Thomas, Alito, Gorsuch, and Barrett dissented. Facilities in the 24 states impacted have until March 15 to implement the vaccine requirement for their employees, while facilities in the 25 states not involved in the litigation have until February 28 to ensure employees are fully vaccinated.

In a 6-3 [decision](#), SCOTUS halted enforcement of the Occupational Safety and Health Administration's (OSHA) vaccinate-or-test mandate for businesses with 100 or more employees, which means that OSHA cannot enforce without additional court rulings.

The third federal vaccine rule—the federal contractor vaccine mandate—remains subject to multiple legal challenges, and, at this time, the government is blocked from enforcing the mandate nationwide. In response to the nationwide injunctions, the Office of Management and Budget (OMB) issued guidance stating "the Government will take no action to enforce the clause implementing requirements of Executive Order 14042, absent further written notice from the agency, where the place of performance identified in the contract is in a U.S. state or outlying area subject to a court order prohibiting the application of requirements pursuant to the Executive Order." The Court has not yet weighed in on this mandate.