



H&K Health Dose June 8, 2021 *A weekly dose of healthcare policy news*

Legislative Update

Congress This Week

Both chambers of Congress returned from the Memorial Day Recess this week to begin the June legislative session. The Senate will continue considering the Endless Front Act (the \$100 billion technology innovation package). Additionally, budget hearings across all agencies are ongoing this week.

Biden/Capito Infrastructure Negotiations Collapse

President Biden and Senator Shelley Moore Capito (R-WV) met again this week to negotiate a bipartisan agreement on infrastructure. Biden on Friday rejected the Republicans' offer, proposed by Capito to add about \$50 billion to their \$928 billion infrastructure plan. With Biden calling for \$1 trillion in new spending, both sides remained hundreds of billions apart. Accordingly, it has been reported that bipartisan infrastructure talks between Biden and Capito are over as of this evening. The president will now focus on working with a bipartisan group of 20 senators.

Meanwhile, Senate parliamentarian Elizabeth MacDonough has effectively ruled that Democrats can only use the budget reconciliation process one more time during 2021. MacDonough determined that a revision to the 2021 budget resolution cannot be automatically discharged from the Senate Budget Committee, requiring Democrats to secure at least one Republican vote on the panel whose members are split 11-11 along party lines. Democrats had hoped to use reconciliation to advance the President's Build Back Better agenda – passing the American Jobs Plan, the American Families Plan, and health care reform proposals to expand the Medicare program and lower the price of prescription drugs over multiple reconciliation packages. Instead, likely, Democrats will only be able to use reconciliation to pass one legislative package with a simple majority vote during the remainder of this year.

Pascrell Requests GAO Report on Private Equity in Health Care

House Ways and Means Subcommittee on Oversight Chair Bill Pascrell (D-NJ) has [asked the GAO](#) to investigate the impact of private equity investment in the health care industry. In his letter, he asks that GAO complete an analysis examining private equity investment and subsequent bankruptcies, including how many facilities or providers declared bankruptcy following private equity investments; how many facilities closed; in what industries were such bankruptcies most common; how the closure or bankruptcies rates compare to those of other facilities; whether there are geographic trends; and to what extent a closure resulted in the loss of services for a community. The panel's request and the ensuing report are potentially setting the stage for future legislative action.

New Bill Aims to Address Primary Care Physician Shortage

A bill was introduced in the House Tuesday that would permanently authorize the Teaching Health Center Graduate Medical Education program that trains primary care doctors and boost funding to more than \$500 million per year for a decade. The Doctors of Community Act is expected to fund an additional 100 medical education programs and 1,600 resident and physician slots across the country and is expected to be introduced in the Senate next week.

Warren Seeks Gilead Testimony for Hearing on Pharmaceutical Competition

Sen. Elizabeth Warren (D-MA) [invited](#) Gilead's chief executive to testify in a hearing on the pharmaceutical market competition scheduled for June 16 before the Senate Finance Subcommittee on Fiscal Responsibility and Economic Growth. Warren, chair of the subcommittee, states that the panel is interested in focusing on anti-competitive behavior that impacts consumer access, innovation, and pricing.



Regulatory/Administrative/Judicial Update

The FDA's Very Busy Week

In what is being considered a controversial move, yesterday, the Food and Drug Administration (FDA) approved the use of the experimental drug aducanumab, also known as Aduhelm, for early phases of Alzheimer's disease despite an FDA advisory committee concluding last year insufficient evidence to support the treatment's effectiveness. The drug was approved through the FDA's Accelerated Approval Program, which allows for the earlier approval of a drug for a serious or life-threatening illness even if more study into the drug's benefits may be needed. The last time the FDA approved a novel therapy for the illness was in 2003.

Several Biden administration health agencies jointly released a [detailed report](#) with recommendations to strengthen the U.S. pharmaceutical supply chain that centers on four pillars: 1) boost local production and international cooperation; 2) promote innovative, resilient research, development, and manufacturing processes; 3) establish robust quality management protocols, and 4) drive constant data-driven improvement. The plan follows up on Biden's executive order. It includes an initial commitment of approximately \$60 million in American Rescue Plan Act funding to boost domestic manufacturing capacity of active pharmaceutical ingredients.

The FDA also published [new guidance](#) for complying with the Drug Supply Chain Security Act and ensuring a more secure drug supply chain, including how to identify and notify the FDA of illegitimate drug products, include product identifiers on product packages, and how to enhance drug distribution security.

The FDA updated a [web posting](#) reemphasizing a July 2020 Consumer Alert about regenerative medicine therapies.

HHS is [asking a judge to dismiss](#) PhRMA's lawsuit pertaining to the FDA's rule that would allow states to import Canadian drugs on the basis that it is not close to such a policy, and it is unclear if Canada would allow exports.

HHS Launches Health Emergency Focused Venture Capital Public-Private Partnership

HHS [unveiled](#) a new type of public-private partnership that will use venture capital to accelerate private sector development of breakthrough products and technologies to enhance the public response to future health emergencies and security threats. HHS' Biomedical Advanced Research and Development Authority (BARDA), part of its preparedness and response arm, will provide the nonprofit Global Health Investment Corporation (GHIC) with a minimum of \$50 million over five years with potential for up to \$500 million over ten years. GHIC will, in turn, match capital from other private investors. Proceeds from BARDA Ventures funding will be returned to GHIC for reinvestment and sustainment of future BARDA projects.

Key Biden Health Officials Signal Future Priorities As Others Await Their Turn

Chiquita Brooks-LaSure said in one of her first interviews that her top priorities would be ensuring health equity and broadening coverage, including addressing the "Medicaid gap" in non-expansion states and potentially expanding Medicare benefits.

Liz Fowler, Director of the CMS Innovation Center, signaled an openness to mandatory alternative payment models and engaging all payers, including Medicaid, but did acknowledge the importance of ensuring models are not overly prescriptive. She also noted a general shift in focus from savings to enhancing access, health equity, and individualized care, including virtual care. She also noted that checking in with Congress more to ensure Congressional oversight and alignment with Congress's strategic vision for CMMI would be a priority for her, which comes a day after 24 lawmakers wrote her a [letter](#) urging more transparency with Congress. Fowler also indicated she would defer to Congress on drug pricing reform, suggesting that CMS will likely take a different approach than the favored-nation demo that was finalized in the final hours of the Trump administration and now help up in the courts.

HHS Secretary Xavier Becerra is expected to shed additional light on HHS priorities himself, making the rounds this week testifying before the House Ways and Means, Senate Appropriations, and Senate Finance Committees.



Meanwhile, the Senate HELP Committee held a hearing on two other key health posts: Dawn O'Connell to serve as Assistant Secretary for Preparedness and Response and Miriam Delphin-Rittmon to head up SAMHSA. O'Connell currently serves on the HHS COVID-19 response team, and Delphin-Rittmon leads the mental health and addiction services branch for Connecticut.

California v. Texas - Challenge to the ACA - Decision in the Coming Weeks

The Affordable Care Act (ACA) will be tested again in California v. Texas. The plaintiffs claim the tax-power justification of the ACA's individual mandate fell apart when Congress repealed the tax penalty in 2017. The closely related question is whether the rest of the ACA can stand even if the mandate falls. The case has made its way to the Supreme Court, and we are expecting the Court's ruling very soon.

More States Extend Medicaid Postpartum Coverage

On June 2, Florida became the latest state to sign into law legislation to extend coverage to one year after a woman gives birth after Congress created a new, streamlined pathway for states to do so without CMS approval through the American Rescue Plan. HHS Secretary Becerra recently approved such waivers in Illinois, Georgia, and Missouri. Virginia, Massachusetts, and New Jersey's waivers are still pending, and a similar law recently passed the Texas legislature and is sitting on the Governor's desk.

MACs to Resume Medical Review on a Post-payment Basis

CMS recently announced that beginning August 2020, Medicare Administrative Contractors (MACs) resumed post-payment reviews of items and services with dates of service before March 2020. MACs may now begin conducting post-payment medical reviews for later dates of service. The Targeted Probe and Educate program (intensive education to assess provider compliance through up to three rounds of review) will restart later.

MA Ratings Pause Upheld by Federal Court

Three Medicare Advantage plans lost their attempt to require the CMS to collect data on patient care and satisfaction and update MA quality ratings for the 2020 plan year. The U.S. District Court for DC [sided](#) with HHS finding that the Agency had not exceeded its statutory authority nor acted arbitrarily and capriciously when it decided to temporarily suspend data collection during the pandemic to not divert resources and rely on the previous year's data instead.

ACA Marketplace

According to new HHS data, a record-breaking nearly 31 million Americans have obtained health coverage through the ACA marketplace exchanges in 2021, including 1.2 million sign-ups during the federal government's special enrollment period.

Applications for \$80 million in grant funding for navigators in states with a federally facilitated marketplace for 2022 will close on July 6. One hundred twenty total awards are expected to be given out, and awardees will be notified in late August. This represents an eight-fold increase over the drastically reduced funding during the Trump administration's last year in office.

CMS is [giving the state of Georgia until July 3 to prove](#) that its proposal to lower marketplace plan premiums by creating a reinsurance pool and setting up its website and brokers instead of using the federal marketplace.gov website will not reduce access to coverage. However, most suspect the Biden administration will eventually reject the waiver, which was approved under the Trump administration.



COVID Update

Biden announced a “national month of action” to ramp up vaccination efforts to reach his goal of at least 70% of Americans receiving at least one dose by July 4 amidst declining vaccination rates, which have fallen off more than 70% since April, particularly in the South and Midwest.

The heads of four key international organizations jointly called for world leaders to support a three-pronged, \$50 billion plan devised by the IMF, which includes 1) speeding up global vaccinations in low- and middle-income countries; 2) reducing the emergence and spread of new variants; and 3) boosting testing, tracing, and access to therapeutics. Their plan also includes a formal negotiation on waiving intellectual property obligations for vaccines, which President Biden has come out in support of but has not provided further details. The White House has announced that it will ship 80 million doses internationally by month’s end, with more than three quarters going to Covax, the UN global vaccine-sharing program. Biden is also considering whether to export unused vaccine doses set to expire, including tens of thousands of J&J doses.

Federal health officials have started a new study exploring whether mixing different COVID-19 vaccines can prolong immunity and better protect people from concerning variants of the coronavirus.