



[H&K Health Dose– March 16, 2021](#)

A weekly dose of healthcare policy news

With COVID Relief Barely in Rearview, Congress Will Address a Few Leftovers Before Moving onto a Massive New Infrastructure Package

Last Friday, President Biden signed into law the American Rescue Plan (ARP), a massive \$1.9 trillion COVID relief package. Biden addressed the public in a primetime speech, and Biden, Harris, and other surrogates have been traveling the country touting the achievement. The bill provides funding to support vaccine distribution and COVID-19 testing. It makes policy adjustments to Medicaid, including coverage of pregnant and postpartum women, and provides \$8.5 billion through a Provider Relief Fund look-alike to support rural providers. Don't feel like reading the 640-page bill? Check out Holland & Knight's analysis [here](#).

House Democratic leadership is expected to take up a bill (HR 1868) this week that would address a few budgetary hangover items that didn't make it into last week's package, including waiving "pay as you go" requirements that would otherwise trigger \$36 billion in automatic Medicare cuts according to CBO [estimates](#) to pay for the stimulus package's \$1.9 trillion price tag. The bill would also extend the moratorium on the Medicare sequester cuts through the end of the year, which is currently set to expire at the end of the month unless Congress intervenes. In addition to the Medicare sequester relief, the bill would also make several technical changes to the rural health clinic (RHC) provisions that were included in the Consolidated Appropriations Act. The bill is expected to pass in the House.

The path in the Senate is less clear. Key senators have indicated an interest in moving quickly on the sequester moratorium extension but have been less forthcoming about where they stand on waiving PAYGO at this time as it does not need to be addressed immediately. Democrats will need some Republican support to reach the 60 votes needed in the upper chamber. Democratic leadership could attempt to tie one or both provisions to a future bipartisan vehicle, such as an omnibus package.

Meanwhile, Biden is already gearing up to roll out another massive infrastructure package dubbed his "Build Back Better" plan that would extend well beyond bridges and highways with a large focus on strengthening the domestic supply chain, including on pharmaceutical drugs and medical devices. The House Energy and Commerce Democrats [introduced](#) the Leading Infrastructure for Tomorrow's (LIFT) America Act – a more than \$312 billion package that includes funding for public health and health care infrastructure and increased broadband internet access. The LIFT Act informs the Energy and Commerce panel's contribution to the infrastructure package.

President Joe Biden has not yet unveiled his infrastructure proposal but may do so in the coming weeks. The legislative path for a comprehensive infrastructure package is not yet clear, though budget reconciliation is a possibility, especially if Democrats are unable to reach a compromise with Republicans.

In July, House Democrats could begin the process of drafting a Fiscal Year (FY) 2022 budget resolution that includes reconciliation instructions, with the goal of adopting the budget resolution before the August recess and passing the budget reconciliation package in September.

Medicare Accelerated and Advance Payments Coming Due

The Medicare Accelerated and Advance Payment Program (AAP) provided loans to applicants facing financial disruption due to COVID-19 based on historic Medicare billing. Repayment of AAP loans begins one year from the date the payment was issued, which means repayment could begin as early as next month for many providers.



CMS has not provided further details on the repayment process, such as when exactly claims recoupment will begin, so groups should direct questions to their Medicare Administrative Contractor's (MACs). The repayment will be repaid through automatic claims recoupment or lump-sum payments to your MAC.

Are We There Yet? HHS Nominations Slowly Falling Into Place

After Senate Majority Leader Chuck Schumer cleared the final procedural hurdle yesterday, HHS Secretary nominee Xavier Becerra is set for a final confirmation vote as soon as Thursday. He is expected to be confirmed along a thin, mostly partisan margin similar to the procedural vote to hold his confirmation vote, which was 51-48 after Maine Republican Susan Collins crossed party lines to back a confirmation vote and moderate West Virginia Democrat Joe Manchin decided to support him after being on the fence.

The Senate Health, Education, Labor, and Pensions (HELP) Committee will hold a March 17 vote on Dr. Vivek Murthy's nomination to serve as Surgeon General and Rachel Levine to serve as Assistant Secretary of Health and Human Services.

Shalanda Delores Young's nomination for Deputy Director of the Office of Management and Budget was cleared out of committee by a party-line vote. She has received some nods for the top spot after controversial pick Neera Tanden's nomination floundered last week. Still, the Biden Administration has not yet indicated their plans for the senior post.

Biden is under pressure to nominate an FDA chief formally. In a letter, six former FDA heads call on Biden to decide, saying it plays a critical role in helping the nation confront the evolving pandemic. While they praise acting FDA Commissioner Janet Woodcock as "highly effective," the letter does not make a formal endorsement. Several news reports indicate the administration is currently vetting other candidates for the job.

Longtime House Ways & Means staffer and health policy expert Melanie Egorin has been tapped to serve as deputy director of the HHS Office of Legislation.

No news yet on nomination hearings for CMS Administrator appointee Chiquita Brooks-LaSure.

The Latest Round of Trump-Era "Midnight" Rules Receive Their Moment in the Sun

- On March 9, several provider and consumer advocacy organizations filed suit over a Trump-era rule that requires health regulations be assessed every ten years or be automatically scrapped. The coalition warned thousands of public health and 2,000 food safety regulations could be eliminated and put Americans at risk and argues that forcing a re-review of existing regulations would add to existing rulemaking delays, waste HHS and sub agency resources, and that the rushed process in which the rule was finalized in the final days of the Trump administration violates the Administrative Procedures Act. The rule was finalized on Jan. 8, just days after the comment period closed, and officially published on Jan. 19 with an effective date of March 22. It was temporarily delayed by Biden's "regulatory freeze" memo. The freeze would lift just before the rule's March 22 effective date pending further action, which is considered likely.
- The comment deadline for proposed modifications to the HIPAA privacy rule has been extended to May 6 (from March 22). The proposed regulation was initially released in December to ease the transition to value-based models by making it easier to coordinate patient care. According to the HHS press release, the rule would primarily accomplish this by strengthening individuals' rights to access their health information, improve information flow, facilitate greater family and caregiver involvement, and enhance flexibilities for disclosures in emergencies. However, experts warn the modifications could create new burdens.



- After the Pharmaceutical Care Management Association (PCMA) sued earlier this month, the Biden administration agreed to delay until at least Jan. 1, 2023 a controversial rule that would significantly alter the Medicare Part D drug reimbursement system by basing rebates on fixed administrative fees rather than a drug's list price.
- HHS further delayed until July 20 a rule that requires community health centers to pass on all their insulin and epinephrine discount savings onto patients. Health centers argue they already pass on those savings, and this rule would merely increase the administrative burden and cut into already razor-thin margins.
- CMS delayed until May 15 another rule that would alter Medicare coverage requirements in an attempt to facilitate faster access to medical devices designated by the FDA as “breakthrough” technologies. The announcement says the administration may revise, further delay or rescind the proposed action after considering additional public input.

Turning the COVID Corner?

The weekly U.S. Covid-19 death toll has fallen to a four-month low. The Biden Administration has set a new goal of having enough vaccines for all adult Americans by the end of May and getting the nation “closer to normal” by the Fourth of July. Anthony Fauci, President Joe Biden’s chief medical adviser, cited reluctance to get vaccinated, particularly among Republican men, as one of the largest hurdles.

To get across this new finish line- HHS announced a slew of actions to boost national inoculation efforts:

- HHS nearly quadrupled the number of HRSA-supported health centers that will be invited to participate in the Health Center COVID-19 Vaccine Program, increasing the total number from 250 to 950. The second wave of health centers includes those that serve high proportions of low-income and minority patients, provide services to rural populations, operate Tribal/Urban Indian Health Programs, and/or utilize mobile vans.
- The Agency also formally expanded the types of healthcare personnel that will be eligible to administer vaccines, including dentists and veterinarians, and nearly doubled the Medicare payment amount for administering the COVID-19 vaccine. Effective for vaccines administered on or after March 15, the national average payment rate will increase from \$23 to \$40 per dose. The exact payment rate for the administration of each dose of a COVID-19 vaccine will depend on the type of entity furnishing the service and geographic location.
- The Biden Administration has also proposed to terminate a Trump-era rule that would hinder people injured by vaccines from seeking federal compensation. Covid-19 vaccines aren’t currently included on the list, but they could be added in the future. Disallowing potential claims of injury could dissuade some people from getting vaccinated, some argue.

The World Health Organization’s top scientist said over the weekend that 6-8 new vaccines might be ready for use by the end of this year, including candidates that don’t require needles and can be stored at room temperature. So far, ten vaccines are on the global market, and more than 80 candidate vaccines are being studied in people, though some are still in the early stages of testing. One approach the WHO is exploring is a global trial that would compare three or four candidate vaccines simultaneously along with a placebo so that up to 80% of trial participants would get a real vaccine instead of only 50%. However, global vaccine efforts were dealt a setback this week as a growing number of countries are halting or limiting the use of AstraZeneca shots over safety fears due to clotting complications. The WHO is convening to discuss, and Europe's medicines regulator, the European Medical Authority, has scheduled an emergency meeting for Thursday. The vaccine has not yet been cleared for use in the United States.



COVID Silver Linings

NIH Director Francis S. Collins said last week he would like to keep a COVID-era initiative called [RADx](#) that sets up a venture capital-like fund within NIH to fund cutting-edge medical research and technology. Created by last spring's stimulus package to speed the development of COVID testing and vaccines, Collins said the program worked "better than he would have guessed" and sees the advantage this type of expedited process could have in accelerating research and development for other types of medical innovations and technologies, including wearable technology to monitor hypertension. The NIH chief also said he wants to take steps to improve the nation's clinical trial infrastructure, including leveraging another COVID-era program called [ACTIV](#) to bring together drug and biotech companies and public sector experts as part of a public-private partnership.

In its annual [report](#) released earlier this week, MedPAC, an advisory panel to Congress, warned it wants to see more evidence on telehealth services before Congress makes any permanent changes. However, the panel recommended that policymakers continue some expanded telehealth services for one to two years beyond the public health emergency so data can be collected about telehealth's effects on Medicare access, quality, cost, and fraud. The Center for Telehealth and e-Health Law is planning to conduct its national study on the surge in telehealth use during the pandemic. Data is being gathered from several large academic medical centers and hospitals that have been offering telehealth visits, and the goal is to publish preliminary findings by the summer.

Alternative Payment Model Status Report

The CMS Innovation Center has frozen or delayed several value-based models or demonstrations finalized under the Trump Administration

- According to the Geographic Direct Contracting Model [website](#), the models is currently "under review." CMS will share additional information when available.
- The Primary Care First Seriously Ill Population Track that was originally delayed until April 1 due to COVID-19 is also now "[under review](#)" with no set implementation date.
- The Kidney Care Choices model has been delayed until Jan. 1, 2022.
- CMS extended the application deadline for the Community Transformation track of its [Community Health Access and Rural Transformation model](#) to May 11.
- CMS released the [Request for Applications \(RFA\) for Cohort 2](#) of the Primary Care First (PCF) Model.
- CMS announced updates to the Calendar Year (CY) 2022 Request for Applications (RFA) for the Part D Payment Modernization (PDM) Model. A link to the CY 2022 PDM Application will be posted on the [PDM Model overview page](#).

Senate Shake-Up: Departure of Senior Republican Senator will Have a Ripple Effect on Senate Politics, Medical Research Funding

Sen. Roy Blunt (R-Mo.) [announced](#) last week he won't seek reelection when his term expires next year. The 71-year-old 4th ranking Republican Senator serves as the Chairman of the Senate Appropriations Subcommittee on Labor, HHS, Education, and Related Agencies, which oversees medical research funding. During his tenure, he was a powerful champion for the NIH, securing a series of funding increases. NIH Director Francis Collins [told a Senate panel](#) back in May 2020 that the Agency will lose about \$10 billion in research as a result of the pandemic due to shuttered laboratories



and that the best way to fund medical progress is through steady, stable increases that lead to discoveries that take decades of work, like cancer immunotherapies. The perpetual challenge is that non-defense discretionary spending, which includes NIH's appropriations, tends to be one of the first on the chopping block for budget/deficit hawks. The good news- boosting NIH funding tends to have strong bipartisan support. Blunt's announcement will also have wider implications for Senate politics, making a Republican comeback in 2022 one degree harder and potentially further widening the partisan divide, as Blunt is considered a mainstream conservative Republican.