



H&K Health Dose– May 25, 2021 *A weekly dose of healthcare policy news*

Legislative News

Congress this Week

The Senate reconvened this week and confirmed Chiquita Brooks-LaSure to lead the Centers for Medicare & Medicaid Services (CMS) by a vote of 55 to 44. Brooks-LaSure is the first Black woman to lead the agency. Brooks-LaSure previously served as deputy director for policy at the Center for Consumer Information and Insurance Oversight within the agency. As director of coverage policy, she also led the agency's implementation of the Affordable Care Act.

This week, the Senate also resumed consideration of the U.S. Innovation and Competition Act amendments, the former Endless Frontier Act (EFA). The goal is to wrap up by the end of the week.

Meanwhile, House lawmakers have finished votes for the month but will meet for Committee Work Days before the Memorial Day recess. The House will resume voting next month on Monday, June 14.

Infrastructure Package - Time is Running Short on a Bipartisan Deal

A group of Senate Republicans plans to present their latest offer to the White House on a significant new infrastructure package on Thursday, with one member saying it will weigh in at almost \$1 trillion. To date, the parties have remained far apart, and there has been little to no agreement on pay-fors.

Democratic lawmakers have warned that time is running short to determine whether a bipartisan deal on infrastructure is possible, with progressives already calling for a go-it-alone approach using budget reconciliation. A new offer around \$1 trillion would still be well short of the \$1.7 trillion proposal from the White House.

Importantly, if the Democrats decide to pursue passage via the budget reconciliation process to avoid a Republican filibuster, the entire bill must be paid for. Adding complication, the Congressional Budget Office (CBO) projections of savings may come in well below Treasury estimates under current scoring guidelines. For example, \$240 billion in savings is projected to come from increased IRS enforcement, but the CBO cannot count expected revenues from increased IRS funding. Some are calling for tweaks to CBO scoring policies, but even if this were to happen, the Treasury's original savings estimates are still considered by many to be optimistic.

We will continue to watch how the infrastructure package(s) come together over the next few weeks to get a better sense of the timeline. As of now, the goal is still to have a bipartisan package by the week June 7-11th (although that timeframe is highly likely to slip).

Budget is Coming Friday Without Key Health Proposals

The President's fiscal year (FY) 2022 budget proposal is slated to be released on Friday, May 28, according to the Office of Management and Budget (OMB). On April 9, 2021, the Biden Administration released a "skinny" budget. In the full budget, we are expecting specific information on policy, tax, and spending proposals. White House officials confirmed last week that President Biden's upcoming budget proposal would not include campaign health platform promises, such as the creation of a public health insurance option and drug pricing reform. Instead, the budget is likely to call on Congress to pass legislation strengthening the Affordable Care Act, Medicare, and Medicaid, as well as to allow Medicare to negotiate lower drug prices.

House and Senate Appropriation Committees have begun the budget processes and have held hearings over the last few weeks. The House Budget Committee is set to hold a June markup on a budget resolution. However, Chairman John



Yarmuth (D-KY) is expressing reservations that an agreement will happen, saying Democrats are so far apart on a defense spending topline figure that they will likely have to informally “deem” spending figures, which would allow appropriators to start their work without passing a full budget resolution.

Further complicating matters, lawmakers will need to act soon to raise or spend the debt limit, with reports increasingly saying the limit could be hit sometime over the summer well before government spending formally runs out on Sept. 30. Meanwhile, Senate Finance Committee ranking Republican Mike Crapo (R-ID) and House Ways & Means Ranking Member Kevin Brady (R-TX) are putting pressure on the Treasury to release updated Medicare Trust Fund projections as soon as possible. The latest figures released more than a year ago say the funds will run out in 2026 but do not reflect the impact of the pandemic.

Tax Corner

The Senate Committee on Finance held a nomination hearing on May 25, 2021, to consider the nominations of four individuals, including Lily Batchelder. Professor Batchelder (NYU School of Law) was nominated to be Treasury Assistant Secretary (Tax Policy). Professor Batchelder previously served in government as the Majority Chief Tax Counsel to then Finance Committee Chairman Max Baucus (D-MT), Deputy Director of the White House National Economic Council, Deputy Assistant to the President under President Obama. She advised the Biden campaign on tax policy.

Health Care Workforce Legislation

The Association of American Medical Colleges (AAMC) spearheaded a letter to congressional leadership pushing for support for physician training in the infrastructure package. The letter endorses the passage of the *Resident Physician Shortage Reduction Act* (S. 834/H.R. 2256) to alleviate the shortage of physicians in the U.S. The legislation would gradually provide 14,000 new Medicare-supported GME positions targeted at hospitals serving patients in health professional shortage areas, hospitals in states with new medical schools or branch campuses, and hospitals already training over their Medicare caps.

Meanwhile, Sen. Bernie Sanders (I-VT) introduced legislation to address the nation’s health care workforce shortages. The [Addressing the Shortage of Doctors Act](#) will add 14,000 Medicare-funded graduate medical education (GME) slots over the course of 7 years, reserving half of the new slots for training primary care physicians. It would also increase funding for the National Health Service Corps (NHSC) by \$1 billion per year for ten years and permanently authorize the Teaching Health Center GME program.

Senate Judiciary Subcommittee Examines Hospital Consolidation

The Senate Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights held a hearing entitled [“Antitrust Applied: Hospital Consolidation Concerns and Solutions.”](#) The hearing provided a broad overview of the expansion of hospital consolidation and the purchasing of provider practices by hospitals over the last several years. Committee members of both parties expressed concern that hospital systems were rapidly consolidating, causing prices to increase. Members also focused on the impact of hospital consolidation on patient access and the effects on the labor market. Committee members agreed on the need to appropriate additional funding to the Federal Trade Commission for the enforcement of anti-competitive laws. Chairwoman Klobuchar (D-MN) indicated that the Department of Justice and the Federal Trade Commission should consider revising guidance regarding antitrust enforcement practices.



Bipartisan Action on Telehealth

A bipartisan group of four senators, led by Susan Collins (R-ME) and Ben Cardin (D-MD), reintroduced S. 1309, which would allow the CMS to pay for home health services provided via telehealth during a public health emergency.

Another bipartisan duo of House lawmakers introduced another bill that would permanently cover audio-only telehealth visits through Medicare and remove site-of-service requirements.

Sens. Steven Daines (R-MT) and Catherine Cortez Masto (D-NV) introduced a bill that would allow Americans with high-deductible health plans with HSAs to use telehealth without first needing to meet their deductible, which is currently allowed but set to expire at the end of the year.

Drug Pricing

Findings from a new Milliman study found that progressive Democrat's signature drug pricing reform bill H.R. 3 that would allow Medicare to negotiate drug prices could save employers nearly \$200 billion and workers almost \$100 billion by 2030. However, several moderate House Democrats are reportedly drafting alternative drug pricing legislation that includes several more moderate proposals considered more palatable for Democrats and Republicans, such as capping seniors' out-of-pocket costs or making it easier for generics to enter the market.

Administration/Regulatory & Court News

CMS Delays Effective Date for "Reasonable and Necessary" Rule

CMS recently [delayed](#) the effective date of the final rule titled, "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of 'Reasonable and Necessary,'" published on January 14, 2021. The January 2021 final rule established the MCIT pathway to provide coverage to new, innovative medical devices designated as breakthrough devices by the Food and Drug Administration (FDA). The new effective date is Dec. 15, a change from May 15. CMS previously delayed the rule from March 15 to May 15 as part of the Biden administration's "regulatory freeze pending review."

Pressure Mounts to Delay Provider Relief Fund Reporting Requirements as the June 30 Deadline Looms

As the June 30 reporting deadline looms and HHS has yet to release additional guidance or open the application portal, hospitals are getting increasingly anxious about the process for reporting to HHS on how they spent provider relief funds. The reporting requirements apply to any provider who received more than \$10,000 in funding. Those who received more than \$750,000 in relief must also undergo an audit. In recent weeks, efforts have picked up lawmakers and hospitals to call on HHS to extend the deadline and tie it to the end of the public health emergency instead.

HHS to Dedicate \$4.8 Billion from American Rescue Plan to COVID-19 Testing for the Uninsured

Today, HHS, through the Health Resources and Services Administration (HRSA), [announced](#) that it is dedicating \$4.8 billion from the American Rescue Plan (ARP) to support the HRSA COVID-19 Uninsured Program. This funding will allow the program to continue reimbursing health care providers for testing uninsured individuals for COVID-19. As of May 19, 2021, the program has issued nearly \$4 billion in testing reimbursements to providers.

Court Orders HHS to Recalculate Medicare DGME Payments

The U.S. District Court for the District of Columbia ordered HHS to recalculate Medicare Direct Graduate Medical Education payments for hundreds of hospitals after it [ruled](#) that HHS acted arbitrarily and capriciously and contravened



the Medicare Act when it capped the number of FTEs a hospital is permitted to factor in at 1996 levels. The case applies to payments dating as far back as 2005. The decision may impact any teaching hospital that is both over its DGME FTE cap and that trains residents who are beyond the five-year initial residency period.

Next Gen Model Will Not Be Extended

On May 21, CMS announced that it would not extend the Next Generation (Next Gen) Accountable Care Organization (ACO) demonstration beyond 2021. However, CMS announced that it would allow Next Gen ACO participants to apply to participate in the Global and Professional Direct Contracting (GPDC) Model for 2022. Next Gen ACO participants have until June 14 to show that they can participate in the GPDC Model.

Drug Makers Ask Court to Delay Drug Discounts

AstraZeneca and Eli Lilly asked a federal court to delay by two weeks a June 1 compliance deadline to resume 340B drug discounts to contract pharmacies after HHS ordered it last week and threatened civil monetary penalties for non-compliance. The company said this would allow the court to hear arguments on the matter which are already scheduled for June 9. They gave the government until Friday to respond.

Private Sector Check-Up

Anthem has partnered with Epic to create an information exchange platform between health plans and providers, to automate prior authorization requests, providing data-driven insights into patient care, and facilitating value-based payment. The program is being launched as a pilot with MetroHealth System in Cleveland.

JPMorgan Chase & Co. announced plans to invest \$250 million in healthcare startups and create its healthcare arm called Morgan Health to pursue more affordable healthcare options for its employees.

CVS Health Corp announced it is getting into the clinical trial game by offering assistance with determining eligibility for and enrolling in clinical trials for new drugs.

COVID Update

The Health Resources and Services Administration (HRSA) announced an additional \$4.8 billion in American Rescue Plan (ARP) funding for the HRSA COVID-19 Uninsured Program, which reimburses healthcare providers for COVID-19 testing expenses for the uninsured.

Moderna announced positive results of its effectiveness in 12 to 17-year-olds and plans to seek FDA authorization. The Pfizer vaccine was approved for those 12 and older earlier this month. President Joe Biden said Friday that the U.S. could produce up to 1 billion Covid-19 vaccine doses and be able to vaccinate every American, including children, by year's end.

Stark geographic and racial disparities are persisting in vaccination rates across the country. Just 22% of black Americans have gotten at least one shot, compared with 33% of white Americans. In the northeast, nearly 64% of the population has one shot, while 8 out of 10 states with the lowest vaccinations are in the south. The governors of New York and Maryland announced lottery prizes to incentivize vaccine holdouts after a similar program in Ohio yielded a 28% increase in vaccination rates.

A dozen Republican senators wrote to Biden urging him not to waive IP rights for vaccines after he announced plans to do so last week, though the practical effects of such a decision would not be seen for months. International distribution of domestically produced vaccines continues to be widely considered the most promising way to address the global



vaccine shortage. As U.S. demand slows, Moderna and Pfizer are shipping an increasing proportion of U.S.-produced doses worldwide. The global vaccine alliance Gavi also agreed this week to buy and distribute 200 million doses of Johnson & Johnson's COVID-19 vaccine to countries worldwide.

Federal health officials are closely monitoring a variant first identified in India that could be up to 50% more transmissible than the U.K. variant. Currently, the most dominant strain in the U.S. studies shows that existing vaccines are “highly effective” against variants. Still, Pfizer and Moderna CEOs and Dr. Anthony Fauci, said this week, Americans might require a third “booster” shot as early as September.

Also, this week, the Biden administration called for a closer look into the origins of the COVID-19 pandemic.