



H&K Health Dose June 29, 2021

A weekly dose of healthcare policy news

Legislative Updates

Status Update on Infrastructure

President Joe Biden endorsed a bipartisan Senate infrastructure deal last week. The bipartisan outline would total \$973 billion over five years or \$1.2 trillion over eight years. In addition to investments in roads, highways, electric vehicles, and transit systems, the bill includes \$65 billion for broadband and \$47 billion to address climate change. While the full list of pay-fors has not been released, some spending will be offset by repurposing unspent coronavirus funding and possibly extending the sequester.

As has been reported, this package will be sequenced with a larger reconciliation package. Democrats will kick off the budget resolution process next month to craft legislation on the President's American Jobs Plan and American Families Plan, including policies on home and community-based services, child care, education, paid leave, climate change, and healthcare, among others. According to the President and congressional Democratic leadership, the two plans – a bipartisan infrastructure bill and a larger reconciliation package – will move together.

The current plan is to have legislative text for the infrastructure package and a budget resolution ready to go when the Senate returns from recess – the week of July 12th. A preliminary outline of Senate Budget Committee Chairman Bernie Sanders' (I-Vt.) budget resolution began circulating on Capitol Hill last week. The document calls for nearly \$6 trillion in spending. It includes expanding dental and vision within the Medicare program and lowering the Medicare eligibility age from 65 to 60. These costs would be offset by allowing Medicare to negotiate drug prices.

The infrastructure package will be on the floor under regular order, so it will likely eat up most of the legislative days in July. This also means that while the Senate might pass this infrastructure package before they leave in August, that would only set up the actual activity in September. The Senate will not leave until they pass a budget resolution. This means that it is highly likely August recess is delayed.

House Appropriations Begins to Move FY 2022 Bills

The House has resumed its work on the appropriations process for fiscal year (FY) 2022. Four appropriations subcommittees released and advanced their spending bills last week: Agriculture-FDA, Financial Services-General Government, Legislative Branch, and Military Construction-VA. Appropriators are expected to move six bills through the full committee this week, with the panel completing its work the week of July 12. Leadership plans to bring the bills to the floor for a vote during the last two weeks of July. The Senate Appropriations Committee has not yet announced a markup schedule. A continuing resolution (CR) will likely be necessary to avoid a government shutdown at the end of the fiscal year on September 30.

House Energy and Commerce Subcommittee Hearing on Health Equity

On June 24, the House Energy and Commerce Health Subcommittee held a hearing entitled "[Empowered by Data: Legislation to Advance Equity and Public Health](#)." The subcommittee held the hearing to help address the technological gap exasperated by the COVID-19 pandemic. Witnesses discussed low levels of interoperability, inadequate data governance and data sharing policies, the need to standardize data, utilize data to address social determinants on health, and an inability to collect high-quality data. Witnesses present included: Karen DeSalvo, Chief Health Officer, Google Health; Dr. Romilla Batra, Chief Medical Officer, SCAN Health Plan; Beth Blauer, Executive Director, Johns Hopkins University Centers for Civic Impact; Dr. Faisal Syed, National Director of Primary Care, ChenMed; and Dr. Kara Odom Walker, Executive Vice President, and Chief Population Health Officer, Nemours Children's Health System.



Telehealth Expansion Legislation Introduced

Reps. Liz Cheney (R-WY) and Debbie Dingell (D-MI) recently introduced [the Advancing Telehealth Beyond COVID-19 Act of 2021](#). This legislation would permanently remove the originating site and geographical limitations beyond the Public Health Emergency. Providers would also be able to continue billing audio-only services as telehealth permanently.

Regulatory/Judicial Updates

Supreme Court Declines to Hear Site Neutral Case Leaving Contested Policy in Place

The U.S. Supreme Court on Monday declined to hear an appeal challenging HHS' controversial site-neutral payment policy, allowing the U.S. DC Circuit Court of Appeals ruling to stand, which will allow the regulation to move forward despite heavy opposition from the American Hospital Association (AHA) and other industry groups. Under the controversial policy initially issued in 2018, Medicare cut payments for E&M visits performed in hospital-owned clinics by 60% to match physician practice rates.

Ruling May Stop Insurers from Withholding Payment due to Unrelated Claims

Experts are saying that a recent ruling from a New Jersey federal district court may give providers the legal backing they need to stop insurers from engaging in “cross-plan offsetting,” a practice in which they withhold payments for claims as a way to offset overpayments for separate patients. The court ruled Aetna’s policy violates ERISA.

Rulemaking Season in Full Swing As Home Health Rule Released

In its FY 2022 [home health rule](#) released Monday, CMS proposed expanding its home health value-based purchasing program nationwide, a 2% pay reduction for home health agencies that fail to meet quality reporting requirements, and is seeking feedback on promoting health equity among other changes. Comments are due Aug. 27. The Medicare Physician Fee Schedule (MPFS) and Hospital Outpatient Prospective Payment System (HOPPS) proposed rules are expected in the coming week. Finally, the first surprise medical billing interim final rule focused on payment methodology is expected by July 1.

Biden Administration Makes Moves to Shore Up Access and Coverage

In a [proposed rule](#) released Monday, the Biden administration proposed several changes intended to shore up Affordable Care Act (ACA) coverage and access, including extending the annual enrollment period by 30 days plus a special enrollment period for low-income Americans, reinstating requirements that ACA navigators help educate consumers and assist them post-enrollment, and formally ending a Trump-era policy that would allow states to bypass the federal or state-based exchanges and purchase marketplace plans directly from insurers. The administration is revoking Trump-era waiver guidance and is calling for new waivers that aim to overcome structural barriers to coverage and access for underserved groups. Comments are due July 28.

Meanwhile, CMS issued letters to Arizona and Indiana formally revoking their Medicaid work requirement demonstrations.



And the Appointments Keep Rolling In...

On Monday, CMS announced that Massachusetts Medicaid director Daniel Tsai would be the agency's Medicaid chief starting July 6.

Dawn O'Connell was confirmed to serve as assistant secretary for preparedness and response, and Miriam Delphin-Rittmon as assistant secretary for mental health and substance use, both by voice vote.

FDA Calls on Pharma to Expand Patient Eligibility for Clinical Trials

In the new draft guidance, the FDA encourages the pharmaceutical industry to include non-curable cancer patients, including those who have not received prior therapies. Many clinical trials require that patients previously receive multiple therapies. ASCO and others have previously called for clinical trial expansion criteria to new groups, such as those between treatments or actively taking medications for other conditions.

Feds Seek Input on Insurer Drug Pricing Reporting Rule

A trio of government agencies is seeking feedback on implementing reporting requirements for drug pricing required under the 2020 Consolidated Appropriations Act. Under the law, health plans must report any drug discounts they receive, the amount they spend on top drugs, and the impact on premiums and patient out-of-pocket costs. Comments are due July 20.

Industry Consolidations on the Rise

Hospitals or corporations such as private equity firms or health insurers now own almost half of U.S. medical practices and employ nearly 70% of physicians, according to a new Avalere study. Another study found that transactions in the HIT, life sciences and pharmaceuticals, and medical devices and supplies sectors are up nearly 70% compared to last year. Several states are pursuing legislation to crack down on industry consolidation and antitrust.

OIG Finds CMS Lacks Authority to Assure Quality and Safety for Future Pandemics

According to a new OIG report, CMS has "well designed" quality and safety controls but lacks the proper authority to enforce them, which could hinder hospitals' readiness for future pandemics. OIG recommended CMS develop regulations that require targeted quality and safety surveys during public health emergencies, which it can now only request. CMS agreed with the recommendations.

COVID Update

The Delta variant continues to dominate globally and is now the most common U.S. strain. The good news- vaccines continue to prove effective against it. A new study also shows that mixing vaccines (specifically AstraZeneca and Pfizer) is safe and produces a robust immune response.

As employees return to in-person work, experts expect litigation against insurance companies for failing to pay disability benefits for long-haul COVID to rise steadily.