



## H&K Health Dose— May 4, 2021 *A weekly dose of healthcare policy news*

### **Infrastructure: Hold the Healthcare**

In his first joint [address](#) to Congress, President Biden unveiled the details of his highly anticipated [American Families Plan](#), which would channel hundreds of billions of dollars to tuition-free college, preschool, childcare subsidies, and paid family and medical leave paid for by an increase in capital gains and individual income taxes for high earners. The plan would also make the Affordable Care Act (ACA) ACA tax credits permanent; the Urban Institute predicts marketplace enrollment would rise by just over 5 million people, or 60%, in 2022. Some employers have expressed concern that such an expansion could draw younger, healthier employees away from company plans.

He also endorsed the creation of the Advanced Research Projects Agency for Health (ARPA-H) during his speech. The agency would be housed within the National Institutes of Health (NIH) and charged with developing breakthrough treatments to prevent, detect, and treat diseases such as Alzheimer's, diabetes, and cancer.

Biden left out other more controversial healthcare provisions in an attempt to make a more straightforward, potentially bipartisan pathway to passage and called on Congress in his address to expand Medicare coverage and reform prescription drug pricing in separate legislation. However, many are skeptical of the chances of such a bill passing, and many Democrats have publicly said they have not given up on including Medicare expansion or prescription drug spending in larger budget or infrastructure legislation.

Negotiations around drug pricing are picking up this week with the House Energy and Commerce Health Subcommittee and Education and Labor Subcommittee on Health and the House Education and Labor Subcommittee on Health, Employment, Labor, and Pensions, each holding hearings focusing on prescription drug pricing reforms. Finance Committee Chair Ron Wyden said he would work to construct a new drug pricing package that would draw enough support from Democrats to pass, though not necessarily aim for bipartisan support. Meanwhile, Senate Budget Committee Chairman Bernie Sanders said elements of Biden's infrastructure package could be wrapped into a larger budget package, and E&C Chair Rep. Frank Pallone says he is open to including drug-pricing into the infrastructure package.

### **Proposed FY 2022 IPPS Rule Released**

On April 27, CMS released the fiscal year (FY) 2022 hospital inpatient prospective payments system (IPPS) [proposed rule](#). The Proposed Rule would update the payment policies and annual payment rates for the inpatient payment system, update various quality programs, and evaluate New Technology Add-on Payment (NTAP) applications. The Proposed Rule also contains several graduate medical education (GME) proposals that implement three sections of the Consolidated Appropriations Act, 2021. Specifically, 1,000 new slots will be phased in at no more than 200 slots per year beginning in FY 2023.

The Rule also proposes to abandon market-based rate setting for hospitals and updates the wage index calculations for hospitals. CMS is also proposing to allow eligible Accountable Care Organizations (ACOs) participating in the BASIC track of the Medicare Shared Savings Program (MSSP) to elect to forgo automatic advancement along the glide path's increasing levels of risk and potential reward for the 2022 performance year.

Several significant issues were not addressed in the Proposed Rule, including enforcement of hospital price transparency requirements and implementation of surprise medical billing requirements. We anticipate future agency action on these issues in a separate rulemaking.

Please find a high-level summary of the Proposed Rule [here](#). Comments on the rule are due June 28, 2021.



## Telehealth Reform Picks Up Congressional Support

On April 28, 2021, Congress held its second major telehealth hearing this session. The House Ways & Means Subcommittee on Health convened a hearing to discuss the path forward for telehealth post-pandemic. The Subcommittee heard from an expert panel of witnesses that weighed in on issues surrounding telehealth, such as its potential implications on health equity, cost and utilization, quality, and broadband infrastructure. Notably, Democratic members appeared to favor an emerging proposal to extend telehealth flexibilities on a temporary basis after the pandemic as a means to better study and understand its broader implications. Some members noted recent suggestions from the Medicare Payment Advisory Commission (MedPAC) around a time-limited expansion of telehealth under Medicare to allow for greater study of its effects. Republican members, by contrast, were more open to a permanent expansion of telehealth coverage, suggesting that there is little reason not to implement a permanent expansion and that any suggestion that Congress may not do so could limit the degree to which providers invest in telehealth adoption.

Notably, Senate HELP Committee leaders joined Energy and Commerce Health Subcommittee Chair Anna Ashoo (D-DA) in expressing support for continuing pandemic-related Medicare telehealth flexibilities, saying the increased access was particularly critical in meeting the increased demand for mental health services during the pandemic. Telehealth accounted for 44% of primary care services for Medicare beneficiaries in April 2020, compared to less than 1% just two months prior.

## HHS Launches New Reimbursement Program for COVID-19 Vaccine Administration Fees not Covered by Insurance

The Department of Health and Human Services (HHS) launched the [COVID-19 Coverage Assistance Fund \(CAF\)](#) – a new program at the Health Resources and Services Administration (HRSA) that will reimburse providers for the costs of administering COVID-19 vaccines to underinsured patients ([press release](#); [fact sheet](#); [educational toolkit](#)). The new HRSA program aims to provide financial relief to providers since they are prohibited from billing patients for COVID-19 vaccination fees under the [COVID-19 Vaccination Program](#).

## Fentanyl Ban Extension Clears Senate

The Senate cleared a House-passed bill (H.R. 2630) that would extend a federal ban on fentanyl analogs until Oct. 22, from May 6, clearing it for the President's signature. The measure would continue the drug's temporary classification as a Schedule I substance, the most strictly controlled drug category. Civil rights groups have urged to end the ban, which they argue disproportionately affects black Americans and focuses instead on addiction treatment programs and safe injection sites. Regina LaBelle, acting head of the Office of National Drug Control Policy, told lawmakers at an April 14 hearing that they should temporarily extend the classification of fentanyl while the administration looks at how to tackle broader issues such as mandatory minimum sentencing for drug crimes.

## COVID: States Grapple with Vaccine Requirements As International Pressure Mounts

As most U.S. states witness a significant decline in new cases over the past two weeks, several states are faced with decisions over a return to "normal" policies, including several statewide bans on vaccine passports and employer vaccine mandates. President Biden called whether or not to require vaccination of U.S. troops a "tough call." Friday, President Biden extended face mask requirements across U.S. transportation through Sept. 13. As demand dwindles, particularly in certain areas, the White House announced today that vaccines left unordered will be made available to other states.

Meanwhile, as global cases rise, pressure is mounting on the U.S. to do more. The U.S. joined several other countries in blocking a proposal spearheaded by South Africa and India for a patent waiver that would temporarily allow companies worldwide to produce generic versions of vaccines without being sued. Last week, White House officials met with



several lawmakers who support the waiver and confirmed it was under consideration but said no decision had been made.

In the meantime, the White House announced it would not interfere with U.S. companies directly distributing vaccines overseas as Moderna announced it would supply 34 million doses to a WHO-backed initiative to distribute free shots to low-income countries, and Pfizer sent more than 10 million doses to Mexico and expects to ship 4.5 million doses to South Africa by June. President Biden announced more than \$100 million worth of aid to India, including raw materials for 20 million doses of the AstraZeneca vaccine, yet approved for use in the U.S. However, the company recently confirmed plans to seek authorization by the end of June.

After several contamination issues, Emergent says it has materials for more than 115 million doses worth of the J&J vaccine, 60 million doses of which are in vials and ready to deploy, pending FDA approval. The FDA is also reportedly expected to authorize the emergency use of Pfizer's COVID-19 vaccine for children ages 12 to 15 by next week.

### **HHS Extends, Expands Medicare CJR Model by Three Years**

In a [final rule](#), the Biden HHS extended a Medicare payment system for joint replacements for three years and extended the program to outpatient settings. The rule also makes adjustments to the target price calculation, reconciliation process, beneficiary notice requirements, and appeals process. The program is projected to save Medicare \$217 million from 2021 through 2024, roughly \$50 million less than estimated in the proposed rule. The model started as mandatory but was made voluntary in 2018. Four hundred thirty-two hospitals were [participating](#) in the model as of Jan. 1.

### **HHS Rolls out American Rescue Plan Health Center Grants**

HHS will be accepting grant applications up to \$1 billion for HRSA-funded health centers for COVID-19 related capital needs, new facility construction, renovation and expansion of existing facilities, and purchasing of new equipment. Applications are due by 5:00 p.m. ET on June 24. Click [here](#) for award submission guidance, technical assistance information, and other resources.

HRSA awarded another \$32 million to 122 organizations that provide training and technical assistance support to health centers for COVID-19 related training, technical assistance, and HIT support.

### **HHS Eliminates Buprenorphine Barriers**

HHS released new buprenorphine [guidelines](#) that, among other changes, allow any physician, PA, NP, CNS, CRNA, or CNM to treat up to 30 patients without meeting certain specialized training requirements. According to the [press release](#), the CDC predicts more than 90,000 drug overdose deaths occurred from September 2019 to September 2020, the highest ever recorded in a one-year period. Overdose deaths have continued to accelerate during the pandemic.

### **Hospitals Fare Better Overall with Winners and Losers in New Star Ratings**

Nearly one-third of hospitals scored higher under CMS' new star ratings methodology, according to new data. 45% of hospitals scored the same, while 22.7% had worse ratings. The new formula gives equal weight to each quality/safety measure and groups hospitals by the number of measures they report. In total, 59 additional hospitals received five stars, and 45 fewer hospitals received 1 star. Ratings tended to worsen for critical access hospitals, while community hospitals and teaching hospitals tended to fare better under the new system.



## **FDA Revokes Trump-Era Policy to Publish Drug Review Timelines**

HHS withdrew a Trump-era policy requiring the FDA to publish review timelines for certain drug applications, saying that the information is already publicly available on its website as part of its monthly and quarterly metrics. The agency added that in many cases, the FDA could not actually begin its review of an application when the application is first received (and the clock starts ticking) due to missing information or necessary discussions with industry groups and other relevant stakeholders. HHS initially instituted the rule after conducting a review of 48 new drugs approved by FDA in 2019 and found that 38 were approved after the 180-day review timeline with an average approval time of 273.8 days.

## **HHS releases Part 2 of 2022 ACA Exchange Rate Notice**

HHS released [Part 2](#) of its 2022 ACA exchange payment notice which included a number of changes intended to improve affordability and ability to compare plans, including lowering out of pocket maximums by \$400, expanding opportunities to sign-up for coverage outside of the annual open enrollment period, and expanding eligibility to purchase catastrophic coverage.

## **ICER Makes Accelerated Approval Recommendations**

The Institute for Clinical and Economic Review published a new [white paper](#) with a series of recommended reforms that could broaden the FDA's accelerated approval pathway for prescription drugs with certain guardrails to help ensure patient safety, including establishing an annual renewal process, creating a separate pathway focused on confirming drug safety, rather than efficacy, developing application templates, requiring more clinical trials, regulating pricing, and demanding higher Medicare and Medicaid rebates.

## **HELP Announces Effort to Improve Preparedness System**

Senate Health, Education, Labor, and Pensions (HELP) Committee Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) sent a Dear Colleague [letter](#) detailing their plans to revamp the nation's pandemic preparedness system. The lawmakers outlined their intention to work on bipartisan, consensus legislative proposals.

## **House Panel Examines Healthcare Consolidation**

On April 29th, the Subcommittee on Antitrust, commercial and Administrative Law of the House Judiciary Committee held a [hearing](#) on anticompetitive behavior and consolidation in the healthcare market. While the hearing primarily focused on consolidation in the pharmaceutical industry, there also was discussion of insurance market consolidation and hospital closures. Rep. David Cicilline (D-RI), the subcommittee chair, said that consolidation in the healthcare industry has led to increased prices, without better outcomes or quality improvements. Rep. Ken Buck (R-CO), the subcommittee's ranking member, said he was concerned about hospital closures in low-density areas. He also said he was worried about pharmaceutical companies blocking generic drugs from the market.

Sen. Amy Klobuchar (D-MN) testified before the subcommittee, urging that Medicare Part D negotiate drug prices. Sen. Charles Grassley (R-IA) also testified, noting that Congress should codify regulations requiring hospitals and insurers to disclose their low, discounted cash prices and negotiated rates to consumers before they receive medical care.

## **HHS Nominations**

Congress currently stands in recess. The Senate will resume consideration of the nomination of Andrea Palm to serve as Deputy Secretary of Health and Human Services when the chamber returns on May 10.