



[H&K Health Dose– April 27, 2021](#) *A weekly dose of healthcare policy news*

Infrastructure Unveiling Tees up Intra-Party Battle over Healthcare Priorities

President Biden is expected to reveal the second portion of his infrastructure package dubbed “the American Families Plan” tomorrow as part of his joint address to Congress to commemorate his first 100 days in office. Some congressional Democrats are pushing the administration to include significant health care reform proposals, including H.R. 3, the *Elijah E. Cummings Lower Drugs Costs Now Act*, in the infrastructure package. Rep. Lauren Underwood (D-IL), for example, led a group of 30 House Democrats in [calling](#) on the administration to prioritize health care coverage and affordability, including a permanent expansion of advance premium tax credits (APTCs) used to purchase marketplace plans under the Affordable Care Act (ACA). Sen. Bernie Sanders (I-VT) and 15 additional Democratic Senators also [wrote](#) to the White House asking them to propose reducing the Medicare eligibility age; expanding Medicare benefits to include hearing, dental, and vision care; implementing a cap on out-of-pocket expenses under traditional Medicare; and negotiating lower drug prices as a part of the plan.

Meanwhile, a group of Senate Republicans unveiled a \$568B counter-proposal, with White House meetings set up for this week. Privately, Republicans have hinted that they would be comfortable with an \$800-900B package that focused on more traditional infrastructure elements. However, this would still be less than half of Biden’s \$2.2 trillion proposal. The House Problem Solvers Caucus released its list of priorities Friday. Though it did not include a target price tag, the group did suggest doling out infrastructure funds outside of the federal budget process, which would not be subject to the same “pay-as-you-go” requirements, as well as using dynamic scoring, which could help to lower projected costs.

Pandemic Relief Rules Expedited

White House officials will aim to speed up their sign-off on pandemic-related rules by months. Agencies should expect the Office of Information and Regulatory Affairs (OIRA), the regulatory arm of the White House, to take at least five days to approve urgent regulations connected to the \$1.9 billion *American Rescue Plan* Congress passed in March, [wrote](#) Shalanda Young, acting director of the Office of Management and Budget, in a Monday memo.

Major Drug Pricing Legislation Introduced

This latest flurry of legislative proposals is part of an ongoing dialogue in Congress on the issue of drug costs. House Democratic leadership reintroduced their signature drug pricing bill mentioned above - H.R. 3. The bill directs the government to negotiate drug prices and biological products that lack competition from generic drugs or biosimilars. It would also expand coverage and create a \$2,000 out-of-pocket cap for Medicare beneficiaries. The House Energy and Commerce Health Subcommittee [announced](#) a hearing for May 4 at 11: 30 ET. In the last Congress, the Congressional Budget Office (CBO) estimated that the bill would result in approximately \$456 billion in savings over the next decade; some of the savings would be used for capping Medicare beneficiaries’ out-of-pocket spending on prescription drugs at \$2,000 per year.

House Republicans reintroduced their drug pricing alternative/counterpoint, the [Lower Costs, More Cures Act \(H.R. 19\)](#), which includes a combination of more incremental changes, such as expanding transparency or tweaking incentives and capping what seniors pay out of pocket for Medicare drugs. The sponsors claim H.R. 3 would limit innovation and would have delayed the COVID vaccine response. CBO predicts H.R. 3 would lead to a modest decline in the number of new drugs (around 2 per year), but it also comes with much more significant cost savings. The Republican Committee Ranking Members also published a [letter](#) encouraging their colleagues to support the bill.

It is not clear if either H.R. 19 or the newly re-introduced H.R. 3 will be enacted into law, especially because H.R. 19 and the re-introduced H.R. 3 represent only the latest of recently introduced drug pricing bills. Congress also is currently considering or developing other drug pricing bills.



Budget Catching the Late Train

The White House set a goal of sending a full budget proposal for fiscal 2022 by Memorial Day, a late start. One option to help speed the process could be setting top-line figures to allow appropriators to start their work before adopting a formal budget resolution, which isn't expected to occur until June.

Senate Republicans decided to continue their official ban on earmarks and signaled they might oppose any future increase to the debt ceiling without comparable federal spending cuts. However, neither is binding. At least a handful, including crucial swing vote Senator Collins of Maine and top Senate GOP appropriator Richard Shelby (R-AL) have indicated plans to use earmarks. Earmarks, rebranded as "community funding projects," have several limitations this time around, including additional transparency requirements and strict funding level caps.

Public Health Emergency Declaration is Extended to July 20

HHS Secretary Becerra [renewed](#) the public health emergency (PHE) declaration on April 21, 2021. This extends the PHE another 90 days to July 20, 2021.

The Biden administration sent governors a letter in January noting its intention to keep the PHE declaration in place for the entirety of 2021, and asserting that states will be given 60 days' notice before the PHE is ended. Statute requires that the declaration be renewed every 90 days.

Senate GOP to Keep Nonbinding Ban on Earmarks

Senate Republicans have decided to retain their nonbinding prohibition against congressionally-directed spending. The choice was made during an internal party meeting last Wednesday. While some GOP senators have pledged to continue abstaining from seeking earmarks, others – like Sens. Susan Collins (R-Maine), Richard Shelby (R-Ala.), Shelly Moore Capito (R-W.Va.), and Roy Blunt (R-Mo.) – have said they will join Democrats in seeking specific funding for projects in their home states.

Vaccine Demand Down, Supply Up in U.S.

Global vaccine administrations passed a major milestone this week with over 1 billion doses administered across 172 countries. The U.S. far outpaces any other country in inoculations. However, herd immunity may prove elusive as U.S. vaccination rates are slowing dramatically- down 11% from last week. Over five million Americans also missed their second dose, according to new CDC data. The main hurdles: vaccine hesitancy and access, particularly among certain groups. About one-third of U.S. adults are unsure or unwilling to get a shot. Access is also an issue, particularly among minorities and elderly adults with mobility issues. To close the gap, the Biden administration intends to bring vaccines into communities in more creative ways and urged businesses to offer paid leave for vaccinations, announcing a tax credit for small businesses to do so. HHS also [rescinded](#) a Trump-era policy that would have made it more difficult for those who suffer shoulder injuries or faint after vaccination to get compensated.

After a temporary pause to investigate a handful of severe blood clots, the J&J vaccine was cleared for use in the U.S. by the FDA and by European regulators. Shots are expected to resume in the U.S. this week. Experts worry the pause may add to vaccine hesitancy. There are also lingering concerns over quality control.

The Biden administration announced Monday that it would divert AstraZeneca's vaccine to India as it experiences a surge amid calls for the U.S. to do more to combat the disease globally. According to the World Health Organization (WHO), the U.S. also withdrew a Trump-era initiative to stop other nations from filling government contracts for COVID medical supplies. However, the White House has not publicly commented on calls to waive patent rights to boost global vaccine production, which prompted Pfizer and J&J executives to balk.



The FDA is studying whether vaccines can be mixed and matched and whether COVID variants will make boosters necessary. A growing body of evidence suggests that the Moderna and Pfizer vaccines do protect against variants.

The CDC is expected to announce new recommendations for fully vaccinated people today, including easing outdoor mask requirements.

White House (Still) Staffing Up

The Senate Finance Committee advanced the nominations of Chiquita Brooks-LaSure for CMS administrator and Andrea Palm for HHS deputy secretary. Palm passed by a vote of 20-8, and Brooks-LaSure was a tie vote. Senate Majority Leader Chuck Schumer (D-N.Y.) will need to file a procedural motion to bring her nomination to the floor, which could delay but isn't expected to derail her confirmation. The White House announced a slew of nominations, including Donald Remy at the VA and Miriam Delphin-Rittmon as Assistant Secretary for Mental Health and Substance Use. Still no word on a permanent head for the FDA, OMB, or HRSA.

The Other Epidemic

The House passed a bill (H.R. 2630) that would extend a temporary ban on fentanyl substances through Sept. 30. A Senate bill (S. 1216) would continue the drug's temporary classification as a Schedule I substance until July 6, 2022, though no vote has been scheduled. The ban is currently set to expire May 6. Advocates argue the ban is necessary to keep dangerous substances off the streets. Civil rights groups say the ban disproportionately impacts communities of color and have been calling for an end to the ban along with an increased focus on addiction treatment and safe injection sites. Senate Minority Leader Mitch McConnell has called for the ban to be made permanent.

Don't Call it An (ACA) Comeback

The Labor Department appealed a decision that allowed two Texan companies to offer health plans to individuals who agreed to have their internet activity tracked and sold. Under ERISA, large employer plans are preempted from state and federal coverage requirements. If upheld, opponents say the decision would allow "junk" health plans and attract healthy people away from federal marketplace plans, driving up the cost for others.

Six states plan to appeal to the Supreme Court over an ACA policy that would impose nearly \$500 million in fees on state Medicaid programs that operate managed care plans through insurers.

The Biden administration will provide federal marketplace navigators with \$80 million in funding for the 2022 open enrollment period. The Trump administration famously slashed funding for navigators to \$10 million in 2018.

According to a new [FAQ](#), CMS will recalculate the federal pass-through funding available to states administering reinsurance programs under an ACA Section 1332 waiver to account for expected reductions due to increased tax credits under the American Rescue Plan and the new ACA special enrollment period.

Medical Devices, DME, and Clinical Trials... Oh My!

The FDA is [withdrawing](#) the Trump-era [proposal](#) to permanently exempt certain medical devices from premarket review, citing patient safety and access concerns.

HHS [extended](#) until May 11, 2022 an interim rule that allows Medicare to pay a higher, blended payment rate for medical equipment like wheelchairs and oxygen equipment in rural areas. HHS also withdrew a 2020 proposed rule that would have streamlined Medicare coding, coverage, and payment for durable medical equipment, prosthetics, orthotic devices, and supplies (DMEPOS).



The FDA and the pharmaceutical industry intend to collaborate on decentralized trials, which have gained momentum since first being allowed in March 2020 due to the pandemic largely due to their convenience. First, they must standardize data collection and develop robust security protocols. The House Energy & Commerce Committee previously published a 21st Century Cures [concept paper](#) that included several clinical trial reform proposals.

CMS Innovation Center Head Signals Future Direction for Medicare Payment Models

CMS Innovation Center chief Liz Fowler indicated the center is evaluating current models focusing on a path forward and what makes the most sense in terms of transforming healthcare, not necessarily certifying existing models to be a permanent part of Medicare. MedPAC recently recommended the Innovation Center reduce its number of APM offerings. Fowler said key focus areas include multi-payer partnerships, including state Medicaid agencies, advancing health equity, and advancing policy priorities like drug pricing reform. Fowler said the agency was exploring whether to weigh quality improvement equally to savings and questioned the focus on financial risk.

340B Drug Dispute Resolution Panel Finally Getting Off the Ground?

The Biden administration is expected to imminently designate new panelists for a Medicare 340B drug discount dispute resolution panel after nixing several Trump-era appointees earlier this year. NACHC brought a lawsuit in October 2020 to force HHS to fill the panel. The court granted a stay request and ordered a status report by May 19.

Congressional Composition

Under new Census numbers released Monday, while states in the Northeast and Midwest will lose seven seats, southern states including Texas will gain, advantaging Republicans for 2022 midterms.

This week, Louisiana state Sen. Troy Carter won a special election to replace Cedric Richmond in the House. Once Carter is seated, Democrats will have a 219-seat majority. Three more vacancies are yet to be filled by special elections this year, all expected to be Democratic seats.

And the Trump-Era Medicaid Complications Continue...

The National Health Law Program and Tennessee Justice Center sued to overturn a Trump-era decision to approve Tennessee's capped Medicaid funding demonstration without a required public comment period.

Private Sector Shaking Up Prescription Drug Supply Chain

Navitus and Costco are testing a new strategy to make Costco the preferred pharmacy for one California employer. In contrast with other PBMs, Navitus operates on a fee-based model and passes discounts onto its employer clients.