



[H&K Health Dose– March 23, 2021](#)

A weekly dose of healthcare policy news

HHS takes important steps on drug pricing as it runs into roadblocks in Congress

HHS [delayed](#) until March 22, 2023, a Trump-era [rule](#) that would have changed payments to pharmacy benefit managers such that they can't fluctuate based on the price of a drug. The delay follows a [court order](#) that freezes litigation pending HHS review of the rule. The Biden Administration also formally [reversed](#) Trump-era changes to the Part D Payment Modernization Model that would have eased certain Medicare Part D formulary requirements, including the six protected drug classes and the requirement that formularies cover at least two drugs in all other classes. CMS will also maintain penalties for exceeding spending targets, which would have been removed. To learn more and access the updated 2022 request for applications, visit the [CMMI model website](#).

On March 16, the U.S. District Court for the Southern District of Indiana granted a preliminary injunction against a final rule that would create a process to resolve disputes in the 340B drug discount program based on a technical violation of the Administrative Procedures Act. The ruling could impact a separate lawsuit by PhRMA against a rule to eliminate drug rebates.

Meanwhile, in Congress, two drug pricing bills that were scheduled to be taken up by the House this week are now sitting on ice after Republicans signaled they planned to object. S. 415 would strengthen the criteria for a drug to receive market exclusivity for five years as a new chemical entity, which would allow generics to enter the market faster. S. 164 would direct HHS to establish a central website for educational content on biosimilars. According to an aide, both passed the Senate earlier this month and are now to be considered "at a later date". The Senate HELP Committee also held the first [hearing](#) of the new Congress on prescription drug prices earlier today.

The U.S. Biomedical Advanced Research and Development Authority separately issued a [request for information](#) to identify gaps in the pharmaceutical supply chain and how those could be filled domestically. Responses are due April 23.

Will they or won't they? PAYGO Edition

On Friday, the House passed H.R. 1868, a bill that would continue the temporary moratorium on 2 percent Medicare sequester cuts until the end of the year and wave the "pay as you go" rules that would trigger \$36 billion in automatic Medicare cuts next year to pay for the \$1.9 trillion pandemic relief bill. The bill was introduced by Budget Committee Chairman John Yarmuth (D-KY) and passed by a vote of 246-175 with unanimous support from Democrats plus 29 Republicans. However, the bill faces an uphill battle in the Senate, where Republicans are not keen on waiving the costs of the American Rescue Plan.

Senators Jeanne Shaheen (D-NH) and Susan Collins (R-ME) introduced their bill (S. 748) that deals only with the sequester and does not address PAYGO. It is considered to have a much higher likelihood of picking up the necessary 10 Republican votes to block a filibuster, particularly given the timing as the sequester moratorium is scheduled to end April 1. Both chambers are scheduled for a two-week recess starting March 29. Most suspect Congress will act on the sequester moratorium and leave the PAYGO battle for another day since the cuts will not take effect until next year.

More American Rescue Act Housekeeping Items

President Joe Biden tapped Gene Sperling, a former director of the National Economic Council who served as an economic adviser to Biden's 2020 campaign, to oversee the implementation of the \$1.9 trillion COVID-19 stimulus package, which was signed into law on March 11.



The Biden administration is also reportedly considering extending the special enrollment period beyond May 15, which would give middle-income Americans who previously couldn't afford Affordable Care Act (ACA) premiums but also didn't qualify for aid to take advantage of new enhanced subsidies finalized under the American Rescue Act, which can be claimed beginning April 1.

Meanwhile, the Senate is expected to vote on the House-passed bill H.R. 1799, which would extend the March 31 deadline to apply for Paycheck Protection Program loans for an additional two months.

House GOP joins Dems in bringing earmarks back; Verdict in the Senate is still out, but chances are looking good

House Republicans voted to lift their 10-year ban on earmarks in a 102-84 secret ballot vote, joining their Democratic House counterparts who have already begun plowing ahead. House Appropriations Chair Rosa DeLauro (D-Conn.) announced a plan that creates certain limitations, including capping overall earmark spending at 1 percent of discretionary spending, capping each lawmaker at ten project requests, and requiring that all requests be supported by evidence, go to only non-profit entities that lawmakers and their immediate families have no financial stake in, and be posted online and subject to periodic auditing by federal watchdog groups. A summary of the process is attached to this email and can also be found [here](#).

Senate leadership is working on a separate agreement to bring the practice back in the upper chamber. Minority Leader Mitch McConnell said he would defer to Alabama Senator Richard Shelby, the top Republican on the Senate Appropriations Committee, who has signaled support.

Next batter up - Infrastructure

The latest word on Biden's ambitious "Build Back Better" infrastructure package is that it could reach the \$3 trillion mark and that the White House is currently "exploring different options," including breaking the legislation into two, possibly even three separate packages so that at least some could garner bipartisan support, while others could be done through the expedited reconciliation process. The administration is discussing funding offsets and is said to be considering the first major federal tax hike since 1993, which may include raising corporate tax rates to 28%, increasing the income tax rate for individuals earning more than \$400,000, and raising the capital-gains tax rate for those earning at least \$1 million.

Another pay-for under consideration for the massive infrastructure bill is federal drug pricing measures. Democrats have been tight-lipped on strategy. A previous pricing negotiation bill that passed the House in the last Congress but never came up for a vote in the Republican-controlled Senate was scored at just under half a trillion in savings over a decade. A narrower [bill](#) out of the Senate Finance Committee that would curb price hikes for Medicare drugs and cap seniors' out-of-pocket spending would be an easier lift. Still, they would only generate \$50 billion in savings. Sen. Joe Manchin (D-WV), a critical moderate Democratic vote in the Senate, has co-sponsored legislation that would allow Medicare to negotiate prices but hasn't yet indicated whether he would support including drug price negotiations as part of the infrastructure package.

Democrats on the House Committee on Energy and Commerce on March 11, 2021, reintroduced a signature infrastructure package, the Leading Infrastructure for Tomorrow's America Act (LIFT America Act). See more [here](#).

Where is the telehealth revolution?

The Medicare Payment Advisory Commission (MedPAC) is [urging](#) an extension of telehealth flexibilities instituted in response to the COVID pandemic for up to two years after the public health emergency (PHE) concludes. According to the recommendations published on Monday, these telehealth expansion policies would allow more time for data to be



gathered on the use of virtual care to inform a decision on which measures should be made permanent. The recommendations were far from the clear path for long-term telehealth policy; many hoped the Commission would advance.

Additionally, the Centers for Medicare & Medicaid Services (CMS) announced four codes on the approved list of telehealth services were included incorrectly and will be removed after the COVID-19 public health emergency (PHE) ends. In a [technical correction](#), CMS indicated the codes were added to the Category 3 list of approved services. Category 3 describes services added to the Medicare telehealth list during the PHE for the COVID-19 pandemic that will remain on the list through the calendar year in which the PHE ends. The codes are 96121 (Neurobehavioral status exam by a physician or other qualified health professional) and 99221-99223 (Initial hospital care).

Money, Money, Money - Medicare increase in COVID vaccine administration amount

CMS [increased](#) the Medicare payment for administering a COVID-19 vaccine to \$40 per dose, effective for vaccines administered on or after March 15, 2021. This represents an increase from approximately \$28 for single-dose vaccines and \$45 for two-dose vaccines.

The battle over Medicaid work requirements heats up

Last Wednesday, Arkansas and New Hampshire Medicaid officials received letters informing them that the Biden administration had formally rescinded the federal government's permission to allow Medicaid work requirements. Arkansas is the only state where work rules ever entirely took effect, causing more than 18,000 people to lose Medicaid coverage during a brief stretch in 2018 before a judge halted the policy. Last month, the Biden administration sent letters to every state with a Medicaid demo in place directing them to submit evidence defending the programs. At least seven states defended their policies in recent letters to CMS, and several indicated they would challenge any decision to revoke the work rules. In a separate [report](#) released last week, HHS highlighted the negative impact of state Medicaid work requirements.

Meanwhile, the Supreme Court has a pending case on the legality of Medicaid work requirements. The Biden administration formally asked the court to drop the case. The court called off a scheduled March 29 hearing but has not yet dismissed the case and has asked the Department of Justice to provide a written brief on its request for dismissal by March 22.

Biden Delays Trump-Era Healthcare Regulatory Review Rule

Last week, HHS formally delayed until March 22, 2022, a [rule](#) that would automatically nullify any health regulations that are not reviewed every ten years, with certain exceptions. The rule was previously frozen by executive order and has come under criticism as adding to the regulatory backlog.

Vaccines highs and lows

After trending down for several weeks, new COVID cases have "plateaued" and are up slightly in some states. The race is on to get more Americans vaccinated before variants spread. According to a new [report](#), 52% of frontline healthcare workers have received a vaccine, and only 42% have received both doses. [13.5%](#) of the total U.S. population has been fully vaccinated so far. CDC Director Dr. Rochelle Walensky warned that increased travel, loosening pandemic restrictions, and variant spread could prompt another "avoidable surge" if Americans do not heed cautions "for just a little bit longer."

After surpassing his initial goal of 100 million vaccine doses on Friday ahead of schedule, President Biden may release an updated goal this week that could double the target to 200 million doses in the first 100 days of his administration.



Dozens of U.S. states are also expanding access to vaccinations earlier than planned for every adult, which puts Biden on the path to meet his goal of doing the same nationally by May 1.

The Biden administration is concurrently preparing a sweeping advertising blitz to promote public confidence in COVID-19 vaccines. The \$1.5 million venture is set to launch within weeks and will specifically target young people, people of color, and conservatives. 15% of Americans say they will not take the vaccine, and 8-9% say they will only take it if forced by their employer.

The administration also announced plans to share 2.5 million doses of the U.S. supply of AstraZeneca's COVID-19 vaccine with Mexico and another 1.5 million shots with Canada, which comes at a critical time with negotiations with Mexico over a surge in immigrants at the border. China, India, and Russia have already been using vaccines as diplomatic tools.

Administration officials are growing worried Johnson & Johnson may not deliver on its promise of 20 million doses by the end of the month. A new Danish study also found older Americans are at greater risk of getting reinfected.

British-based drug manufacturer AstraZeneca has had a roller-coaster week. After dozens of countries froze the use of its vaccine after concerns over clotting complications, the manufacturer released new results which found the vaccine [79% effective](#). Then, the U.S. Data and Safety Monitoring Board released a [statement](#) that at least some of the information included in the trial may have been outdated, impacting the efficacy results. Anthony Fauci weighed in by saying the vaccines are "very likely a very good vaccine." AstraZeneca is being asked to update its data and efficacy results as quickly as possible.

Regeneron Pharmaceuticals plans to apply for emergency authorization for a lower dose of its COVID-19 antibody therapy after data showed half the dosage to be nearly as effective (70% compared to 71%). The company previously said it would produce around 750,000 doses by the end of June based on the higher dosage levels, so that number could essentially double.

Moderna, AstraZeneca, Pfizer, and BioNTech have all begun testing the efficacy of vaccines in children, and Johnson & Johnson has imminent plans to do so. Most are starting with older children, but Moderna will include children as young as six months in its first-round trial. Sinovac said its COVID-19 vaccine is safe in children ages 3-17, based on preliminary data.

And the [political appointees] keep marching in!

Two months in, the Senate has finally confirmed Xavier Becerra as HHS Secretary in a 50-49 mostly party-line vote, with Sen. Susan Collins of Maine, the only Republican to vote in his favor. Becerra will immediately be put to the test, playing a major role in the government's COVID-19 response, shoring up the ACA, clamping down on prescription drug prices, and addressing the current influx of migrants at the border (HHS is responsible for housing and caring for detained migrant children). With Becerra's confirmation now in the rearview, this should clear the way for other HHS appointments to move forward, including Chiquita Brooks-LaSure as CMS Administrator and Andrea Palm as deputy secretary of HHS. Assistant health secretary-designate Rachel Levine's nomination has already been advanced to the full Senate, but a floor vote has not yet been scheduled.

Vivek H. Murthy was confirmed this evening. Seven Republicans joined every Democrat present in supporting President Biden's longtime public health adviser to return to the role he held during the Obama administration.

The Senate also confirmed this evening Shalanda Young to be deputy director of the White House Office of Management and Budget (OMB) after Ann Ann O'Leary withdrew from contention.



Biden also [announced](#) his intent to nominate Dawn O'Connell to serve as the HHS assistant secretary for preparedness and response. O'Connell would be responsible for orchestrating the U.S. response to pandemics and biohazard attacks and overseeing the strategic national stockpile. O'Connell was previously the director of the U.S. Office of the Coalition for Epidemic Preparedness Innovations and served as a senior counselor to former HHS Secretary Sylvia Mathews Burwell on global health issues during the Obama administration.

The contentious battle for FDA Commissioner is heating up. Acting chief Janet Woodcock was once considered a lock for the position but has run into rising opposition over her role in lax FDA regulations that may have contributed to the opioid epidemic as well as close ties to the pharmaceutical industry. This opposition comes mainly from liberal groups, fueling concerns that putting her to a nomination could lead to a potentially embarrassing defeat if Democrats defect. As the White House struggles to find other viable candidates, many industry experts and groups have rallied around Woodcock, putting Biden in a somewhat awkward position.

Biden's nomination for drug czar may be coming into clearer focus- the word is that Rahul Gupta, former West Virginia public health commissioner, is leading the pack. Gupta served on Biden's transition team and oversaw West Virginia's response to the opioid crisis in his role as commissioner.

HHS announced a slew of additional healthcare appointees in a joint [announcement](#).

Biden looks to go back in time; reverse controversial Trump-era "gag rule"

After [ordering](#) an initial freeze and extensive review of 2019 Title X federal family planning program restrictions, HHS [announced](#) that it would propose revised regulations that harken back to those issued in 2000 with a few "definitional updates." The restrictions passed under the Trump administration prevented clinics that referred patients for abortions, such as Planned Parenthood, from receiving federal funding. Planned Parenthood forfeited about \$60 million in federal funds when the restrictions were imposed. HHS is currently drafting the new proposed rule and expects to release it "no later than April 15" with a goal of having the final rule "in place by early fall and effective in time for the Fiscal Year 2022 funding announcement," which is expected to be issued in December 2021. Last week, the Justice Department formally asked the Supreme Court to dismiss the pending case concerning the legality of the original rule.

2022 already, I still want 2020 back!

Julia Letlow (R) won the special election for Louisiana's 5th district, filling the seat of her late husband Luke Letlow. She made history as the first Republican woman elected to Congress from Louisiana. The U.S. Congress now has 149 women serving. The race for the state's 2nd district will head to an April 24 runoff. Rep. Filemon Vela (D-TX) said he would not seek re-election next year in his competitive district along the Gulf of Texas, which was already being targeted by Republicans given the surge of immigrants at the border and his 55% victory margin in 2020. Redistricting is expected to give Republicans an added boost towards potentially recapturing the majority in 2022.