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## IN THE NEWS

### **Fake Vaccine Cards Pose Enforcement Challenge as Mandates Rise**

Fake Covid-19 vaccine cards are presenting a fresh quandary for enforcement efforts: Unlike most consumer fraud, neither the buyer nor seller is taking advantage of the other. From August to September, the number of sellers on the darknet offering forged vaccination records or test results went from about 1,000 to 10,000, according to cybersecurity firm Check Point Research. The rise in sellers coincides with an uptick in mandates for consumers around the U.S. to show proof of vaccination before entering certain venues.

The issue poses a novel challenge for both federal agencies and businesses because fake vaccine cards aren't like typical consumer protection matters, where consumers are the ones to report the fraud, said Josh Stein, North Carolina's attorney general. "It's hard to know how extensive a problem this is because this is an instance where you have an illegal transaction where the seller and buyer are complicit," Stein said. "In this instance, the buyer is part of the problem because they're not getting a real vaccine." Buyers of fake vaccine cards aren't "coming clean," he said.

The FBI, Federal Trade Commission, Justice Department, Health and Human Services, and state agencies are all policing the creation and sale of such records. But no coherent approach has emerged to deter their use, or to provide guidance to businesses responsible for checking proof of vaccination. And because buyers can prolong an illegal scheme unless someone tips off the government to the fraud, businesses are on their own to check these cards. They're trying to minimize legal risk by not collecting personal health data, but the lack of verification technology means they're unable to properly detect fraud. "They're really trying to walk the line and balance public safety, safety of their environment, the law if required," said Cynthia Cole, a partner at Baker Botts LLP in Palo Alto and San Francisco. "But they're also frankly not wanting to get their hands too dirty in the sense that they have all this extra info they don't need and don't want."

Almost 80% of the adult U.S. population has received at least one Covid vaccine dose, according to data from the Centers for Disease Control and Prevention. Still, reports about potentially fraudulent vaccine cards have increased "exponentially" lately as proof of vaccination is requested more often, according to Matthew Charette, special agent in charge at the HHS Office of Inspector General. Charette said the office gets tips from a hotline and from regional offices across the U.S. Los Angeles and New York City are among several major cities with Covid-19 vaccine mandates in place for consumers. L.A. requires proof of vaccination or a negative test from guests attending large events such as outdoor concerts and ballgames. It will also require proof of vaccination to enter restaurants, shopping malls, and other indoor venues under an ordinance that takes effect Nov. 4. New York City has a vaccine mandate for patrons of restaurants, gyms, clubs, and other businesses.

The HHS watchdog is in regular communication with the Justice Department, the FBI, and other partners to track Covid-related fraud. Since the beginning of the pandemic, the HHS-OIG has opened approximately 400 formal investigations into Covid schemes. Anyone who makes, buys, or sells a fake vaccine card or fills in cards with false information could be fined or face prison time, according to a warning from the FBI. The warning indicated that the unauthorized use of a government agency's seal on such cards is punishable under a section of U.S. criminal code. So far, enforcement cases have focused on sellers of fake vaccination records, rather than buyers. People who knowingly purchase fraudulent vaccination cards could be considered part of a conspiracy with sellers of such cards, meaning both the buyer and seller face potential charges. In one case, a California-licensed naturopathic doctor was arrested for allegedly selling counterfeit Covid-19 vaccination cards, along with so-called immunization pellets that she falsely claimed would provide lifelong immunity to the virus.

A high-profile case involves San Jose Sharks ice hockey player Evander Kane, who allegedly submitted a fake vaccine card earlier this month to his team and the National Hockey League. The NHL, which doesn't have a vaccine mandate but imposes fewer restrictions on vaccinated players, said Kane violated Covid-19 protocol and handed him a 21-game suspension without pay. The FTC has warned consumers against buying fake Covid-19 vaccine cards or negative test results. It says offers like these could turn out to be scams that seek personal information to commit identity fraud. The commission said it hasn't received many fraud complaints related to vaccine cards or test results. Fraudulent vaccine cards could potentially run afoul of the FTC Act's prohibition against unfair and deceptive business practices.

Though federal agencies are handling the oversight, enforcement isn't trickling down to the local businesses that are checking vaccination proof by choice or due to public safety measures mandated by local law. Owners of bars, clubs, and restaurants, and organizers of conventions and professional gatherings will need to train their staff to meet their obligations under local or state ordinances requiring proof of vaccination for entry, restaurant and entertainment industry lawyers say. But venues and their owner and managers will likely face little legal risk related to counterfeit vaccination cards since there is no formal fraud detection procedure or guidance to follow. Without a credible system, restaurants and bars will check vaccination cards in the same way that they check driver's licenses or other ID cards to verify that customers are old enough to drink, said Travis Gemoets, a partner at Jeffer Mangels Butler & Mitchell LLP in Los Angeles. The task could also be more complicated in jurisdictions allowing the use of a recent negative Covid-19 test as an alternative to proof of vaccination. "Servers and bartenders aren't required to be forensic document examiners," he said. "I think if a card presented by a customer appears to be valid, that's going to be good enough to protect the business, just like with driver's licenses." Making sure a vaccine card wasn't purchased on eBay is "almost certainly beyond the scope of duty of any restaurant or bar," said Nathan J. Breen, a partner at Howe & Hutton Ltd. in Chicago. "You can't hold these establishments responsible for the wrongful or potentially criminal actions of third parties," he said. "I don't think that's going to happen."

Consumer-facing businesses are shying away from collecting Covid-19 information for the most part, attorneys say. Some are checking vaccine cards or negative test results at the door, but they're generally not requiring consumers to upload those to an online portal for verification. Retailers and restaurants don't want to collect that sort of information online because bad actors could breach it or it could be mishandled by employees, said Cole, the Baker Botts attorney. Breaches of that information could potentially implicate state data breach notification statutes or the California Consumer Privacy Act, she added. With no federal database or registry for companies to vet vaccination cards against, requiring that information to be digitally uploaded or for consumers to show an uploaded record—instead of a paper copy checked at the door—likely would be unfeasible for the average business, said Tom Zych, a partner at Thompson Hine LLP in Cleveland. "Most businesses are doing the best they can, but they're not in the position to actively detect fraud," he said. "Businesses aren't law enforcement—they're trying to avoid injecting themselves into that role."

### **Covid Vaccines Protect Better Than Earlier Infection, CDC Says**

A new study offers more evidence that Covid-19 vaccines provide stronger protection against hospitalization than immunity from an earlier infection, the U.S. Centers for Disease Control and Prevention said Friday.

Hospitalized patients who weren't vaccinated but had been previously infected with Covid were about five times more likely to test positive for the infection than people who had been vaccinated, according to the CDC study.

The CDC has long recommended that people get vaccinated even if they have already had Covid-19.

“We now have additional evidence that reaffirms the importance of Covid-19 vaccines, even if you have had prior infection,” CDC Director Rochelle Walensky said in a statement. “This study adds more to the body of knowledge demonstrating the protection of vaccines against severe disease from Covid-19.”

The study of 7,000 adults hospitalized with Covid-like symptoms compared how many tested positive for the virus with rates of vaccination and prior infection.

### **U.S. Spies Say Covid-19 Origins Unclear Without China’s Help**

Covid-19 was probably not a biological weapon and most U.S. analysts believe it wasn’t genetically engineered at all, but a final conclusion on the virus’s origins is impossible without cooperation from China, a declassified U.S. report says.

The Office of the Director of National Intelligence released its long-awaited public findings on the virus’s origins on Friday, a declassified version of the secret report submitted to President Joe Biden this summer. The intelligence community remains divided on where the outbreak began, but believes two causes are plausible -- that it spread through animals to humans, or that it sprang from an incident at a lab in the city of Wuhan.

“China’s cooperation most likely would be needed to reach a conclusive assessment of the origins of COVID-19,” according to the report. “Beijing, however, continues to hinder the global investigation, resist sharing information, and blame other countries, including the United States.”

The report sets out key outstanding questions, including information about the earliest cases of Covid-19, Chinese hospital occupancy rates, and information on animals present in a series of Wuhan markets. The U.S. previously released declassified highlights of the same report.

China’s resistance to working more without other nations and outside groups to investigate the virus’s origins reflect its “uncertainty about where an investigation could lead as well as its frustration the international community is using the issue to exert political pressure on China,” according to the report.

### **Pfizer Shot Cleared for Kids 5 to 11 in Pandemic Milestone**

Pfizer Inc. and BioNTech SE’s Covid-19 vaccine was cleared by U.S. regulators for children ages 5 to 11, a long-awaited pandemic milestone that opens a new phase of the immunization campaign. The emergency authorization, announced Friday in a statement by the Food and Drug Administration, brings the U.S. a step closer to shots being administered at schools, pediatricians’ offices and pharmacies around the country. The formulation for young kids is one-third the dose of the adult shot.

Before youngsters can begin to receive the vaccine, the Centers for Disease Control and Prevention’s immunization advisory committee will also meet to make more specific recommendations about who should get it and how to administer it. The panel is currently scheduled to convene on Nov. 2 and 3. CDC director Rochelle Walensky will then need to sign off on the advisers’ guidance.

The FDA’s action on Friday allows shipments of the doses to begin -- the first time the U.S. has distributed anything other than the regular Pfizer dose for teens and adults. The shipments would position the shots at pediatricians’ offices, pharmacies and other locations across the country so that inoculations can begin promptly after any CDC clearance. “Vaccinating younger children against COVID-19 will bring us closer to

returning to a sense of normalcy,” Acting FDA Commissioner Janet Woodcock said in the statement. “Our comprehensive and rigorous evaluation of the data pertaining to the vaccine’s safety and effectiveness should help assure parents and guardians that this vaccine meets our high standards.”

Pfizer shares rose 1.3% at the close in New York. BioNTech’s American depositary receipts lost 1.9%. Officials at hospitals and clinics have been discussing the rollout for children. In Washington, for example, health officials plan to make newly authorized doses for kids available at clinics and pharmacies such as those of CVS Health Corp. and Walmart Inc. The city will also host pop-up clinics at elementary schools and Children’s National Hospital plans to distribute the shots to children at its eight primary care locations and via a mobile unit canvassing the community. New York’s Westchester Medical Center has served as a coordinator for the distribution of vaccines throughout the Hudson Valley. Michael Gewitz, physician-in-chief at the center’s Maria Fareri Children’s Hospital, said the process of vaccinating 5- to 11-year-olds will be different from earlier campaigns. That means they’ll focus vaccination efforts on pediatricians’ offices in their network as well as at a small vaccine site on the medical center’s campus. “For the children in the 5-to-11 age bracket, we want to administer it in a more friendly, personal environment,” Gewitz said. “We think it will be a better environment for children, especially young children.”

Many doctors are looking to hear what the experts on the CDC’s Advisory Committee on Immunization Practices recommend for the vaccine’s use, said Buddy Creech, director of the Vanderbilt Vaccine Research Program. “I think the desire is for pediatricians to begin having those conversations with families, answering questions that the parents might have, and then waiting for what the ACIP provides guidance on next week,” said Creech, who’s helped conduct a trial of Moderna Inc.’s Covid vaccine in children. Megan Ranney’s son Clark is anxiously awaiting his shot. Her 10-year-old is jealous of an elder sister who’s already been vaccinated and can do more socializing, said Ranney, an emergency physician and researcher at Brown University in Rhode Island.

“Our family rule is you could do sleepovers the summer going into third grade, and he missed that because of Covid,” she said. “He’s never done a sleepover and he really wants to.” She didn’t make the decision on immunization lightly, she said, given the risk of a rare form of heart inflammation called myocarditis that’s associated with the vaccine in some adults, particularly males. The data show the shot is safe, she said. “The risk of myocarditis from the vaccine, even for boys, is lower than the risk of myocarditis from Covid itself,” she said. “Covid is one of the top 10 leading causes of death this year in children. I do a lot of things to protect my kids from injury and illness that are less common than Covid. This seems like a no brainer.” President Joe Biden’s administration has said they have enough vaccine for all 28 million kids in the 5 to 11 age group, and they’re ready to ship the shots. “Upon FDA authorization of the vaccine, millions of doses will be shipped immediately to tens of thousands of pediatricians, family doctors, children’s hospitals, community health centers, rural health clinics, and pharmacies — providers parents and kids know and trust,” Jeff Zients, Biden’s Covid-19 response coordinator, said Wednesday at a press briefing. “We will be ready immediately following FDA and CDC’s decisions so that parents can get their kids vaccinated quickly, easily, and conveniently.”

The recent surge in infections fueled by the delta variant and the return of in-person learning have increased calls for younger children to be immunized. While FDA advisers unanimously recommended approval of the shot, some expressed concern about a lack of data on side effects, the prevalence of Covid in children, and other issues. The advisers supported the vaccine in part because so many children with Covid don’t show risk factors before catching the disease, said Peter Marks, head of the FDA’s Center for Biologics Evaluation and Research, during a media briefing following the announcement. “Trying to limit it to just a high risk group could create issues, including issues of making sure that the general population was protected,” he said. It may be a few months until authorities consider shots for children under age 5, Marks said. “As we

get down to younger children the benefit-risk gets to be even more of a careful consideration because the youngest children are affected the least directly in terms of severe Covid-19,” he said.

The U.S. has been focusing on ways to bolster its defenses and prevent another virus surge. Just last week, the FDA paved the way for millions of recipients of Moderna Inc. and Johnson & Johnson vaccines to receive their Covid boosters.

## **LEGISLATIVE/REGULATORY**

### **Biden Vaccine Rule Will Let Employers Make Workers Pay for Tests**

The Biden administration’s highly anticipated vaccine mandate rule for private-sector employers will allow businesses to force workers who refuse to get the Covid-19 shot to pay for required weekly tests and masks, two sources familiar with the matter said.

The emergency rule, which will apply to companies with at least 100 employees and is expected to be released next week, will give employers the option of paying for testing and masks for unvaccinated workers or compelling those employees to foot the bill themselves, according to the sources, who requested anonymity because they didn’t have approval to discuss the rulemaking.

Employers will be required to absorb testing and mask costs in cases where a worker qualifies for an exemption to vaccination under federal law, the sources said. For instance, employers could be required to finance testing and masks for a worker who is entitled to a religious exemption or to an accommodation under the Americans with Disabilities Act. Companies also may be ordered to pay when testing costs are subject to a union bargaining agreement. Unvaccinated workers will be required to wear masks while indoors and in close contact with coworkers, the sources said.

The emergency rule, being developed by the U.S. Labor Department’s Occupational Safety and Health Administration, remains under consideration at the White House’s regulatory office. Final decisions on its parameters, including on testing costs, are still subject to approval by the White House Office of Information and Regulatory Affairs.

After it is released, the rule will allow for an implementation period before employers must comply or face citations of up to \$14,000 per violation, the sources said. The White House and Department of Labor declined comment. An administration official, speaking on condition of anonymity, said that any details of the forthcoming OSHA rule are premature and that the rule will be discussed in detail once publicly available in the Federal Register.

The OSHA emergency rule is at the heart of the Biden administration’s effort to increase the federal government’s response to the coronavirus’s delta variant. President Joe Biden directed the Labor Department in September to write an emergency rule to require businesses with 100 or more employees to ensure workers are either fully vaccinated or receive a weekly test, but the issue of who will pay for testing emerged as a major point of contention inside the administration. The mask requirement for unvaccinated workers wasn’t part of the president’s initial directive for OSHA to implement through rulemaking. The testing-cost question has been the subject of significant lobbying pressure because of the enormous logistical and financial ramifications for many companies.

By giving employers the flexibility to pass costs on to vaccine-resistant workers, the administration appears to be seeking a way to further encourage more Americans to get the shot. But the move also could increase

backlash from opponents of vaccination and government mandates. Several state attorneys general from Republican-led states have already vowed to file lawsuits challenging the administration's authority to impose a workplace vaccination mandate. Many businesses welcomed Biden's announcement of the impending rule, seeing it as providing government cover for them to require vaccinations for workers to return to the office. OSHA released another Covid-19 emergency temporary standard earlier this year that applies only to the health-care sector.

### **Fault Lines Emerge Among Democrats on Drug Price Negotiations**

Democrats remain at odds over how to design legislation to allow the government to negotiate for lower drug prices, a divide that may keep a solution out of their sweeping domestic policy package.

The White House omitted measures meant to lower drug prices from its framework for a \$1.75 trillion domestic spending package released Thursday. There isn't enough agreement among Democrats on drug price negotiation to include it in the framework, a Biden administration official told reporters Thursday.

The fault lines were on display as lawmakers rush to reach a deal to get it back into the package (advancing in the House as H.R. 5376). Sen. Kyrsten Sinema (D-Ariz.) has sought to limit negotiations to just drugs in Medicare Part B, the outpatient service, that aren't under patent protections, according to a person familiar. Ron Wyden (D-Ore.), chairman of the Senate Finance Committee, said he wants negotiations to include Part D, the prescription drug benefit, as well as Part B. "That's where seniors live and they see it in line at the pharmacy counter," he said Thursday.

Two House aides, including a senior staffer on the Energy and Commerce Committee, said they don't think a drug pricing package that includes just Part B or off-patent drug negotiations could pass the House. The concern is that it could lead to more patient gaming by drugmakers, which don't want their products to face negotiations.

Senators said they see a deal coming together and are just ironing out the criteria for which drugs face negotiations. Wyden said he spoke to Sinema shortly after the framework was released and won't drop the issue. Others say they see a deal nearing fruition. "I am hopeful there is still a path towards getting prescription drug price negotiation that would reduce out of pocket costs into the final bill," Sen. Chris Coons (D-Del.) said. "We are very close to having a path forward on that, but it wasn't resolved in time to be part of this."

### **Biden's \$1.75 Trillion Gambit Shifts Focus to Party Divides**

President Joe Biden delivered a framework for the latest version of his economic agenda to congressional Democrats on Thursday, drawing widespread praise within the party but leaving many details yet to be filled in.

Biden delayed his departure for a series of meetings in Europe to rally his party behind the \$1.75 trillion outline, scaled back from a previous \$3.5 trillion proposal. Even as Democrats welcomed it as a break in the months-long stalemate over the president's agenda, some angled to jam back in priorities such as family leave that were left out. The president told House Democrats that his future, and theirs, depends on translating the framework into agreed legislative text and getting it passed. "I don't think it's hyperbole to say that the House and Senate majorities and my presidency will be determined by what happens in the next week," Biden told House Democrats during a private meeting at the Capitol, according to three people in the room.

As Biden left for his European summit meetings, House Democrats released a rough draft of legislation to enact the plan, but then adjourned until next week. It likely will take days or even weeks before legislation is ready for a vote.

Progressives in the House largely embraced Biden's \$1.75 trillion tax and spending plan but continue to hold up the other piece of his economic agenda -- a \$550 billion infrastructure bill -- until both bills are ready for a vote. "This is a significant set of investments that will be transformational for people," Representative Pramila Jayapal, head of the Congressional Progressive Caucus, said. "We intend to vote for both bills when the text is ready." That's a reflection of the lack of trust between liberals and two moderate Democrats in the Senate, Joe Manchin of West Virginia and Kyrsten Sinema of Arizona -- who through protracted negotiations with Biden have whittled down his plan and left some progressive priorities by the wayside. Neither gave their explicit endorsement of Biden's framework, even though it appeared to meet most of their demands.

Sinema met Thursday afternoon with Jayapal and Senator Brian Schatz. She said little afterward, except that they "made progress." Jayapal called it "a great meeting. That's all I'm going to say about it." Manchin abruptly brushed aside questions about whether he supported the framework. "We're working in good faith, how is that?" he said.

The Biden plan, known as Build Back Better, includes provisions Democrats called unprecedented that would combat climate-change measures, universal preschool for three- and four-year-olds, subsidies for most Americans' childcare costs and the creation or expansion of other social-welfare programs. It's offset by tax increases and other revenue measures totaling about \$2 trillion, according to a White House fact sheet. "Any single element of this framework would be viewed as a fundamental change in America," Biden said in remarks at the White House after leaving the Capitol. "Taken together, they're truly consequential."

In his comments to House Democrats, Biden urged them to quickly clear the infrastructure measure for his signature. The White House wants the president to have a legislative accomplishment in hand in advance of both international summits in Rome and Glasgow, Scotland, this weekend and gubernatorial elections in New Jersey and Virginia on Nov. 2. House Speaker Nancy Pelosi had moved Thursday morning to potentially set up a vote on the Senate-passed infrastructure bill later in the day. But progressives said they wouldn't vote for it. Pelosi, having no margin of error, relented and didn't force the issue. The House Thursday night passed another temporary extension of highway funding to give time for work on the larger package to proceed.

Some progressives expressed anger that she would try to ram through a vote on the infrastructure bill before an agreement on the larger plan is put on paper. House progressives Juan Vargas of California and Cori Bush of Missouri said after a meeting among their caucus that they would not vote for Biden's infrastructure bill until the other legislation is ready. "I felt a little bit bamboozled," Bush said. "This was not what I thought was coming today." Biden assured the House lawmakers that the framework the White House released Thursday would win the votes of all 50 Senate Democrats. But several of them declined to commit to it. "The administration may have negotiated with Sinema and Manchin. They've got to get 48 other people," said New Jersey Senator Robert Menendez.

Like many other northeast Democrats, he wants the legislation to include at least a partial reversal of a Trump-era cap on federal income tax deductions for state and local tax payments. "The framework is not a final product as far as I'm concerned," he said. Senator Tina Smith of Minnesota urged liberals in the House



to continue to block action on the infrastructure measure, saying it wasn't clear 50 senators would support Build Back Better as outlined.

Senate Finance Committee Chairman Ron Wyden, an Oregon Democrat, said he's still negotiating to add provisions to regulate prescription drug prices and to tax billionaires' unrealized capital gains. Separately, some House Democrats are demanding the Build Back Better legislation also include an immigration overhaul that would give undocumented people in the U.S. greater protections against deportation. The White House framework allows for such a program, but it isn't clear if Senate rules would permit new immigration policies in the bill.

### **Pelosi Leading Talks to Add Drug Price Cuts in Biden Plan**

House Speaker Nancy Pelosi is leading an effort to add a plan to cut prescription drug prices to President Joe Biden's \$1.75 trillion economic plan, and lawmakers are optimistic a deal can be reached within days.

Biden left mention of cutting drug prices out of the outline he presented to Congress on Thursday, but even opponents of the original House provision said they would be open to a more limited version. Arizona Senator Kyrsten Sinema had agreed to at least some version of drug price cuts in a deal with the White House, according to a person familiar with her views.

To win over the handful of House and Senate Democrats who were holding out support, Democrats will have to drop or modify a proposed 95% excise tax on drug companies that was to be used to force them to lower prices for younger patients not part of Medicare, according to Vermont Democratic Representative Peter Welch.

Welch said Pelosi is "intimately" involved in the talks and they are working with drug price provision holdout Representative Scott Peters of California. He said Peters is on track to prevail in his quest to have the 95% tax penalty changed. "We have to change that," Welch said on a conference call with reporters. "It was a dealbreaker for Scott and a couple of my other colleagues, but there are other ways you can do it." Peters in a Friday interview said that he was "very optimistic" a deal can be reached in the coming days. Peters said he is still fighting against the excise tax penalty because he said it would stifle innovation for life-saving drugs, but that he favors reducing ability of drug companies to extend patent exclusivity indefinitely.

"To clarify, the excise tax is still part of these discussions," Welch said later in an emailed statement. "In these ongoing conversations some of my colleagues have expressed concern about this enforcement mechanism, but all of us agree that we need to ensure the pharmaceutical companies come to the table for real negotiation in order to lower costs for consumers."

Pelosi "continues to push for this important priority of House Democrats," a spokesman, Henry Connelly, said on Friday, referring to lowering drug prices.

The original House proposal would have imposed a 95% excise tax on drug firms that failed to extend the lower prices negotiated with Medicare to private insurers. Democrats have debated replacing that with either a lower tax or an alternative that wouldn't cut as deeply into drug-makers' profits, according to a person familiar with the discussions. Other options include excluding drug-makers who refuse to negotiate from federal programs like Medicare, or a binding arbitration process, the person said. But no agreement has been struck.

Welch said lawmakers are homing in on a deal that would provide rebates for seniors who see prices for certain drugs rise faster than the inflation rate. The emerging plan could allow Medicare to negotiate drug prices for the first time, and talks continue on what categories of drugs will be subject to the cost-cutting negotiation power. Welch said the plan centers around drugs no longer under patent protection rather than drug company exclusive products, but is tied to patent reforms meant to stop repeat extensions.

Welch said also under consideration is excluding the smallest bio-tech firms from negotiation or offering other protections to them to foster innovation. Peters said he is not opposed to the idea. Welch told reporters that given the needs, lawmakers are outraged at the prospect of drug prices not making it into the budget bill. “A lot of my colleagues are saying ‘Really, that’s political malpractice’,” he said.

Peters said that once both sides firmly agree to protect patent exclusive drugs, then the talks will be on the exact levels of inflation rebates and other parameters in the bill. “There don’t see any real reason that we should exclude common sense prescription drug measures from this bill,” he said.

### **Dialysis Centers to Get \$220 Million Medicare Payment Bump**

Medicare payments to freestanding dialysis centers will increase an estimated 2.5% in 2022 while hospital-based facilities will see a 3.3% payment bump, the Centers for Medicare & Medicaid Services reported Friday.

The increases announced in the final payment rule (RIN 0938-AU39) will hike Medicare payments by \$220 million next year, while total program spending will increase by \$290 million for dialysis patients with kidney failure, or end-stage renal disease (ESRD). Medicare beneficiaries who receive dialysis treatments will see their coinsurance payments increase by an estimated 2.5%, or roughly \$60 million, next year.

The final payment rates were more than double the rate increases the CMS had first proposed in July. At that time, the agency proposed a 1.2% payment increase for freestanding dialysis centers and a 1.3% increase for those based in a hospital. The final rule also changes the ESRD Treatment Choices payment model to encourage dialysis facilities and providers to cut disparities in the rate of home dialysis treatments and kidney transplants among low-income patients. The payment model is one of the agency’s first to address health equity, which is a top priority of the Biden administration. “Today’s final rule is a decisive step to ensure people with Medicare with chronic kidney disease have easy access to quality care and convenient treatment options,” CMS Administrator Chiquita Brooks-LaSure said in a statement. “Enabling dialysis providers to offer more dialysis treatment options for Medicare patients will catalyze better health outcomes, greater autonomy and better quality of life for all patients with kidney disease.”

Under current law, the base payment rate for dialysis services in traditional Medicare was projected to increase by 1.5% in 2022. But the Medicare Payment Advisory Commission had recommended no payment update, noting in its March Report to Congress that the cost of providing dialysis services had declined in recent years.

For people with kidney failure, dialysis machines replace the filtering function of the failed organ. In 2019, traditional Medicare spent \$12.9 billion on dialysis treatments for nearly 395,000 beneficiaries, the commission reported. About 7,700 dialysis facilities treated Medicare beneficiaries that year.

About 10% of Medicare dialysis spending in 2019 went to two medications that qualified for an add-on payment adjustment. Cost and payment data from 2018 and 2019 show per-treatment dialysis costs fell 4%

over this period, while Medicare's payment per treatment increased by 2%. The aggregate profit margin for dialysis centers on Medicare patients increased from 2.1% to 8.4% over the same period.

### **Biden's Spokeswoman Diagnosed With Covid After Skipping Trip**

White House Press Secretary Jen Psaki said she tested positive for Covid-19 on Sunday, sidelining President Joe Biden's top spokesperson.

Psaki, who has been vaccinated, revealed her diagnosis while Biden was in Europe to attend a Group of 20 talks and a climate summit -- a trip she skipped after citing a family emergency last week. Psaki, 42, said she last saw the president on Tuesday, sitting outside more than six feet apart and wearing masks. Biden tested negative for Covid most recently on Saturday, a White House official said.

Psaki is among the highest profile figures in the Biden administration to test positive. Homeland Security Secretary Alejandro Mayorkas tested positive recently after an outdoor event with Biden. State Department spokesman Ned Price said he tested positive in late September. Biden in late September received his booster shot, which health experts say restores vaccine protection to original levels, amid concerns that the Pfizer Inc.-BioNTech SE vaccine fades after roughly six months. Biden received the Pfizer vaccine. Vice President Kamala Harris received her booster shot Saturday. "While I have not had close contact in person with the president or senior members of the White House staff since Wednesday -- and tested negative for four days after that last contact -- I am disclosing today's positive test out of an abundance of transparency," Psaki said in a statement. "I last saw the president on Tuesday, when we sat outside more than six-feet apart, and wore masks."

The White House didn't consider Biden a close contact of Mayorkas because they'd been at an outdoor event more than 48 hours before the cabinet member tested positive. Psaki's circumstance matches that, suggesting Biden again won't be considered a close exposure.

Psaki said she decided to forgo Biden's trip on Wednesday after members of her household tested positive for Covid. She said she quarantined after that, followed by the series of negative tests until Sunday. She said she has experienced mild symptoms thanks to the vaccine, allowing her to continue working from home, and plans to return to work in person at the end of the 10-day quarantine. Psaki isn't the first White House press secretary to get Covid. Kayleigh McEnany, former President Donald Trump's chief spokesperson, tested positive in the fall of 2020.

Trump was hospitalized for four days in October 2020 after contracting the virus, putting a temporary damper on his re-election campaign. In a video released shortly afterward, he sought to play down the peril of a virus that had killed more than 210,000 Americans at the time. Biden has been moving to quell the pandemic as part of his push to reopen society and the economy. The U.S. has opened eligibility for booster shots widely, though not fully, and is poised to begin inoculating kids ages 5 to 11 this week, pending approval by the Centers for Disease Control and Prevention.

## **LEGAL**

### **HCA Healthcare Beats Payment Coordinator's Retaliation Suit**

A former payment coordinator for a medical center failed to show that HCA Healthcare Inc. violated federal laws by firing her in retaliation for raising complaints about receiving Medicare payments despite not satisfying contractual requirements, a federal court in Texas said.

Clarisse C. Toledo “complained about mistakes, glitches, poor work, and her frustrations—but not fraud or illegal activity,” Judge Lynn N. Hughes of the U.S. District Court for the Southern District of Texas ruled in an opinion granting HCA summary judgment.

The record also shows Toledo was fired because she continually made mistakes despite receiving targeting training, the court said. These mistakes could lead to lost revenue and leave patients without necessary care, Hughes said in the ruling issued Tuesday.

The court also said that the two individuals who made the decision to fire Toledo never heard her concerns about allegedly illegal or fraudulent activity. Toledo worked at the Bayshore Medical Center near Houston, which HCA operates. Toledo brought claims under the False Claims Act and National Defense Authorization Act.

Toledo alleged in her December 2017 complaint she was fired for complaining that Bayshore’s therapists didn’t give patients sufficient care, nurses didn’t document patient scores or discharge assessments, and that one supervisor asked her to back-date missing admissions orders.

The case is Toledo v. HCA Healthcare Inc., S.D. Tex., No. 19-cv-3683, 10/26/21.

### **Ten GOP-Led States Sue Biden Over Covid-19 Vaccine Mandate**

Missouri and nine other states on Friday became the latest to join a Republican-led effort to sue the Biden administration over vaccine mandates.

The complaint filed by Missouri Attorney General Eric Schmitt (R), Nebraska Attorney General Doug Peterson (R), and the other states’ attorneys general asks the U.S. District Court for the Eastern District of Missouri to block mandated Covid-19 vaccines for all employees of federal contractors. The Biden administration doesn’t have the authority to require the vaccines, the states say. “President Biden has arrogated to the Executive Branch the unilateral power to mandate that all employees of federal contractors be vaccinated,” the complaint said. “This power grab is sweeping in its scope.”

One-fifth of the total U.S. workforce are federal contractors, according to the complaint. The mandate will apply even to employees whose work isn’t related to a federal contract or who work from home, it says. The mandate is “unconstitutional, unlawful, and unwise,” the complaint says.

It harms the states by affecting state agencies that are federal contractors, preempting state public health orders, and—in those states with constitutional protections for them—violating privacy rights, it says. “This is a once in a generation pandemic that has taken the lives of more than 700,000 Americans, and the president has committed to pulling every lever possible to save lives and stop the spread of the virus,” an Office of Management and Budget spokesperson told Bloomberg Law in reply to a request for comment. “Vaccine requirements work: they’re good for workers, good for the economy, and good for the country,” the spokesperson said, adding that President Joe Biden “has authority to promote efficiency in federal contracting in this way.”

Missouri also will sue to halt the employer vaccine mandate when the Occupational Safety and Health Administration publishes its upcoming rule, Schmitt hinted in an Oct. 27 press release. So far, Arizona and Florida have sued the administration to stop the mandates. Alabama Gov. Kay Ivey indicated in an Oct. 25 executive order that her state also will sue. Alaska, Arkansas, Iowa, Montana,

Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming also signed on to Missouri's complaint.

Causes of Action: Procurement Act, Procurement Policy Act, Tenth Amendment, anti-commandeering doctrine, Administrative Procedure Act, separation of powers doctrine, and the spending clause.

Relief: Declare guidance and executive order unconstitutional; declare mandate violates procurement laws and was adopted in violation of APA; and block enforcement of vaccine and masking mandates.

The case is Missouri v. Biden, E.D. Mo., No. 4:21-cv-1300, complaint filed 10/29/21.

## **AROUND THE STATES**

### **Colorado**

#### **Colorado Lets Hospitals Turn Away Patients as Covid Surges Anew**

The state of Colorado, where the Covid-19 vaccination rate is one of the highest in the U.S., will allow overwhelmed hospitals to turn away new patients, the governor's office announced Sunday.

The executive order by Governor Jared Polis, a Democrat, authorizes the state health department to "order hospitals and freestanding emergency departments to transfer or cease the admission of (and redirect) patients to respond to the current COVID-19 Disaster Emergency in Colorado."

The governor's order also brings the state closer to full-blown rationing of medical care. It allows for implementation of so-called crisis of care standards, a detailed protocol for health care workers to decide in an emergency who should be treated first.

Acute care hospital bed occupancy -- that's both intensive care unit and medical-surg unit beds -- has been averaging about 90%, state data show. Staffing shortages have been severe in many parts of Colorado, both urban and rural.

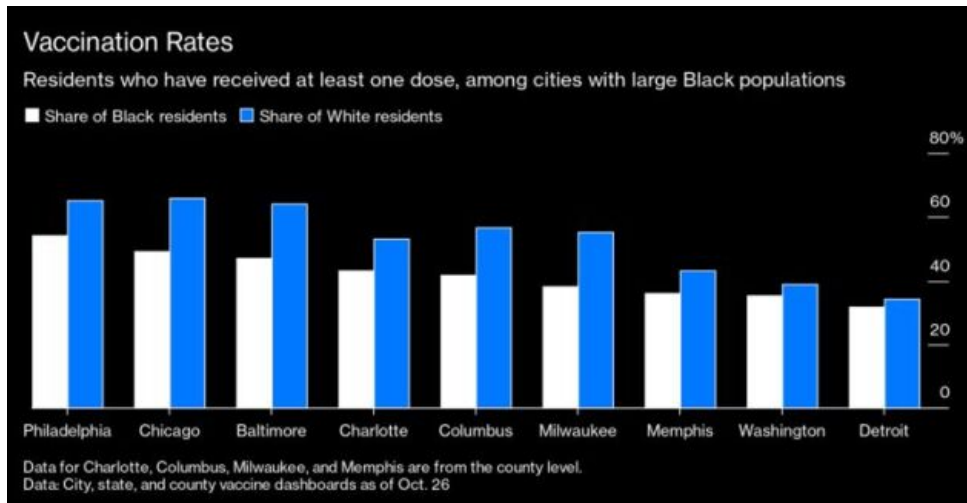
Last week, Polis announced Colorado will begin moving monoclonal antibody treatment for Covid-19 out of hospitals to a fleet of mobile clinics, effective Monday.

### **Pennsylvania**

#### **Philadelphia Recruits Black Doctors to Boost Covid Vaccine Rate**

Earlier this year, Philadelphia's partnership with the student-led group Philly Fighting Covid Inc. abandoned testing sites in Black neighborhoods. It seemed like the latest affront in a long legacy of racism that has fueled distrust in the medical system, dating back to the infamous Tuskegee experiments in the 1930s. But Philadelphia, after a slow start, is closing out the year with one of the highest Black vaccination rates in a major U.S. city.

In Philadelphia, 54% of Black citizens are now vaccinated. That puts it at the top of a group of the country's 10 most Black cities, with populations of 500,000 or more and with Black people making up anywhere from 77% to 28% of the population. (The country's second-largest city, Los Angeles, has vaccinated 55% of its Black residents, but they're just 8% of the population.)



The Black Doctors Covid-19 Consortium, a group of 50 Black health-care professionals, is a big reason Philadelphia—where Black people are 38% of the population—turned vaccination rates around. Doctors fanned out into hard-hit neighborhoods citywide, initially using their mobile unit to test residents. As demand grew, they worked with community leaders to set up testing sites in churches and community centers. They also conducted general health checkups, treating any ailments they could. “From Day 1, we were trust-building,” says Ala Stanford, a pediatric surgeon and founder of the consortium. The group has administered more than 53,000 shots, of which about 80% went to African Americans. On some days it vaccinated more than 1,000 people, reserving shots for poorer ZIP codes and keeping clinics open late into the evening. And because some residents were reluctant to provide personal details, the consortium streamlined and simplified the sign-up process.

The city government helped by repurposing its census outreach team to go door to door combating vaccine misinformation. “The neighborhoods that are what the Census Bureau calls hard to count aligned pretty neatly with our low-vaccination neighborhoods,” says Stephanie Reid, who heads Philly Counts, Philadelphia’s census canvassing program. Now the city is honing its messages to reach residents aged 18 to 44, the Black age group with the lowest vaccination rates.

That demographic is also a reason why vaccination efforts are lagging in Black communities in many other cities. Detroit, for instance, has vaccinated less than a third of its Black population, says Denise Fair Razo, its chief public health officer. The city has launched a new campaign under the tagline “Get the Vax, Not Fiction,” targeting unvaccinated millennials and other younger adults who are susceptible to social media misinformation, such as the false claims that vaccines make people magnetic or infertile or cause mutations, she says.

It remains a mystery why what works in one place may not work in another. Detroit, which has the largest share of Black residents among big cities, has already tried most of the same things that succeeded in Philadelphia. City workers have gone back out and knocked on 320,000 doors. The city has 10 fixed sites and a mobile unit, and it offers in-home vaccination to residents who request it, usually within 24 hours. It’s even offered shots at restaurants, churches, festivals, barbershops, and salons. “This is not a sprint, it’s a marathon,” says Fair Razo.

## Texas

### Doctors Sue Agencies Over ‘No Surprises Act’ Regulation

The Texas Medical Association sued HHS and other agencies in federal court to halt a new regulation governing the No Surprises Act, which takes effect Jan. 1.

The regulation unfairly favors health insurers and other providers over health-care providers in a dispute resolution process intended to resolve issues over surprise billing of patients, according to TMA’s complaint filed in the U.S. District Court for the Eastern District of Texas. The new procedure gives insurers a “windfall,” and undermines providers’ ability to receive fair compensation for their services, TMA says.

The No Surprises Act limits the amount patients must pay when treated by health-care providers who aren’t in their health insurers’ physician networks, the complaint says. It also restricts out-of-network providers from billing patients for amounts that exceed patients’ in-network cost-sharing obligations.

Congress created a procedure for binding arbitration before a certified independent dispute resolution entity to resolve provider-payer disputes over how much the insurer must pay the provider. The law contains a detailed list of factors the IDR entity must consider when determining the appropriate amount, the complaint says.

But an interim final rule issued by the Health and Human Services, Labor, and Treasury departments and the Office of Personnel Management in September adds a rebuttable presumption requiring IDR entities to “give outsized weight to a single statutory factor—the ‘qualifying payment amount,’” TMA says.

The qualifying payment amount is the median amount of a payer’s contracted rates for an item or service, as determined by the payer, the complaint says. The rebuttable presumption doesn’t appear anywhere in the No Surprises Act and is “manifestly unlawful,” TMA says.

Additionally, the federal agencies adopted the regulation without putting it out for notice and comment, as required by the Administrative Procedure Act, the complaint says. The agencies’ decision that there was “good cause” for skipping the notice-and-comment step also was unlawful, TMA says. There was no need to issue the regulation so quickly, as the first arbitrations under the law won’t take place until March 2022, the complaint says.

The TMA is the U.S.’s largest state medical society. It represents more than 55,000 physicians and medical students, Thursday’s complaint says.

The case is *Tex. Med. Ass’n v. HHS*, E.D. Tex., No. 21-cv-425, filed 10/28/21.