



Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



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Editor's note

This note is produced every Friday by the [KPMG Center for Healthcare Regulatory Insight](#) and is intended to be short and succinct, no more than 360 words, to provide a digestible bite of healthcare and life sciences news from the past week. Please share this email with colleagues and other interested individuals, and encourage them to [subscribe to our mailing list here](#).

We welcome your feedback. Let us know if KPMG can help. Please [reply here to me](#), **Larry Kocot**, principal and national leader, KPMG Center for Healthcare Regulatory Insight or simply reply to this email with any comments or requests.



Special Supplements: COVID-19 News

In light of the continuing daily volume of COVID-19 activity and news, we have summarized [COVID-19 news for the week in this special supplement](#).



Healthcare regulatory news

An [HHS-Labor-Treasury interim final rule](#) requires employer health plans and other insurance plans to [report prescription drug/health coverage costs](#); data will be used to [evaluate drug pricing trends](#) and rebates, and impacts on premiums/out-of-pocket costs... HHS [delayed by six months](#) the deadline for [pharmaceutical manufacturers to comply](#) with Medicaid “best price” calculation changes.

CMS announced [standard 2022 Medicare Part B premiums will increase](#) from \$148.50 to \$170.01, the largest increase in 15 years, largely attributable to a [“contingency reserve”](#) pending coverage decisions on Biogen’s Aduhelm... a European Medicines Agency advisory panel [appears unlikely to approve](#) Aduhelm.

CMS reported [1,624,349 individuals \(286,905 new enrollees\) selected ACA coverage](#) during open enrollment week 1/2...CMS guidance [permits hospitals to co-locate](#), as long as each entity [complies with Medicare/Medicaid participation requirements](#)... CMS leadership [outlined principles](#) for expanding coverage, improving equity, and encouraging innovation in Medicaid/CHIP.

CMS reported it [reduced improper Medicare fee-for-service payments 2014-2021 by over \\$20B](#) and improper payments were down to a record 6.26% in FY2021; the [Medicaid improper FY2021 payment rate was 21.69%](#) or \$98.72B.



Healthcare law and policy news

House passed Democrats’ social spending reconciliation bill [with several healthcare provisions](#)... CBO [estimated](#) expansion provisions would cost roughly \$300B, but be largely offset by drug pricing provisions; the overall package would [add \\$160B to the deficit over 10 years](#).

A federal judge approved a [\\$345M Pfizer settlement over alleged EpiPen price-gouging](#).

Novo Nordisk [will acquire Dicerna Pharmaceuticals](#) (\$3.3B)... Kaufman Hall [will acquire Healthcare Real Estate Capital](#)... Jefferson Health and BAYADA [plan to form a home health joint venture](#)... CVS will [close about 900 stores over the next three years](#) to focus on digital strategies.

BLS reported [589,000 healthcare industry workers left their jobs](#) in September, the highest one-month in 20 years... CDC [data show](#) for the first time [more than 100,000 Americans died from drug overdoses](#) in a 12-month period... ICER reported drug manufacturers significantly [raised prices on seven widely used medicines in 2020 without new clinical evidence](#) to justify increases.

Representatives Diana DeGette (D-CO) and Fred Upton (R-MI) [unveiled Cures 2.0](#) legislation, including [provisions](#) to enhance biomedical research, [overhaul federal telehealth policy](#), expedite medical device approval, and provide \$6.5B for President Biden’s proposed biomedical research agency.



Questions or comments, please send to us-hcinsight@kpmg.com.

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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There have now been [roughly 47.5 million confirmed COVID-19 cases](#) in the US, with a death toll over 765,000... Cases are [up roughly 20% over the last two weeks](#) (nearly [90,000/day](#)) with higher increases in parts of the Upper Midwest and New England.

445 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 1.26 million/day over the past week)... More than 228.5 million Americans ([79.8% of Americans 12 and older](#)) have received at least one COVID-19 vaccine dose; over 195.7 million Americans are fully vaccinated (69% of Americans 12 and older); 32.5 million Americans have received a booster dose... The White House reported that roughly [10% of eligible children](#) (2.6M) have received a first dose of Pfizer's COVID-19 vaccine.

Executive and Administrative Action

The White House [announced plans to invest billions of dollars](#) to expand US manufacturing capabilities for COVID-19 vaccines and produce at least 1 billion doses a year to increase the supply for poorer countries.

The 5th Circuit Court of Appeals [extended its order halting OSHA](#) from enforcing the mandate that businesses with more than 100 employees require COVID-19 vaccination or proof of a negative test, criticizing the rule as “fatally flawed”... The 6th Circuit Court of Appeals [will next consider the case](#) and a response from the Biden Administration... OSHA was developing [new guidance on individual exemptions to the vaccine requirements](#), although it has paused implementation work pending legal resolution.

President Biden [directed agencies to share real-time data](#) about eligibility for federal COVID-19 benefits to [prevent distribution of benefits to deceased](#) individuals.

CMS [guidance lifts restrictions](#) on nursing home visitation.

HHS [withdrew a Trump Administration rule](#) that blocked FDA from requiring premarket review of certain laboratory-developed tests, including COVID-19 tests.

Healthcare Law, Business, and Policy News

More than 60 healthcare groups, including the AMA, [urged employers to voluntarily adopt](#) the Biden Administration's employer vaccine mandate.

A Morning Consult survey found that [70% of American adults are concerned about another pandemic happening in their lifetime](#); just 47% of respondents believe the country will be prepared to handle the public health impacts of another health crisis like COVID-19... A KFF [study found that 60% of](#)

[unvaccinated Americans](#) identify as Republicans, compared to just 17% who identify as Democrats and 17% who identify as Independents.

Surveillance, Testing, and Treatment

The FDA [authorized booster shots](#) of the Pfizer-BioNTech and Moderna COVID-19 vaccines for all adults... CDC's Advisory Committee on Immunization Practices (ACIP) [will meet today](#) to discuss expanded eligibility of the Pfizer-BioNTech vaccine; it's unclear if they will formally consider the Moderna vaccine.

Moderna [applied for emergency use authorization](#) of COVID-19 vaccine booster doses for all adults 18 and older... Moderna is also [nearing a deal with COVAX to provide millions more COVID-19 vaccine doses](#) to low- and middle-income countries over the next year.

A [comparative study](#) of Pfizer-BioNTech's, AstraZeneca's, Sputnik V, and Sinopharm COVID-19 vaccines found that Pfizer-BioNTech's vaccine produced the strongest immune response, while Sinopharm's was most susceptible to breakthrough infection from variants.

Novavax is [facing a class action lawsuit from shareholders](#) alleging that the company misled investors about how soon its COVID-19 vaccine could be ready for emergency use authorization.

Pfizer [applied for emergency use authorization of its COVID-19 antiviral pill](#), Paxlovid, in combination with Abbvie's ritonavir to treat mild-to-moderate disease in unvaccinated patients who are at increased risk for hospitalization or death... The federal government [will buy 10 million courses](#) of the antiviral treatment for \$5.29 billion... Pfizer also [reached a licensing agreement with the Medicines Patent Pool](#) for its COVID-19 antiviral pill, allowing the UN-backed organization to establish arrangements with other manufacturers to produce versions of the drug for low- and middle-income countries.

AstraZeneca reported that its [injectable COVID-19 antibody treatment was 83% effective at preventing symptomatic disease](#), while significantly reducing serious illness in those who did become infected.

U.S. government [agreed to buy roughly 300,000 more doses \(\\$651.1M\) of the monoclonal antibody developed by GlaxoSmithKline and Vir Biotechnology](#), bringing its total order to nearly \$1 billion.

A [JAMA study found that use of selective serotonin reuptake inhibitor \(SSRI\) antidepressants appears to reduce the risk of death](#) in patients admitted to the hospital with severe COVID-19.

NIH launched a [study on long-term COVID-19 in children](#).