



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

Center for Healthcare Regulatory Insight



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Due to the holidays, ATW 360 will not publish on the next two Fridays. We'll be back with our next issue on January 7th. The KPMG Center for Healthcare Regulatory Insight team wishes you the best of the holiday season and a great New Year!

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 Supplement: 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

HHS' twice-yearly [Regulatory Agenda](#) includes [fixing the ACA "family glitch,"](#) curbing [short-term, limited duration](#) insurance plans, and [expediting coverage](#) for emerging technologies.

President Biden [directed agencies to better coordinate](#) enrollment/receipt of health benefits.

CMS told Congressional members [it plans to issue regulations to rein in pharmacy payment](#) to PBMs.

FDA approved [a Bristol Myers Squibb treatment](#), in combination with immunosuppressants, for prevention of acute graft versus host disease in patients undergoing bone marrow or stem cell transplantation... FDA [granted accelerated approval for Calliditas Therapeutics' treatment](#) to reduce proteinuria.

FDA will ask FTC to [investigate "anticompetitive business practices"](#) by Endo International to delay competition to a blood pressure treatment.



Healthcare law and policy news

Senate HELP Committee [considered the nomination of Robert Califf](#) as FDA Commissioner; full Senate confirmation is expected.

Senate [Finance](#) and [HELP](#) committees released updated portions of the \$1.75T Build Back Better Act, which would, among other things, [eliminate a plan to cut DSH payments](#) in states that have not expanded Medicaid and [exempt generic drugs at risk of shortages and biosimilars](#) from inflation rebates... President [Biden acknowledged](#) that enactment will not be possible until 2022.

A Humana [federal antitrust lawsuit against Gilead, Teva, Bristol Myers Squibb, and Janssen alleges they conspired](#) to delay HIV generic competition.

A federal court judge [overturned a \\$4.5B Purdue Pharma bankruptcy settlement](#) that shielded the Sackler family from future opioid-related lawsuits.

CSL [plans to acquire Vifor Pharma](#) (\$11.7B)... Pfizer [will acquire Arena Pharmaceuticals \(\\$6.7B\)](#)... Eli Lilly will [partner \(\\$380M\) with Foghorn Therapeutics](#) on genetic treatments for cancer... Centene is [evaluating options for offloading its \\$2B overseas](#) operation.

Biogen is [planning a clinical trial](#) to confirm benefits of its Alzheimer's drug Aduhelm.

CMS Office of the Actuary [reported healthcare spending increased 9.7%](#) in 2020 to \$4.1T; federal healthcare expenditures increased 36%... A Gallup-West Health study found [30% of Americans have skipped needed medical care](#) in the previous three months over cost concerns, up from 18% in March... A Mercer [survey found 2021 employer health insurance costs rose 6.3%](#) to \$14,542/employee; costs rose 3.4% last year.

A [JAMA study found benchmarking physicians against peers](#) significantly decreased the number of [potentially unnecessary endovenous thermal ablations](#), [resulting in reduced Medicare spending](#).



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

Succeeding in the new reality

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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There have now been [roughly 50.5 million confirmed COVID-19 cases](#) in the US, with a death toll over 800,000... Cases are [averaging approximately 122,000/day](#) up 41% over the past two weeks, with deaths averaging roughly 1,300/day.

488 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 1.55 million/day over the past week)... More than 240 million Americans ([82.7% of Americans 12 and older](#)) have received at least one COVID-19 vaccine dose; over 203 million Americans are fully vaccinated (70.5% of Americans 12 and older); over 57 million Americans have received a booster or additional dose... CDC [data show that only 44% of adults 65 and older](#) had received a booster shot as of just before Thanksgiving.

Executive and Administrative Action

HHS Secretary Xavier Becerra suggested that the [Administration may need Congress to provide additional funding](#) to combat the pandemic in the wake of the Omicron variant.

HHS [distributed \\$9 billion in COVID-19 relief to more than 69,000 providers](#); remaining Phase 4 provider relief funding is expected to be distributed throughout the beginning of 2022... HHS [reopened the Provider Relief Fund reporting portal through December 20](#) for recipients who experienced technical and other issues when reporting use of funds.

HHS estimates [demand for COVID-19 tests in the US could reach 3 to 5 million tests per day](#) by late January, far above the current level of 1.6 million/day.

More than [165,000 government employees have been granted](#) exemptions from or extensions for the Administration's vaccine mandate.

US Equal Employment Opportunity Commission [guidance states that workers who contract COVID-19 can be protected from discrimination](#) under the Americans with Disabilities Act.

Healthcare Law, Business, and Policy News

Early in the week, the U.S. Court of Appeals for the 8th Circuit [denied the federal government's request](#) that its COVID-19 vaccination mandate for healthcare workers proceed while appeals continue; however, the 5th Circuit [subsequently ordered that the vaccine mandate continue in about half of the states](#) while the appeal moves forward... Meanwhile, the Supreme Court [denied a request to block](#) New York's [requirement that healthcare workers be vaccinated](#) against COVID-19... The Biden Administration [asked the Supreme Court](#) to allow the nationwide mandate to remain in place.

A [JAMA meta-analysis found](#) that 40.5% of tested individuals with confirmed cases of COVID-19 were asymptomatic, highlighting the potential transmission risk of asymptomatic infections in communities.

A Yale-Commonwealth Fund study [estimated that US deaths and hospitalizations from COVID-19](#) would have been 3.2 times and 4.9 times higher, respectively, without the country's vaccination efforts, effectively preventing 1.1 million deaths and 10.3 million hospitalizations.

51% of respondents to an [Axios/Ipsos poll believe it should be illegal for companies to deny services or employment](#) to individuals who are not vaccinated against COVID-19; 52% believe returning to pre-pandemic life right now is a large or moderate risk, up from 44% in late November.

A [FAIR Health study found](#) that New Jersey had the highest average in-network cost for complex COVID-19 hospitalizations (\$128,650), while Maryland had the lowest (\$49,127).

Surveillance, Testing, and Treatment

White House Chief Medical Advisor, Anthony Fauci, said that [existing COVID-19 booster shots appear to perform well enough against the Omicron variant](#) and there is no need for an adjusted vaccine.

CDC's Advisory Committee on Immunization Practices unanimously [recommended Pfizer-BioNTech's and Moderna's mRNA COVID-19 vaccines over Johnson & Johnson's vaccine](#) for adults 18 and over due to evidence of rare, but serious blood clot risks... FDA is [updating its fact sheet for Johnson & Johnson's COVID-19 vaccine](#) after finding that 15% of those who developed the rare, but severe blood clot complications died.

Pfizer and BioNTech [asked FDA to grant full approval](#) for use of their COVID-19 vaccine in children ages 12 to 15.

A [study in South Africa found](#) that a two-shot course of Pfizer-BioNTech's COVID-19 vaccine [may be only 22.5% effective against symptomatic infection](#) with the Omicron variant... A UK study found that COVID-19 vaccine boosters [improve protection against the Omicron variant by as much as 75%](#).

A preliminary [study found two doses of the Moderna COVID-19 vaccine](#) are less effective at neutralizing the Omicron variant, as compared to other variants; antibodies produced by individuals who had received a booster dose were highly effective at blocking the variant.

Sanofi and GlaxoSmithKline reported preliminary clinical trial data showing [a single dose of their COVID-19 vaccine provided strong](#) immune responses.

Moderna will [allocate 150 million additional doses](#) of its COVID-19 vaccine to COVAX... COVAX [expects access to 1.38 billion COVID-19 vaccine doses](#) by the end of the month, down from earlier projections of 1.425 billion.

Regeneron reported that its COVID-19 monoclonal antibody therapy [has diminished potency against the Omicron variant](#), while AstraZeneca said that its antibody, authorized to prevent COVID-19 in people who may not respond to vaccines, [retained neutralizing activity](#) against the variant.

Pfizer reported that final clinical trial results show its COVID-19 oral antiviral pill, Paxlovid, [retained its 89% efficacy at preventing hospitalization and death](#) in high-risk adults... President Biden said that the country has [ordered enough Pfizer antiviral pills to treat 10 million patients](#).