



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

Center for Healthcare Regulatory Insight



November 12, 2021 | Issue 197

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

CMS [rescinded](#) the [Medicare Coverage of Innovative Technology final rule](#).

HHS [named 200 hospital participants](#) for the [HHS Maternal Morbidity and Mortality Data and Analysis Initiative](#) to improve maternal/infant

health outcomes... CMS increased funding for Basic Health Program insurance coverage for 1.1 million [New York](#) and [Minnesota](#) recipients.

OMB is reviewing an [FDA proposed rule establishing federal standards](#) for licensing prescription drug wholesale distributors/third-party logistics providers and the [2023 ACA exchanges proposed rule](#).



Healthcare law and policy news

President Biden [nominated Robert Califf](#) as FDA Commissioner.

Supreme Court [will hear a dispute over the scope of federal laws governing](#) employer-sponsored health plan coverage of end-stage renal disease care... Two [federal courts diverged](#) on [whether the federal government can require](#) pharmaceutical manufacturers to resume passing on 340B discounts to contract pharmacies... Oklahoma Supreme Court [overturned a \\$465M judgement](#) against Johnson & Johnson (J&J) over its role in the opioid epidemic.

Justice Department is [investigating Oak Street Health](#) for possible False Claims Act violations related to [third-party marketing agents and "free transportation"](#)... Two Sun Pharmaceuticals subsidiaries will [pay \\$85M to settle generic pharmaceutical](#) pricing antitrust litigation... Kaleo will [pay \\$12.7M to resolve False Claims Act allegations](#) related to its opioid overdose treatment.

GE will [split into three public companies](#), including GE Healthcare... J&J will [split into two public companies](#): consumer goods and prescription drug/medical devices... Anthem [will acquire Integra Managed Care](#)... Tenet will [acquire SurgCenter Development \(\\$1.2B\)](#), gaining ownership interest in 92 ambulatory surgery centers... Blackstone will [invest upwards of \\$250M in Autolus Therapeutics](#) to fund development of a leukemia therapy.

Biogen is [investigating the death of a 75-year-old patient](#) who took Aduhelm... Roche said [its Alzheimer's drug, if approved, would be priced competitively](#), likely below the cost of Aduhelm.

A KFF survey found the [cost of employer-sponsored family health insurance coverage](#) increased 4% to \$22,221; 95% of large employers [cover telehealth](#) in their largest health plan... A JAMA study found [hospitals are charging private insurers "considerable markups"](#) on commonly used Part B drugs, in some cases several times Medicare prices... Lown Institute estimated [Medicare could save \\$8B/year if all hospitals achieved the same outcomes and cost efficiency](#) as the 750 top performing hospitals.



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

Succeeding in the new reality

Visit the COVID-19 resource center for KPMG analysis, insights, and perspectives.



kpmg.com/socialmedia



[Privacy](#) | [Legal](#)

You have received this message from KPMG LLP. If you wish to unsubscribe from Around the world of U.S. healthcare in 360 words or less, please click [here](#). If you wish to unsubscribe from all KPMG communications, please click [here](#).

KPMG LLP, 3 Chestnut Ridge Road, Montvale, NJ 07645

© 2021 KPMG LLP, a Delaware limited liability partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved. NDP131714-1A

The KPMG name and logo are trademarks used under license by the independent member firms of the KPMG global organization.



COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There have now been [roughly 46.9 million confirmed COVID-19 cases](#) in the US, with a death toll of nearly 760,000... The country averaged [roughly 74,000 new cases per day](#) over the past week, up 4% from the preceding two weeks.

434 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 1.31 million/day over the past week)... More than 224.6 million Americans ([79% of Americans 12 and older](#)) have received at least one COVID-19 vaccine dose; over 194 million Americans are fully vaccinated (68.5% of Americans 12 and older); 26 million Americans have received a booster dose... The White House said roughly [900,000 children under age 12 received a vaccine in the first week of eligibility](#), with another 700,000 scheduled to receive their first dose.

Executive and Administrative Action

The Biden Administration will [invest \\$650 million to ramp up domestic manufacturing](#) of COVID-19 rapid diagnostic tests... The White House [announced \\$785 million in American Rescue Plan funding to combat health inequities](#) in communities most impacted by the pandemic.

The Administration also announced efforts to support global vaccination, including [donating 1.5 million doses of Johnson & Johnson's vaccine](#) to COVAX for people in conflict zones and other humanitarian settings, a [COVID-19 data tracker](#) built by the World Health Organization and other international organizations, and a [public-private partnership to assist with vaccine campaigns](#).

The Administration will also make FEMA pandemic support [available to states, tribes, and territories through April 1, 2022](#).

An [appeals court suspended the Biden Administration's COVID-19 vaccine requirement](#) for private employers with over 100 employees... the White House urged businesses to [move forward with the vaccine requirement for employees](#), while expressing optimism that the requirements would ultimately stay in effect... Surgeon General Vivek Murthy also [defended the mandate as an "appropriate and necessary"](#) step to combat the pandemic... Meanwhile, [10 states sued to halt](#) the Administration's vaccine [requirement for healthcare workers](#) and the American Medical Association [defended the requirement in a friend-of-the-court](#) brief.

FCC [awarded \\$42.16 million in funds](#) to 75 additional applicants in the COVID-19 Telehealth Program, bringing the total awarded to \$166.13 million.

Healthcare Law, Business, and Policy News

Ellume will [recall 2.2 million at-home COVID-19 tests](#) due to the risk of returning false positives. A KFF [survey found that 78% of adults had heard](#) at least one of eight false statements about COVID-19 and either believe it to be true or were unsure what to think... An Axios/Ipsos survey found that [55% of Americans believe returning to normal life is only a small risk or no risk at all](#), up from just 40% in late-August.

Surveillance, Testing, and Treatment

Pfizer-BioNTech asked the FDA to [authorize a booster dose of their COVID-19 vaccine for anyone 18 and older](#)... Pfizer's CEO reiterated his belief that [COVID-19 boosters could be needed annually](#).

Moderna and the National Institutes of Health are [disputing the role that NIH researchers played in development of Moderna's COVID-19 vaccine](#) and whether federal researchers should be listed on the "principal patent application"... NIH Director Francis Collins said that NIH [scientists played "a major role" in development of the vaccine](#) and the agency plans to defend its claim as co-owner of vaccine patents.

AstraZeneca is creating [a separate division within the company for vaccines and antibody therapies](#) in order to better focus COVID-19-related efforts.

Regeneron reported a [single dose of its mAb cocktail reduced the risk of contracting](#) COVID-19 by 81.6% in the two-to-eight-months period following the drug's administration in a late-stage trial.

Pfizer plans to [submit data on its experimental COVID-19 antiviral pill to the FDA](#) by November 25 with hopes of receiving emergency use authorization... according to President Biden, the federal government [purchased "millions of doses"](#) of the pill, pending FDA authorization.

Merck reported that the federal government will [buy another 1.4 million courses of its COVID-19 antiviral pill molnupiravir](#) developed with Ridgeback, bringing the total doses purchased to 3.1 million... The EU is negotiating with Merck and Pfizer [over possible contracts to supply their respective antiviral pill](#) to member states; discussions with Merck have progressed further because the company has already submitted data to the European Medicines Agency.