



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

Center for Healthcare Regulatory Insight



January 14, 2022 | Issue 204

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.



Correction: Last week's ATW360 issue misstated that 6.4% of [healthcare workers quit their jobs](#) in November. According to the U.S. Bureau of Labor Statistics, **[3.7% of health care and social assistance workers separated from their jobs in November](#)**.

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 [proposed limited Medicare coverage](#) of Aduhelm (and other amyloid-beta directed monoclonal antibodies) [for Alzheimer's beneficiaries in qualifying clinical trials](#)... anticipating lower Medicare costs for Aduhelm, HHS Secretary Xavier Becerra ordered CMS to reconsider the 2022 Part B premium increase.

CMS reported [more than 14.2M individuals have enrolled](#) in ACA plans... CMS Administrator Chiquita Brooks-LaSure [indicated the agency would increase partnerships with private companies](#) on addressing costs and health disparities.

HHS transmitted [user fee agreements \(prescription drug, generic drug, biosimilar\)](#) to Congress to advance reauthorization legislation.

HRSA [updated ACA preventive care and screening guidelines](#) for women and children; ASPE also released [a report on how Americans are benefitting](#) from ACA-covered preventive care.

ONC [issued a data standard for patient addresses](#) in health records and urged industry adoption.

White House Office of Science and Technology Policy is [seeking comments on how digital health technologies can](#) transform “community health, individual wellness, and health equity.”



Healthcare law and policy news

Senate HELP Committee [advanced Robert Califf's nomination](#) as FDA Commissioner.

A US District Court [authorized Purdue Pharma and the Sackler family to appeal](#) a ruling that threw out their \$4.5B settlement.

Medtronic [will acquire Affera \(\\$925M\)](#)... R1 RCM [will acquire Cloudmed \(\\$1.4B\)](#)... Pfizer will pay up to \$1.35B to [partner with Beam Therapeutics on gene-editing drugs](#) for rare genetic diseases of the liver, muscle, and central nervous system... Bayer will [pay Mammoth Biosciences up to \\$1.04B](#) to collaborate on gene-editing technologies... Amgen and Arrakis Therapeutics [will partner](#) on targeted RNA degrader therapeutics... Morgan Health will [partner with Kaiser Permanente to address health disparities](#)... [Kaiser Permanente will join Graphite Health](#) as an organizing member to improve interoperability.

46brooklyn reported drug [launch prices are rising faster](#) than prices for existing drugs... FAIR Health reported national telehealth insurance claims [declined 6.8% September to October](#) after two months of increases... Commonwealth Fund reported health insurance [premiums and out-of-pockets costs accounted for 11.6% of median household income in 2020](#), up from 9% in 2010.

Employment at [hospitals and nursing care facilities fell in December](#), while physicians' offices jobs increased.

Provisional CDC data [predict 101,263 drug overdose deaths](#) in the 12-month period ending in June 2021, up 3.3% over those already reported.



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.

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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There have now been [roughly 64 million confirmed COVID-19 cases](#) in the US, with a death toll over 845,000... The country is now [averaging more than 780,000 cases/day](#) more than doubling over the past two weeks; COVID-related deaths are averaging approximately 1,700/day over the past 7 days, up from 1,200 two weeks ago and approaching the peak level of the last wave in September/October.

524 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 1.29 million/day over the past week)... Nearly 248 million Americans ([84.7% of Americans 12 and older](#)) have received at least one COVID-19 vaccine dose; 208.6 million Americans are fully vaccinated (71.7% of Americans 12 and older); over 78 million Americans have received a booster or additional dose.

Executive and Administrative Action

[HHS-Labor-Treasury guidance](#) requires private health insurers to [reimburse individuals for up to eight over-the-counter COVID-19 tests every month](#) beginning January 15; [plans can establish programs at preferred pharmacies and retailers where upfront costs are covered](#) for beneficiaries, although plans must still reimburse up to \$12/test when purchased at other locations.

The White House announced it would [make 5 million rapid COVID-19 tests and 5 million lab-based PCR tests available to schools](#) beginning this week... the Administration announced it would [purchase 500 million more at-home COVID-19 tests](#) and take steps to make N95 and KN95 masks available and free for Americans... the Department of Defense [signed contracts with Abbott, iHealth, and Roche to supply 380 million](#) of the over-the-counter test kits.

The Supreme Court [blocked OSHA's rule](#) that would have required [more than 80 million workers at large employers to get vaccinated or be tested](#) regularly, while [allowing](#) the [healthcare worker vaccine requirement for facilities accepting Medicare and Medicaid to stay](#) in place.

CDC is [considering updating its mask guidance to recommend](#) that people wear N95 or KN95 masks, while the Administration is [considering whether to distribute such masks](#) to all Americans... ASPR [plans to award a contract to increase domestic manufacturing](#) of N95 and KN95 masks.

The Biden Administration is [deploying 1,000 military medical personnel](#) to six states (NY, NJ, OH, RI, MI, NM) to help hospitals that are overwhelmed with COVID-19.

FDA [draft guidance advises device makers](#) to notify the agency at least six months in advance of a potential manufacturing disruption that could threaten the supply chain of products deemed essential during the pandemic.

Federal agencies [must begin testing unvaccinated workers starting February 15](#).

FDA will [permit unauthorized laboratory-developed COVID-19 tests to remain on the market](#) while they undergo agency review, so long as appropriate data is submitted for review by today (January 14).

Healthcare Law, Business, and Policy News

The [Senate HELP Committee pressed](#) White House Chief Medical Advisory Anthony Fauci, CDC Director Rochelle Walensky, Acting FDA Commissioner Janet Woodcock, and ASPR Dawn O'Connell on, among other things, the Administration's [COVID-19 testing strategy and availability, CDC isolation guidance, access to medical grade masks, and availability of therapeutics](#).

Providers, [including the American Hospital Association, are urging the Biden Administration to renew](#) public health emergency and national emergency declarations before they expire on January 16 and March 1, respectively.

House Speaker Nancy Pelosi said [additional federal COVID-19 relief could be added](#) to the legislative package to fund the government after February 18.

An [Axios/Ipsos survey found that 57% of Americans](#) have socially distanced in the last week, the highest rate since early May 2021; meanwhile, the numbers of individuals who have gone out to eat (46%), visited friends or relatives (50%), and visited a non-grocery retail store (52%) are the lowest since March/April 2021... A Harris poll found that [56% of Americans believe protecting the health and safety of teachers and students is more important than opening schools](#) for in-person learning.

A Commonwealth Fund [analysis projected that tripling the pace of COVID-19 booster vaccinations](#) to 2.3 million/day could reduce COVID-19 hospitalizations by more than 35% and deaths by nearly 30% between now and April.

Axios reported that the [average cost of a single at-home rapid COVID-19 test is about \\$12 in the US](#), more than in any other country examined and more than twice the cost of a test in France; Canada and UK provide free rapid tests.

Surveillance, Testing, and Treatment

CDC recommended that adults who received the two-dose Moderna COVID-19 vaccine [receive a booster at least five months afterwards](#), down from six months and consistent with recent recommended changes for the Pfizer-BioNTech vaccine.

CEOs of [Pfizer](#) and [Moderna](#) indicated that vaccines to protect against the Omicron variant should be available within months... Pfizer plans to [manufacture 50 million to 100 million doses of an updated version of its vaccine](#) to target Omicron.

Moderna expects to [report trial data on its COVID-19 vaccine in children ages 2 to 5](#) by March.

FDA [updated the fact sheet](#) for Johnson & Johnson's COVID-19 vaccine to warn about the risk of a rare bleeding disorder.

The federal government [agreed to purchase 600,000 more doses of the GlaxoSmithKline-Vir Biotechnology monoclonal antibody](#), sotrovimab, which appears to be effective against Omicron... the

companies are seeking expansion of the emergency use authorization to [allow for use of the therapy as an intramuscular injection](#) (shot), in addition to currently authorized intravenous administration.

The federal government is [purchasing of 500,000 doses of AstraZeneca's antibody drug](#) to be used by vulnerable individuals as a preventive measure against COVID-19.

Regeneron [plans to test multiple monoclonal antibodies](#) for effectiveness against the Omicron variant and expects to begin trials in humans this quarter.

Novartis is [seeking to bring its experimental COVID-19 drug to patients](#) through emergency use authorization prior to final trial results.

Pfizer's CEO said that the company [expects to make 120 million courses of its COVID-19 antiviral pill this year](#), including 30 million in the first half of the year and 7 million in the first quarter.

Novartis will [seek approval for its injectable COVID-19 antiviral](#) treatment.