



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

Center for Healthcare Regulatory Insight

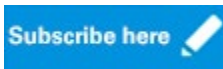


December 3, 2021 | Issue 200

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 reported that [3M individuals enrolled in 2022 ACA](#) coverage through November 27th... CMS is [seeking comment](#) on improving organ transplant programs, [advancing equity and reducing disparities](#), and enhancing quality of life for those with organ failure... CMMI [ended the seriously-ill-population component of the Primary Care First model](#) due to low interest in participation.

OMB is [reviewing a 340B dispute resolution proposed rule](#), although its [purpose/policy is unclear](#).

HHS [warned health systems about the possibility](#) of “zero-day” cyber-attacks.

President Biden [unveiled a five-year National HIV/AIDS Strategy](#).



Healthcare law and policy news

Congress [passed an 11-week continuing resolution](#) to prevent a government shutdown; the CR [does not delay pending Medicare sequester and PAYGO cuts](#).

Supreme Court heard arguments in cases on [calculation of Medicare disproportionate share hospital \(DSH\) payments](#) and [cuts to Medicare 340B drug reimbursement](#).

A [federal jury found CVS, Walgreens, and Walmart guilty](#) of recklessly distributing large quantities of opioids in two Ohio counties... A jury found that [UnitedHealthcare underpaid TeamHealth clinicians](#) for emergency services... An appeals court [upheld a challenge to a patent covering Biogen's multiple-sclerosis drug, Tecfidera](#), paving the [way for generic competition from Mylan](#).

Pfizer and Amazon Web Services will [collaborate on cloud-based solutions to enhance drug development](#) and continuous manufacturing processes... CVS and Microsoft will [partner on digital transformation](#) and co-develop healthcare products... Beginning January 3, Amgen [will no longer offer 340B discounts](#) to contract pharmacies.

KPMG, EBG, and FP reported that [announced/closed healthcare and life sciences deals volume through October](#) already exceeds that of 2020... Blueprint Medicines will [pay \\$250M upfront to acquire Lengo Therapeutics](#)... Sanofi will [acquire Origimm Biotechnology](#).

A [RAND study](#) found that 67% of US patients would like at least some virtual healthcare visits in the future, but 53% prefer traditional in-office visits over a video visit for nonemergent care... An Urban Institute analysis estimated that [13 million adults delayed getting or didn't fill prescription drugs](#) prior to the pandemic due to costs; 25.4% of Medicare enrollees and 5.3% of privately-insured adults spend more than 1% of family income on prescription drug out-of-pocket costs.

More than 60 House members [urged CMS to quickly propose a replacement](#) for the repealed Medicare Coverage of Innovative Technology rule.



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 48.8 million confirmed COVID-19 cases](#) in the US, with a death toll over 785,000... Cases are [averaging over 85,000/day](#) over the past week, with deaths averaging over 800/day.

462 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 950,000/day over the past week)... More than 234 million Americans ([81% of Americans 12 and older](#)) have received at least one COVID-19 vaccine dose; nearly 198 million Americans are fully vaccinated (69.5% of Americans 12 and older); nearly 43 million Americans have received a booster or additional dose.

As of this morning, at least nine [cases of the Omicron variant](#) have been identified in five states across the country... President Biden said the [variant was a “cause for concern, not a cause for panic”](#) and that the Administration would focus on controlling the virus through vaccination and testing, not through lockdowns.

Executive and Administrative Action

The White House [released a comprehensive strategy](#) for addressing the pandemic this winter, including vaccination and boosters campaigns, [increased testing requirements](#) for travelers entering the country, extended mask mandates on public transportation, and private health insurance coverage of rapid, at-home tests... Earlier in the week, the Biden Administration [banned travel to the United States from South Africa and seven other](#) African countries.

As result of the variant, CDC recommended that [all individuals 18 and older “should” get a booster](#) COVID-19 vaccine dose.

The World Health Organization (WHO) classified the new [Omicron COVID-19 variant as a “variant of concern”](#) and urged member states to [increase COVID-19 vaccinations “as rapidly as possible”](#)... WHO also [recommended COVID-19 vaccines for children](#), while encouraging continued sharing of vaccines across the globe.

HHS is distributing [\\$7.5B to more than 40,000 rural healthcare providers](#) to help offset increased expenses and revenue losses during the pandemic.

A Missouri district court [temporarily blocked the Biden Administration from enforcing](#) its healthcare worker vaccine requirement in 10 states, writing that the mandate was “arbitrary and capricious”; the Department of Justice appealed the ruling... A [Louisiana federal district court ruling subsequently halted the vaccine requirement](#) nationwide until a lawsuit from 14 states has been resolved; the [Administration also appealed that ruling](#)... Due to ongoing legal action, CMS [suspended enforcement or implementation](#) of the vaccine requirement.

An Administration official clarified that federal agencies [will not cut ties with contractors that are making a “good-faith effort”](#) to push employees to full COVID-19 vaccination by the January 4 requirement deadline (e.g., workers that have only received one dose of a COVID-19 vaccine).

Healthcare Law, Business, and Policy News

A Willis Towers Watson [survey found that 84% of employers](#) plan to offer COVID-19 testing or test employees regularly as they return to in-person work; 57% require or plan to require COVID-19 vaccination... A Morning Consult survey found that [over three-quarters of Americans support](#) strengthening ventilation systems (81%), social distancing (79%), travel restrictions (78%), increased testing and contact tracing (76%), and providing vaccines in low-income countries (76%) to ensure public safety with the Omicron virus variant... A KFF [survey found that 23% of vaccinated American adults](#) have received a COVID-19 vaccine booster dose; 37% of other vaccinated adults plan to get a booster, while 18% say they probably will not (10%) or definitely will not (8%) get a booster.

Surveillance, Testing, and Treatment

FDA plans to [speed review of vaccines and therapeutics targeting the Omicron](#) variant.

The White House is already working with Pfizer-BioNTech, Moderna, Johnson & Johnson, FDA, and CDC to prepare for quick development and authorization of vaccines and boosters to target the variant; vaccine manufacturers have [already begun development of updated vaccines](#)... WHO [said existing vaccines will likely protect](#) against severe cases from the variant.

An [NEJM study found](#) although both the Pfizer-BioNTech and Moderna COVID-19 vaccines are more than 90% effective, recipients of the Pfizer-BioNTech vaccine had a 27% higher risk of being infected and a 70% higher risk of hospitalization than those who received the Moderna vaccine.

Pfizer [accused a former employee](#) of [stealing more than 12,000 files](#), including confidential documents related to its COVID-19 vaccine.

A federal court [dismissed two patent challenges](#) from Moderna over components involved in producing its COVID-19 vaccine, paving the [way for potential patent infringement suits](#) from Arbutus Biopharma.

South Africa's Aspen Pharmacare [signed non-binding terms with J&J in hopes of establishing a licensing deal](#) to package and sell J&J's COVID-19 vaccine in Africa... AstraZeneca is [dropping plans to test its COVID-19 vaccine](#) as a booster in the United States.

An FDA advisory committee [recommended 13-10 that the agency authorize](#) Merck's COVID-19 antiviral pill molnupiravir developed with Ridgeback Biotherapeutics... Several committee members expressed reservations about authorization, given [full clinical trial data released last week](#) showed that the pill reduced the risk of hospitalization by only 30%, down from 50% reported in earlier clinical trial results. Other concerns about the antiviral raised by the committee were [birth defects caused in animal trials](#), the possibility it could lead to additional viral mutations, and questions about if it could cause permanent changes to DNA. Many committee members recommended that FDA authorize the pill for a narrow set of patients and that authorization be reconsidered as additional therapeutics become available.

Preliminary tests indicate the COVID-19 [monoclonal antibody treatments from Regeneron and Eli Lilly](#) may lose effectiveness against the Omicron variant, while GlaxoSmithKline and Vir Biotechnology said their [COVID-19 antibody treatment was effective against the variant](#) in early lab tests.

FDA [reauthorized the use of Eli Lilly's combination monoclonal antibody in all 50 states](#) and all U.S. territories and jurisdictions based on low frequency of variants resistant to the therapy.

Pfizer announced that it [plans to manufacture 80 million treatment courses of its COVID-19 antiviral pill](#), up from a previous forecast of 50 million courses.

Following CMS permissive guidance last week encouraging Part D plan payment of dispensing fees for emergency authorized COVID-19 antiviral pills without beneficiary cost sharing, six pharmacy groups are [urging CMS to require the Part D payments](#).