



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 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

An [HHS final rule requires](#) most department regulations to be reviewed every 10 years... President-elect Biden [will suspend](#) pending Trump Administration regulations, effective January 20th.

CMS [finalized](#) updated transaction standards for Part D e-prescribing programs... CMS [guidance requires](#) state Medicaid programs to cover all

forms of opioid use disorder treatments... CMS [formally withdrew](#) its Medicaid Fiscal Accountability Regulation... An [HHS advisory opinion says](#) drug manufacturers should provide 340B discounts to contract pharmacies; some [companies are unlikely to comply](#)... CMS issued [guidance to states for addressing social determinants of health](#) in Medicaid/CHIP.

Two federal district courts issued a [14-day temporary restraining order](#) and [injunction](#), respectively, to block implementation of the Most Favored Nation drug pricing model until CMS follows requisite regulatory notice and comment procedures... A federal [appeals court upheld](#) hospital price transparency requirements, which took effect January 1... 115 HCA Healthcare and Christus Health hospitals [sued to block HHS from retroactively changing](#) calculation of DSH payment adjustments.

FDA [approved the first generic of glucagon](#), for treatment of hypoglycemia... FDA draft guidance [aims to support design](#) of single-patient clinical trials for rare diseases.

OIG recommended that [hospital wage index increases target](#) rural hospitals.



Healthcare law and policy news

Congress [certified the election](#) of President-elect Joe Biden and Vice President-elect Kamala Harris.

Haven will [disband by the end of the month](#)... CHI Franciscan and Virginia Mason [completed their merger](#)... New York Life [completed its acquisition of Cigna's group life and disability](#) insurance business... Centene [will acquire Magellan Health](#) (\$2.2B)... Allscripts [sold its care coordination business](#) to WellSky (\$1.35B)... Harvard Pilgrim and Tufts Health Plan [completed their merger](#)... UnitedHealth Group [will purchase Change Healthcare](#) (\$13B)... AmerisourceBergen [will acquire Walgreen's drug distribution unit](#) (\$6.5B)... Methodist Le Bonheur [halted acquisition of two Tenet hospitals](#) after regulatory scrutiny.

A [JMIR study found](#) that the largest increase in telehealth use during the pandemic came from [behavioral health and chronic illness visits](#)... GoodRx reported that pharmaceutical companies [raised prices](#), an average of 4.2%, for 629 brand prescription drugs in the new year... A [Health Affairs study found](#) that hospitals in Medicaid expansion states saved an average of \$6.4M on uncompensated care and increased revenue an average of 8.6M from 2013 to 2017.



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 are now over 21.5 million confirmed COVID-19 cases in the US, with a [death toll over 365,000](#)... The daily death toll [exceeded 4,000 for the first time](#) on Thursday... COVID-19 patients [occupy at least 10% of all hospital beds in 34 states](#)... A more [transmissible variant of COVID-19](#) has been reported in multiple US states.

6.25 million COVID-19 [vaccine doses have been administered in the US](#), just 29% of those distributed to states... NIAID Director Anthony Fauci estimates that the US [could soon be giving 1 million vaccinations a day](#)... CDC reported that [29 people have developed anaphylaxis](#) after receiving a COVID-19 vaccine, or roughly 5.5 per 1 million doses given.

Executive and Administrative Action

HHS will [allocate \\$22 billion to states and local jurisdictions](#) to support testing (\$19B) and vaccination campaigns (\$3B)... HHS announced the Community Based Testing Site program [will operate into April after receiving a \\$550 million](#) funding extension.

Healthcare Regulatory News

FDA granted emergency use authorization to [Quanterix's COVID-19 antibody treatment](#).

FDA [warned that the Curative](#) COVID-19 test, [which is used by Congress](#), is prone to false negative results.

Healthcare Law, Business, and Policy News

Senate Minority Leader Chuck Schumer said [one of his first priorities](#) once becoming Majority Leader will be legislation sending \$2,000 stimulus payments to Americans.... 89% of [respondents to a Politico-Harvard poll](#) believe providing additional financial aid to businesses and individuals impacted by the pandemic is “extremely important” for President-elect Biden and the new Congress.

AHA President and CEO Richard Pollack [urged HHS Secretary Alex Azar to better address ongoing issues](#) related to vaccine rollout and provide more transparency and guidance... Eight Democratic governors [urged the Trump Administration to release the “second doses”](#) of COVID-19 vaccines in order to increase the number of individuals receiving their first dose.

Surveillance, Testing, and Treatment

The Trump Administration plans to [accelerate administration of COVID-19 vaccines](#) at up to 40,000 pharmacies (with 3,000 to 6,000 pharmacies receiving doses within the next two weeks)... HHS Secretary Alex Azar [urged states to start vaccinating people more widely](#), including more seniors and other high-risk populations, to prevent vaccines from going unused.

President-elect Joe Biden plans to [invoke the Defense Production Act](#) to boost COVID-19 vaccine production.

The federal government [discussed with Moderna the possibility of halving the dose](#) of its COVID-19 vaccine... Other countries have [begun delaying second doses of COVID-19 vaccines](#) to increase the rate of people receiving the first dose... FDA released a statement [encouraging following authorized dosing schedules](#)... Pfizer said there was “[no data](#)” to suggest that a [single dose](#) of its COVID-19 vaccine will provide protection from infection after 21 days.

The UK [authorized use of AstraZeneca and University of Oxford’s](#) COVID-19 vaccine and [administered the first dose](#); the US is unlikely to [authorize the vaccine until at least April](#)... The European Medicines Agency [recommended Moderna’s vaccine](#) for authorization in the EU... Moderna plans to increase the [minimum 2021 production of its COVID-19 vaccine](#) from 500 million to 600 million doses... The EU is negotiating to [acquire up to 300 million more](#) doses of the Pfizer-BioNTech COVID-19 vaccines.

Novavax began a [phase 3 trial](#) of its COVID-19 vaccine with 30,000 volunteers... CureVac and Bayer [formed an alliance to seek approval](#) of and distribute CureVac’s COVID-19 vaccine.

Operation Warp Speed chief Moncef Slaoui believes COVID-19 vaccine manufacturers [should “unblind” their trials](#), providing the vaccine to those in the placebo arm, once they gain emergency use authorization.

A team of World Health Organization [researchers have been delayed in beginning a study](#) of COVID-19’s origins in China.

A [study from University of Texas Medical Branch researchers suggests that the Pfizer-BioNTech vaccine](#) may protect against fast-spreading variants of COVID-19... A [Science study found](#) that immunity to COVID-19 [usually lasts at least 8 months after infection](#) and could last longer... A [NEJM study found that blood plasma](#) from recovered COVID-19 patients can help older adults from developing serious illness is treated with the therapy within days of first symptoms.