



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

CMS [extended the ACA special enrollment period](#) until August 15... [Georgia](#) and Arkansas [threatened to sue over CMS revoking](#) Medicaid work requirements.

FDA [approved Merck's Keytruda](#), in combination with platinum/fluoropyrimidine-based chemotherapy, for treatment of esophageal/gastroesophageal carcinoma.

The VA is [reviewing](#) its \$16B Cerner EHR modernization program.



Healthcare law and policy news

The Senate [confirmed Vivek Murthy](#) as Surgeon General and [Rachel Levine](#) as HHS Assistant Secretary for Health... President Biden will [nominate Dawn O'Connell](#) as HHS Assistant Secretary for Preparedness and Response; HHS [announced several other appointments](#)... FDA Deputy Commissioner Amy Abernethy [will leave the agency](#) next month.

The Senate [passed legislation extending the Medicare sequestration moratorium](#) through 2021, which the House is expected to pass and President Biden is expected to sign... The Biden Administration is [developing a \\$3T jobs/infrastructure recovery package](#), likely to [include drug pricing reforms](#)... Senator Bernie Sanders [convened a HELP Committee hearing](#) on drug pricing.

The [Justice Department requested that the Supreme Court](#) give the federal government authority to continue testing future Medicaid demonstrations if the court takes up pending work requirement cases.

Blue Cross and Blue Shield of Michigan [could pay \\$100-125M to settle its portion of a Blues antitrust lawsuit](#) (\$2.67B)... Boston Scientific will [pay 48 states \\$189M to settle deceptive marketing claims](#) related to transvaginal surgical mesh products.

KPMG, EBG, and FP reported that [healthcare IT led all healthcare sectors](#) in February announced/closed deals... Anthem [plans to acquire myNEXUS](#)... Appriss Health [will acquire PatientPing](#)... HCSC and Collective Health [announced a strategic partnership](#) advancing digital health... Nordic Capital will [invest EUR 450M in Leo Pharma](#)... Blackstone Group [will invest \\$100M in Ginger](#)... Pfizer plans to [expand its vaccine business](#) leveraging mRNA technology used in its COVID-19 vaccine... Uber is [partnering with ScriptDrop](#) on prescription delivery.

An AHA-commissioned study estimated that [hospitals could lose \\$53B in total revenue in 2021](#), even with increasing vaccine uptake and decreasing COVID-19 hospitalizations... A [Health Affairs study found](#) that public health spending [declined from \\$80.40 to \\$75.83 per capita](#) between 2008 and 2018... A [JAMA study found](#) 60% of opioids prescribed post-surgery go unused... An AHIP study found that electronic prior authorization [can reduce provider burden and speed patient access](#) to care.



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 are now over 30 million confirmed COVID-19 cases in the US, with a [death toll over 545,000](#)... Confirmed COVID-19 infections [increased in 19 states over the past week](#), while cases remained relatively stable nationwide relative to last week (53,000 cases/day).

NIAID Director Anthony Fauci said that COVID-19 [variants could make up 20 to 30 percent of infections](#) in the United States... CDC Director Rochelle Walensky expressed [concerns about “another avoidable surge” in cases](#) due to new variants if people do not wear masks and social distance.

133 million COVID-19 [vaccine doses have been administered](#) in the US (2.51M/day over the last week)... 87.3 million Americans ([33.7% of Americans 18 and older and 71% of Americans 65 and older](#)) have received at least one dose of a COVID-19 vaccine... An Evercore ISI analysis projected that the US [monthly output for the three authorized COVID-19 vaccines would reach 132 million for March](#), up from 48 million in February.

Executive and Administrative Action

President Biden announced a [new goal of administering 200 million COVID-19 vaccine doses](#) within his first 100 days (April 11th).

The Biden Administration will [commit nearly \\$10 billion to combat inequity in vaccine coverage](#), including \$3B to promote vaccine confidence and \$6B to expand access for community health center workers and patients... The Administration plans to [shift its COVID-19 testing strategy](#) to focus on regularly screening millions of Americans at school or work, rather than just diagnosing individuals who suspect they are infected.

HHS OIG [reported on ongoing challenges](#) for hospitals resulting from the pandemic, with many continuing to operate in “survival mode.”

HHS [removed 25 million out of 26 million isolation gowns](#) from the national medical stockpile in order to validate that they meet Level 2 protection.

Healthcare Regulatory News

FDA granted [breakthrough designation to a neurostimulation device](#) to help wean COVID-19 patients off of ventilators through strengthening their diaphragms... FDA authorized the [first machine-learning-based device](#) to help screen for COVID-19.

FDA indicated it [may not require clinical trials for authorization](#) of some updated COVID-19 vaccines.

BARDA issued [a request for information](#) to identify existing gaps in the pharmaceutical supply chain related to vaccine production.

Healthcare Law, Business, and Policy News

Traditional Medicare [spent \\$10.3 billion on COVID-19 hospitalizations](#) for more than 447,000 beneficiaries in 2020, an average of \$23,000 per patient.

Two *New England Journal of Medicine* studies found that individuals fully vaccinated against COVID-19 very rarely contract the virus ([four out of 8,121](#) in one study and [seven out of 14,900](#) in the other).

The Rockefeller Foundation [released a blueprint for implementing](#) COVID-19 screening programs in schools.

DoorDash launched [an initiative to provide same-date on-demand delivery](#) of COVID-19 test collection kits from Vault and Everlywell.

A Duke analysis estimated that [12 billion doses of 13 different COVID-19 vaccines could become available](#) by the end of the year, enough to vaccinate 70% of the world, although serious barriers remain, including unpredictable manufacturing, emerging variants, and inequitable distribution.

Surveillance, Testing, and Treatment

More than [40 states plan to meet President Biden's goal](#) of making all Americans eligible for COVID-19 vaccines by May 1.

Phase 3 clinical trial data released early in the week found that the COVID-19 vaccine developed by AstraZeneca and University of Oxford was [79% effective at preventing symptomatic COVID-19](#) and 100% effective against severe disease or hospitalization; AstraZeneca will seek emergency use authorization for the vaccine... However, NIH stated that the [Data and Safety Monitoring Board \(DSMB\) expressed concerns about the data](#) used to calculate efficacy of the vaccine, some of which may be outdated, suggesting that [efficacy could be closer to 69 to 75 percent](#)... On Wednesday, AstraZeneca said [revised data show the vaccine was 76% effective](#) against symptomatic infection.

Johnson & Johnson will [likely not be able to meet its goal of delivering 20 million doses](#) of its COVID-19 vaccine to the US government by the end of March... FDA issued an emergency use authorization for a [Catalent Pharma plant to produce and ship doses of Johnson & Johnson's](#) COVID-19 vaccine.

An Israeli study found that the Pfizer-BioNTech COVID-19 vaccine is [less effective against the virus variant that began in South Africa](#)... Pfizer and BioNTech [launched a clinical to test their COVID-19 vaccine in children under 12](#), with results not expected before the second half of the year.

An [American Journal of Obstetrics & Gynecology preprint study](#) concluded that the Pfizer-BioNTech and Moderna vaccines are safe and effective for pregnant women.

COVAX will set [aside 5% of COVID-19 vaccine doses](#) procured as a “buffer” to be used in humanitarian settings or in the case of severe outbreaks.

Late-stage trial data show that Regeneron Pharmaceuticals' [monoclonal antibody therapy cut the risk of COVID-19 hospitalization or death by 70 percent](#) and that it was just as effective at lower doses as at higher doses, prompting Regeneron to seek emergency use authorization for a lower dose than already authorized.

HHS will [stop distributing Eli Lilly's COVID-19 monoclonal antibody bamlanivimab as a single therapy](#) due to increased spread of COVID-19 variants that are resistant to the therapy.

GlaxoSmithKline and Vir Biotechnology [submitted an emergency use authorization](#) application to FDA for their monoclonal antibody therapy.

Zydus Cadila [cut the price of its generic version of remdesivir](#) by 70% to \$12 per injection.

Pfizer began a phase 1 trial of an [experimental oral antiviral drug](#) for COVID-19.