



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

CMMI [released a strategic plan](#) with a goal to place [all Medicare fee-for-service beneficiaries and most Medicaid beneficiaries in accountable care arrangements](#) by 2030... CMS [launched a webpage](#) to support sharing of [state actions to expand Medicaid home and community-based](#) services.

HHS [proposed withdrawing two Trump Administration rules](#) that restricted government enforcement of [agency guidance](#).

FDA approved [Boehringer Ingelheim's Cyltezo](#) as the first [interchangeable biosimilar to Humira](#) and Genentech's [Tecentriq as an adjuvant treatment](#) for non-small cell lung cancer... FDA [proposed establishing](#) an over-the-counter hearing aid market in the US... FDA approved [29 priority abbreviated new drug applications in FY21, up from 28 in FY20](#); approved generics increased from 35 to 53... FDA issued [draft guidance for submitting real-world data](#) to support approval applications.

OIG reported [UnitedHealthcare received \\$3.7B in 2017 MA payments](#) from diagnoses reported only on chart reviews and health-risk assessments.



Healthcare law and policy news

President Biden directed [Congressional Democrats to cut the reconciliation package](#) to \$1.75-\$1.9T... Congressional leaders are [considering vouchers for Medicare dental benefits](#) and [Medicare Advantage cuts](#) to reduce costs... CBO estimated [major provisions of the bill](#), not including new Medicare benefits, would expand coverage to 4.1M people across Medicaid and individual market, while costing \$553.2B over the next decade.

Intelerad Medical Systems [acquired Ambra Health](#)... Everly Health [acquired Natalist](#)... Oak Street Health [acquired RubiconMD](#) (\$130M)... Jefferson Health [will partner with General Catalyst](#) to access tools aimed at digital transformation... Takeda Pharmaceuticals and 32PointHealth [reached an agreement](#) to offer [a significant rebate](#) for a lung cancer drug if it proves ineffective... UnitedHealthcare [launched a virtual-first health plan built primarily around telemedicine](#)-based gatekeeping.

JAMA studies found that [using a blood pressure monitor paired with a smartphone-based](#) self-management program was associated with lowering blood pressure in 85.7% of adults with stage 2 hypertension; and that [parent training in behavior management \(PTBM\)](#) is an underutilized treatment option for preschoolers with ADHD... A Commonwealth Fund analysis found [Medicare Advantage and fee-for-service beneficiaries \(excluding SNP enrollees\) report similar](#) health care experiences.

American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, and Children's Hospital Association [released a joint statement declaring a national mental health crisis](#) among children and teenagers.



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

Succeeding in the new reality

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

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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There have now been [roughly 45.3 million confirmed COVID-19 cases](#) in the US, with a death toll over 730,000... The country is [averaging nearly 80,000 new cases per day](#) over the past week, down 22% over the past two weeks; deaths per day are down 14% to roughly 1,600... A [CDC analysis found that 93%](#) of COVID-19 hospitalizations among children and adolescents June to September occurred among the unvaccinated... CDC data show that even vaccinated Americans who are [80+ years old are at higher risk of dying](#) from COVID-19 than anyone under the age of 50, vaccinated or not.

411 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 834,000/day over the past week)... Nearly 220 million Americans ([77.4% of Americans 12 and older](#)) have received at least one COVID-19 vaccine dose; nearly 190 million Americans are fully vaccinated (66.9% of Americans 12 and older); 11.6 million Americans have received a booster dose.

World Health Organization (WHO) said that [only two in five healthcare workers are fully vaccinated](#) across the globe and roughly 115,000 healthcare workers died from COVID-19 from January 2020 to May 2021.

Executive and Administrative Action

The White House on Wednesday [outlined its plan to distribute doses](#) of Pfizer-BioNTech's Covid-19 vaccine to kids ages 5 to 11 as soon as its authorized by U.S. drug regulators; the administration has secured enough vaccine for all 28 million 5- to 11-year-olds and will distribute these in smaller dosing and with smaller needles.

The US has [now donated and delivered 200 million doses of COVID-19 vaccines](#) to more than 100 countries around the world.

The US will [open its borders to vaccinated foreign](#) travelers, including those with a combination of FDA or WHO-authorized vaccines, on November 8.

HRSA plans to [continue collecting information from Provider Relief Fund recipients](#) even after the public health emergency ends to ensure compliance with statutory and programmatic requirements.

Healthcare Law, Business, and Policy News

A [JAMA study found that 4.6% of privately insured patients](#) had mean out-of-pocket costs of \$3,840 for COVID-related hospitalizations.

UnitedHealth will [repay providers who were underpaid](#) for administering COVID-19 vaccines.

Surveillance, Testing, and Treatment

FDA [authorized the use of COVID-19 vaccine boosters from Moderna and Johnson & Johnson](#) and cleared the use of “mix-and-match” vaccine regimens (i.e., allowing individuals to receive a booster shot of a different COVID-19 vaccine than the one they originally received)... The authorization followed the Vaccines and Related Biological Products Advisory Committee unanimously recommending that anyone who [received a Johnson & Johnson COVID-19 be offered a second dose](#) and that a [subset of individuals who received the Moderna vaccine](#) be given boosters... the CDC Advisory Committee on Immunization Practices followed suit and [unanimously recommended booster doses](#) of Moderna’s COVID-19 vaccine for people 65 and older and other adults at high risk of severe COVID-19 because of health conditions or their employment who received their first dose at least six months ago and of J&J’s COVID-19 vaccine for all individuals 18 and older who received a first dose at least two months ago.

A CDC study found that the Pfizer-BioNTech vaccine was [93% effective against COVID-19 hospitalization for children ages 12 to 18](#)... Pfizer and BioNTech reported that their booster [shot was 95.6% effective](#) against symptomatic COVID-19.

CDC data show that while unvaccinated individuals are more than six times as likely to test positive and more than eleven times more likely to die from COVID-19 than those who are vaccinated, among those vaccinated, individuals [receiving a J&J vaccine were most likely to be infected](#) and those receiving Moderna were least likely to be infected.

Valneva reported that its [COVID-19 vaccine produced protective antibodies roughly 40 percent higher](#) than the Oxford-AstraZeneca vaccine and prevented infection at a similar rate in a phase 3 clinical trial; the company could seek UK authorization by the end of the year.

WHO’s Access to COVID-19 Tools Accelerator is [aiming to obtain antiviral drugs for COVID-19 patients with mild symptoms for as little as \\$10](#) per treatment.

The Gates Foundation is [committing \\$120 million to accelerate production of generic versions](#) of Merck’s antiviral pill to increase access in low-income countries.

Altea Pharmaceuticals reported that its [COVID-19 antiviral pill failed to combat the virus in a clinical trial](#), prompting the company to delay follow-on studies.