



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

Center for Healthcare Regulatory Insight



May 21, 2021 | Issue 173

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

President Biden [revoked](#) a Trump Administration order [blocking green-card applicants U.S admission](#) if unable to afford health coverage.

HHS [plans to rescind](#) a Trump Administration rule requiring health centers pass insulin/epinephrine [340B discounts to patients](#).... HRSA [ordered six](#)

[pharmaceutical companies](#) to [restore 340B drug discounts](#) to contract pharmacies; Eli Lilly [sued over the order](#).

HHS [further delayed](#) until December 15 the Medicare Coverage of Innovative Technology pathway final rule.

SAMHSA [announced \\$3B](#) in state/territory block grants for mental health and substance abuse initiatives... HRSA [announced \\$14.2M to expand pediatric mental health access through telehealth](#)... CMS reported that [mental health services](#) use declined for adults and children by 22% and 34%, respectively, during the pandemic.

FDA [delayed until September 2023 the deadline](#) for manufacturers to [implement unique device identifiers](#).

IRS [detailed how employers can calculate](#) eligible credits for providing former employees with COBRA coverage.



Healthcare law and policy news

A [federal court ruled](#) that HHS must [adjust Medicare hospital direct graduate medical education reimbursement](#) due to an unlawful payment methodology change... Texas [sued HHS over rescinding extension](#) of its Medicaid waiver.

The Supreme Court [declined to hear](#) a Novartis [challenge to Amgen's patents](#) for Enbrel... Democratic House committee chairs [asked FTC to investigate Abbvie's actions](#) to prevent biosimilar competition to Humira.

Essentia ended plans to [acquire 14 CommonSpirit facilities](#)... Ro will [acquire Modern Fertility](#) (\$225M)... Anthem will [partner with Epic](#) on provider data exchange... Google is developing an AI tool [to identify skin, hair, and nail](#) conditions... JPMorgan Chase is [launching an effort](#) to improve employee healthcare.

Altarum reported that national [health spending in March was 12.5% higher](#) than last March when utilization dropped due to the pandemic... KFF reported that [27% of Medicare beneficiaries had a telehealth visit](#) between summer and fall 2020; 56% of visits were telephone-only... A [JAMA study found](#) that 51.5% of US hospitals did not have a machine-readable chargemaster as required by price transparency regulations... Commonwealth Fund projected that [4.4 million individuals could gain insurance](#) if all holdout states expanded Medicaid... Trust for America's Health reported [that a record 156,242 Americans died from alcohol, drugs, or suicide](#) in 2019.

USPSTF [recommended](#) screening for [colorectal cancer at age 45](#), down from 50.





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.



kpmg.com/socialmedia



[Privacy](#) | [Legal](#)

You have received this message from KPMG LLP. If you wish to unsubscribe from Around the world of U.S. healthcare in 360 words or less, please [click here](#). If you wish to unsubscribe from all KPMG communications, please [click here](#).

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

© 2021 KPMG LLP, a Delaware limited liability partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved. NDP131714-1A

The KPMG name and logo are trademarks used under license by the independent member firms of the KPMG global organization.



COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There are now over 33 million confirmed COVID-19 cases in the US, with a [death toll of over 585,000](#)... The US averaged [30,000 cases/day over the past week](#), down 20% from the week before... The White House announced earlier in the week that [COVID-19 cases were down in all 50 states for the first time](#) since the pandemic began.

279 million COVID-19 [vaccine doses have been administered](#) in the US (1.83M/day over the past week)... 160.2 million Americans ([60.5% of Americans 18 and older](#) and 85% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 127 million Americans are fully vaccinated (45.2% of Americans 12 and older)... According to CDC data, [only 22% of Black Americans have been vaccinated](#), compared to 29% of Hispanics and 33% of Whites and 41% of Asians.

Executive and Administrative Action

President Biden announced the US will [send 20 million COVID-19 vaccine doses](#) from Pfizer-BioNTech, Moderna, and Johnson & Johnson to other countries, building on the 60 million AstraZeneca doses already announced.

The Defense Department [awarded \\$56 million to Rhino Health](#) to produce 1.4 billion nitrile gloves domestically by the end of 2022.

GAO [reported that 94% of the nation's nursing homes](#) had more than one COVID-19 outbreak and that 85% of facilities had outbreaks lasting for five or more weeks.

Healthcare Regulatory News

The Department of Justice and HHS OIG [warned providers that charging patients for COVID-19 vaccines](#) may violate the False Claims Act and other civil and criminal statutes.

FDA [updated guidance on drug approvals](#) when COVID-19 travel restrictions prevent facility inspections... FDA [released guidance](#) on [master protocols for evaluating prevention and treatment](#) options for COVID-19... FDA will [release guidance later this year](#) on how device makers can receive full approval for COVID-19 products granted temporary authorization.

OSHA guidance [instructs employers to follow new CDC mask guidance](#) for people fully vaccinated against COVID-19 while it reviews and updates formal employer guidelines.

Healthcare Law, Business, and Policy News

CMS data show that traditional Medicare [spent \\$16.6 billion on COVID-19 hospitalizations for 691,077 beneficiaries](#) from January 2020 to March 20, 2021; a total of 4,103,791 Medicare beneficiaries had confirmed COVID-19 infections over the same period.

A draft document from G20 nations [backs “voluntary licensing” of COVID-19 vaccine patents](#), complicating US efforts to advance compulsory licensing waivers... The head of UNICEF [asked G7 countries to donate supplies](#) to the COVAX vaccine-sharing scheme in order to address shortages caused by disruption to Indian vaccine exports... Major global vaccine manufacturers and biotech companies [committed to a five-point plan](#) for advancing “COVID-19 vaccine equity” and focusing on “responsible dose-sharing.”

Patient advocates and unions [urged Congress to establish a patient registry](#) for COVID-19 “long haulers.”

Johns Hopkins University is [launching a “pandemic data initiative”](#) focused on highlighting COVID-19 data collection and reporting inconsistencies.

Surveillance, Testing, and Treatment

FDA CDER Director, Peter Marks, said it would [take several months before FDA decides](#) whether to grant full approval to COVID-19 vaccines.

NIAID Director Anthony Fauci [expects children as young as 4 to be eligible for COVID-19 vaccines](#) by the end of the year or Q1 2022.

HHS will [not distribute Johnson & Johnson’s \(J&J\) COVID-19 vaccine](#) to states again this week ... Emergent BioSolutions could resume manufacturing of J&J’s COVID-19 vaccine within days and could [produce more than 100 million doses once given clearance](#) by the FDA to release doses... The GAVI Vaccine Alliance [agreed to buy 200 million doses](#) of J&J’s vaccine.

FDA [authorized undiluted, thawed vials of Pfizer-BioNTech’s vaccine to be stored](#) in the refrigerator for as long as a month.

A CDC study found that the Pfizer-BioNTech and Moderna vaccines [were 94% effective against symptomatic COVID-19 of healthcare workers](#) in the real world.

Moderna has [begun exporting its COVID-19 vaccine](#) to other countries.

Sanofi and GlaxoSmithKline [announced positive results from a phase 2 clinical trial](#) of their COVID-19 vaccine, reporting that it produced strong levels of neutralizing antibodies across age groups.

Public Health England reported that two doses of [AstraZeneca’s COVID-19 vaccine provided 85% to 90% protection](#) against symptomatic disease.

A UK-based clinical trial will [evaluate a range of COVID-19 vaccines](#) as potential booster shots.

The European Medicines Agency [issued a positive scientific opinion](#) on GlaxoSmithKline and Vir Therapeutics’ COVID-19 monoclonal antibody... FDA [publicly rebuked CytoDyn](#) for [promoting a monoclonal antibody](#) using erroneous and cherry-picked data.