



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 guidance warns hospitals about [hiding price transparency information from search engines](#)... CMS approved [Illinois' \\$1115 waiver extending Medicaid postpartum coverage](#) to one year... CMS [delayed the application deadline](#) for Primary Care First Model's second cohort... CMS plans next month to [reinstate three nursing home requirements](#) waived during the

pandemic... OMB [completed review](#) of a rule modifying the wage area reclassification process for hospitals.

HHS [withdrew a Trump Administration proposed policy](#) bypassing [FDA review](#) of more than 80 medical device/AI tool types... FDA authorized the [first AI system for identifying polyps](#) during colonoscopies.

FDA released [guidance](#) on [conducting remote interactive evaluations](#) of drug facilities during the pandemic.



Healthcare law and policy news

President Biden released his [first budget request](#), including a [\\$25B \(23%\) increase](#) for HHS... Biden [signed legislation to extend](#) the Medicare sequester [moratorium through December 31](#)... Democrats may [scale back healthcare policies](#) in the forthcoming infrastructure package.

Patrizia Cavazzoni was named [Director of FDA's Center for Drug Evaluation and Research](#) (CDER)... the Administration [expanded its short list of](#) FDA Commissioner candidates... Senate Finance Committee [held a confirmation hearing](#) for CMS Administrator-nominee Chiquita Brooks-LaSure and HHS Deputy Secretary-nominee Andrea Joan Palm.

The Administration [asked the Supreme Court to not hear insurers' lawsuits](#) over ACA cost-sharing-reduction subsidies... KFF estimated that [insurers will pay \\$2.1B in 2021 ACA medical loss ratio rebates](#), the second highest ever.

Microsoft [will acquire AI company Nuance Communications](#) (\$19.7B)... Medline hired Goldman Sachs to [explore a sale value at upwards of \\$30B](#)... LifePoint and Prisma [called off site acquisition plans](#)... DiaSorin [will acquire Luminex](#) (\$1.8B)... Thermo Fisher Scientific [plans to acquire PPD](#) (\$15B)... K Health, Blackstone, and Anthem launched a [joint venture to scale AI-powered](#) digital health solutions... Google launched an [early user feedback program](#) for a patient health record tool... Mayo Clinic [launched two companies](#) to better leverage data from remote monitoring devices and diagnostic tools.

An appeals court [upheld an FTC decision that an Endo International-Impax Laboratories pay-to-delay deal](#) was anticompetitive... Congress [passed two bills](#) to boost [generic](#) and [biosimilar](#) competition... Ohio plans to shift from 7 PBMs to a [single, state-regulated PBM](#) for Medicaid managed care.

CDC reported that [87,203 Americans died from drug overdoses](#) September 2019-September 2020.



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 31.4 million confirmed COVID-19 cases in the US, with a [death toll over 565,000](#)... The country averaged [roughly 71,000 new confirmed cases/day over the past week](#), up roughly 9% from the week before; cases rose in 25 states... *Wall Street Journal* reported that [younger, unvaccinated Americans are driving the recent rise](#) in cases; more than half of new cases are among individuals aged 18 to 54... CDC Director Rochelle Walensky told Congress that [roughly 6% of the country's 420,000 weekly COVID-19 infections](#) are being sequenced.

CDC studies found that 1) Hispanic and Black Americans [have been disproportionately hospitalized due to COVID-19 infections](#) as compared to Whites, and those disparities were more pronounced at the beginning of the pandemic; and 2) that from October-December 2020, Hispanic and American Indian/Alaska Native [had 1.7 times the rate of COVID-19 ER visits](#) as compared to Whites, while Black people had 1.4 times the rate of Whites.

198 million COVID-19 [vaccine doses have been administered](#) in the US (3.35M/day over the last week)... 126 million Americans ([48.3% of Americans 18 and older](#) and 80% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 30.3% of Americans 18 and older are fully vaccinated... Duke University projected that the US [could have around 300 million excess COVID-19 vaccine doses](#) by the end of July... CDC has [identified about 5,800 fully vaccinated people](#) who have contracted COVID-19 so far (approximately 0.007% of the 78 million persons fully vaccinated).

The Biden Administration [will allocate \\$1.7B to track the spread](#) of COVID-19 variants.

Healthcare Regulatory News

FDA is urging healthcare facilities to [transition away from crisis capacity conservation strategies](#) such as decontaminating N95 masks for reuse.

The Veteran's Affairs [OIG found](#) that facilities failed to consistently document COVID-19 vaccination status of veterans living in VA community living centers.

Healthcare Law, Business, and Policy News

The Rockefeller Foundation launched [a \\$20 million initiative to improve vaccination rates](#) in communities of color... Amazon will award \$12M to fund [projects related to COVID-19 testing and other infectious disease diagnostics](#) through its Diagnostic Development Initiative.

Two studies found that the B.1.1.7 coronavirus [variant is more transmissible, but does not appear to increase disease severity](#).

Surveillance, Testing, and Treatment

On Tuesday, FDA and CDC [recommended a pause in use of Johnson & Johnson's COVID-19 vaccine](#) after six cases of a rare blood-clotting disorder within two weeks of vaccination... CDC's Advisory Committee on Immunization Practices [declined to vote on whether use of the vaccine should be resumed](#), with many members wanting more information on the clotting issues.

The Biden Administration says the J&J pause [will not have a "significant impact" on the pace of vaccinations](#) and that Pfizer-BioNTech and Moderna are expected to provide enough COVID-19 vaccines to meet demand by the end of May... Pfizer has [increased production of its vaccine](#) and expects to deliver a total of 300 million doses to the US government by the end of July.

Pfizer and BioNTech [requested FDA authorize use](#) of their vaccine in children over 12... Pfizer's CEO said that [people will "likely" need a third shot of the vaccine as a booster](#) within 12 months of being full vaccinated.

A *NEJM* [study found that Moderna's COVID-19 vaccine](#) is more than 90% effective against overall illness and 95% effective against severe illness six months after second dose.

CureVac hopes its COVID-19 vaccine will be [authorized for use from the European Medicines Agency](#) in May or June.

Novavax [pushed back the timeline for meeting its production target](#) of 150 million COVID-19 vaccines per month until Q3.

Regeneron [reported that its COVID-19 combination monoclonal antibody therapy](#) (administered subcutaneously) reduced the risk of developing disease by 81% among people living with someone recently diagnosed; Regeneron is [seeking emergency use authorization](#) of the therapy as a preventive measure for unvaccinated people who have been exposed to the virus.

Eli Lilly [requested that the FDA cancel emergency use authorization](#) granted for use of its COVID-19 monoclonal antibody bamlanivimab, given that it is not as effective as its combination therapy against emerging strains of the virus... The US government [cancelled its agreement for standalone doses](#) of bamlanivimab.

The European Medicines Agency is [reviewing available data](#) on the use of GlaxoSmithKline and Vir's COVID-19 monoclonal antibody treatment.

A *Science Immunology* study [recommended use of remdesivir and ruxolitinib in combination](#) to treat COVID-19... Gilead [ended its Phase 3 clinical trial for remdesivir](#) in part due to difficulty enrolling patients; no efficacy or safety concerns were cited.

Merck will [launch a late-stage trial testing an experimental antiviral](#) among COVID-19 patients who are at high risk of poor outcomes, but are not yet hospitalized.