



# 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**

President Biden [signed an Executive Order](#) to open a healthcare.gov special enrollment period (February 15-May 15) with [\\$50M in outreach](#) and [reconsider ACA and Medicaid rules and policies](#) that undermine pre-existing condition protections, demonstrations/waivers that reduce coverage, and policies presenting barriers to enrollment or reducing

affordability... KFF [estimated 8.9 of 15M uninsured Americans](#) could be eligible for no-premium bronze plans (4M) or subsidized insurance (4.9M).

HHS [paused drug rebate](#), [Part D e-prescribing](#), and [organ procurement organization](#) final rules... OMB withdrew [several FDA rules and guidance documents](#), including for cannabidiol, antimicrobial drugs, and regulation of tobacco products... HHS [withdrew proposed rules](#) affecting in-center dialysis coverage, allowing seniors to opt out of Medicare Part A, and increasing oversight of accrediting organizations... HHS will [cancel Trump Administration practice guidelines](#) broadening which physicians could prescribe buprenorphine... GAO previously determined that effective dates for [Stark Law](#) and [Antikick-back Statute](#) rules violated the Congressional Review Act and could be subject to delay or withdrawal.

FDA approved [Exelixis' renal cell carcinoma treatment](#) in conjunction with Opdivo... FDA approved Aurinia Pharmaceuticals' [lupus nephritis treatment](#)... FDA released a [five-pronged strategy](#) for use and regulation of AI.

The Office of the Special Counsel reported that funds intended for BARDA health emergency response efforts [were diverted to pay for other expenses in ASPR](#) going back to the Obama Administration.



## Healthcare law and policy news

President Biden [selected nurse Susan Orsega](#) as Acting Surgeon General.

AthenaHealth [will pay \\$18.25M](#) to settle kickback allegations... PhRMA [sued to block implementation](#) of the 340B dispute resolution process rule... FTC [sued Endo International and Impax Laboratories](#) for alleged antitrust law violations related to an opioid.

KPMG, EBG, and FP reported [a record number of announced/closed healthcare deals](#) in 2020 (1,936)... Henry Ford Health System and Michigan State University [signed a 30-year affiliation agreement](#)... MultiPlan will [acquire Discovery Health Partners \(\\$155M\)](#)... Verana Health will [collaborate with Janssen Research & Development](#) on data-driven approaches for ophthalmology and urology treatment.

Colorado is [soliciting vendors to help import](#) prescription drugs from Canada... CivicaRx will [build a manufacturing facility](#) in Virginia to produce sterile injectable medications.

RAND reported that US prescription [drug prices are 256% higher](#) than 32 other countries; brand-name drug prices are 344% higher.



Questions or comments, please send to [us-hcinsight@kpmg.com](mailto: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 25.7 million confirmed COVID-19 cases in the US, with a [death toll over 430,000](#)... The average number of cases/day [fell in 41 states over the past week](#), down 16% total to 165,000 cases/day... CDC forecasted [between 479,000 and 514,000 US deaths](#) by February 20... A STAT analysis found that “excess deaths unattributed to COVID-19” are [far more common in strong Trump-supporting counties](#) across the country, suggesting that COVID-related deaths are likely to be undercounted in those areas.

Minnesota reported the [first US case of a COVID-19 variant](#) first identified in Brazil... South Carolina reported the first US cases of a [COVID-19 variant first identified in South Africa](#); more than [30 countries have now detected](#) the variant... A CDC study found [low incidence of COVID-19 spread in school classrooms](#) when safety precautions, such as mask wearing and “student cohorting,” are followed.

27.3 million COVID-19 [vaccine doses have been administered in the US](#), 56% of total doses distributed to states... CDC [data show](#) that [sixteen states have used less than half](#) of their distributed COVID-19 vaccines... Some states are [rerouting a portion of unused COVID-19 vaccines](#) from nursing homes.

CDC reported that as of January 10<sup>th</sup>, there have been [1,266 total “adverse events” after receipt of Moderna’s COVID-19 vaccine](#), 108 possible “severe allergic reactions,” and 10 cases of anaphylaxis (or just 2.5 per million doses administered).

## Executive and Administrative Action

The White House [held the first of its planned](#) thrice weekly COVID-19 response press briefings... White House COVID-19 Response Coordinator Jeff Zients announced that HHS would [amend rules under the Public Readiness and Emergency Preparedness \(PREP\) Act to permit](#) recently-retired or inactive doctors and nurses to administer COVID-19 vaccines and to permit providers to administer vaccines across state lines.

President Biden issued a [COVID-related travel ban](#) from South Africa and reinstated restrictions from Brazil, the U.K., and dozens of European countries... The Administration is considering [expanding mandatory COVID-19 testing to passengers](#) on US domestic flights.

President Biden signed an executive order [directing HHS to issue guidance](#) on “best practices for advancing cultural competency, language access, and sensitivity towards Asian Americans and Pacific Islanders” through the federal government’s COVID-19 response.

Acting HHS Secretary Norris Cochran [told governors in a letter](#) that the COVID-19 public health emergency, including the 6.2% Medicaid FMAP increase, will likely extend through 2021. GAO [issued 13 recommendations](#) to federal agencies to improve COVID-19 response, including those related to collection of data on COVID-19 testing, addressing supply chain gaps, and vaccine distribution.

### Healthcare Regulatory News

FDA issued [an import alert on all alcohol-based sanitizers from Mexico](#) due to concerns about methanol contamination.

FDA is considering [developing a new pathway for potential changes](#) to emergency-use-authorized COVID-19 products, including vaccines, should changes be needed to address new virus variants.

### Healthcare Law, Business, and Policy News

The House Energy and Commerce Committee is working with the Biden Administration [to develop health-related components of a COVID-19 relief package](#); the Health subcommittee [scheduled a February 3](#) hearing on accelerating delivery of vaccines, expanding testing, and addressing supply shortages... Democratic leaders are [moving forward on plans to use reconciliation](#) if they fail to gain Republican support for a relief package.

Oxfam International reported that the [COVID-19 pandemic could increase economic inequality](#) in nearly every country... Bill and Melinda Gates warned that the lasting [legacy of the pandemic could be "immunity inequality"](#) resulting from inequitable access to COVID-19 vaccines.

41% of US adults in a KFF poll [say they will get the COVID-19 vaccine as soon as possible](#), up from 34% in December... KFF analysis found that the [country would need to administer 2.4 million COVID-19 vaccines doses/day](#) to reach herd immunity (70% of the population) by July 4.

GISAID [data show](#) that the US is [lagging behind other countries in genome sequencing](#) (per 1,000 COVID-19 cases) used to detect virus variants; CDC Director Rochelle Walensky said that the federal government [would increase surveillance](#) of COVID-19 variants.

HCA formed a [consortium with AHRQ and several institutions](#), including medical colleges, to accelerate COVID-19 research using its database of COVID-19 hospital care and outcomes... Google [committed \\$150 million to COVID-19 vaccine education](#), will use some of its building and parking lots for vaccination clinics, and will partner with One Medical to open vaccination sites... 23andMe launched [a "severity calculator"](#) to help predict an individual's risk of developing a severe case of COVID-19.

### Surveillance, Testing, and Treatment

President Biden increased the [Administration's goal of vaccines administered in his first 100 days](#) to 150 million; Biden advisors cautioned that the [vaccine will not be available by this spring](#) to everyone who wants it.

The Administration is [considering using the Defense Production Act to require drug manufacturers](#) to produce already-authorized COVID-19 vaccines from other companies... Novartis is in [discussions to support such an effort](#).

The Defense Department is reviewing [a FEMA request to help administer COVID-19 vaccines](#) at locations across the country.

The federal government [plans to purchase 100 million more doses each](#) of Pfizer-BioNTech's and Moderna's COVID-19 vaccine... The Administration will [increase COVID-19 vaccine shipments to jurisdictions](#) by 16% starting next week, increasing from 8.6 million to 10 million total doses.

Pfizer will [provide the federal government with fewer vials](#) of its COVID-19 vaccine than previously expected, given changes to its emergency use authorization reflecting the fact that vials contain six, not five, doses; however, [sufficient supply of syringes to extract](#) the "extra" dose does not currently exist... Pfizer will [supply the US with 200 million doses](#) of its vaccine by the end of May, two months sooner than expected, as a result of the "extra" doses... Pfizer and BioNTech will [provide 40 million doses](#) of its COVID-19 vaccine to COVAX... Pfizer completed [enrollment of more than 2,000 children ages 12-15](#) in a study of its COVID-19 vaccine.

Moderna reported that its COVID-19 vaccine [produced neutralizing impacts against virus strains](#) identified in the UK and South Africa and that it was developing booster doses to increasing neutralizing impacts against emerging strains.

Johnson & Johnson (J&J) reported that its [single-dose COVID-19 vaccine is 66% effective overall](#), including 72% effective in a US trial and 57% effective in South Africa; the vaccine reduced several disease by 85%... J&J's head of R&D noted that the [vaccine's effectiveness, relative to vaccines from Pfizer-BioNTech and Moderna, could have been impacted](#) by the increasing incidence of potentially resistant variants that were not as present during previously completed clinical trials... J&J hopes to receive [emergency use authorization and administer 100 million doses by June](#).

Novavax reported that its [COVID-19 vaccine is 89% effective](#) in preliminary clinical trial results, but appears less effective against new virus variants.

Merck announced it would [stop development of two experimental COVID-19 vaccines](#) due to inadequate immune responses.

AstraZeneca will conduct a [study on the optimal interval](#) between two doses of its COVID-19 vaccine.

NIH is leveraging the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to [better study how vaccines and monoclonal antibody treatments perform](#) against [new COVID-19 variants](#).

Regeneron reported that [its monoclonal antibody treatments prevented COVID-19](#) in a clinical trial.