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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 <u>reply</u> <u>here to me</u>, **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 will rescind Trump Administration state Medicaid work requirements.

FDA <u>approved Bristol-Myers Squibb's CAR-T therapy</u> for relapsed/refractory large B-cell lymphoma and a Regeneron cholesterol

<u>treatment</u>... An FDA advisory panel <u>voted unanimously to not recommend</u> Merck's Keytruda for early-stage triple-negative breast cancer.

GAO <u>recommended a pause</u> in the \$16B VA EHR overhaul until it addresses "critical" issues.

OCR <u>fined Renown Health \$75,000</u> for failing to provide timely patient access to medical records.





Healthcare law and policy news

The Biden Administration reversed the <u>federal government</u> position on the <u>Supreme Court case challenging the ACA's constitutionality</u>... Hospitals <u>asked the Supreme Court to hear</u> 340B payment cut and site-neutral policy cases.

House <u>Ways & Means</u>, <u>Energy & Commerce</u>, and <u>Education & Labor</u> committees released recommendations for the pandemic response reconciliation bill, including expanding scope/size of ACA subsidies, providing COBRA subsidies, incentivizing states to expand Medicaid, and providing COVID-19 vaccine, testing, and tracing funding.

The US Court of Appeals (DC Circuit) approved the Justice Department's 60-day delay request on proceedings over the association health plan rule... the Court also barred hospitals from reviving a \$840M lawsuit over Medicare payment cuts... The US Court of Appeals (Federal Circuit) agreed to rehear a "skinny labeling" case over Teva's alleged infringement of a GlaxoSmithKline patent.

Nuance <u>acquired AI startup Saykara</u>... Oscar Health <u>filed to go public</u>... Mercy Hospital and Medical Center <u>filed</u> for <u>bankruptcy protection</u>... Tenet will <u>delay spinning off</u> its Conifer <u>business by 12 months</u>.

Healthcare lost 30,000 jobs in January, the first decline since April 2020.

An NBER working paper found that increasing prescription out-of-pocket cost by \$10.40 reduced drug consumption 23%... Chartis reported that 453 rural hospitals are "vulnerable to closure"... One-Percent Steps for Health Care Reform Project released policy briefs on 16 incremental reforms to reduce healthcare spending... Friends of Cancer Research and ASCO issued recommendations to broaden cancer clinical trial participant pools... Eight organizations urged Congress to extend increased Medicaid FMAP and enact a "glidepath" for future reductions.

CDC reported 70,630 drug overdose deaths (driven by synthetic drugs) in 2019, up 56.5% from 2013... CBO projected that the federal budget deficit will total \$2.3T this year and national debt will reach a record 107% of GDP by 2031.





Questions or comments, please send to <u>ushcinsight@kpmg.com</u>.

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COVID-19 by the Numbers

There are now over 27.4 million confirmed COVID-19 cases in the US, with a <u>death toll over 475,000</u>... average daily infections <u>dropped to 108,000</u>, down 24% from last week, while hospitalizations decreased 8% and deaths decreased 3% to roughly 3,000/day.

Incidence of the UK COVID-19 variant is <u>doubling roughly every 10 days in the US</u>, with a transmission rate roughly 30-40% higher than more common variants... A *JAMA* study found that nursing homes with the highest proportion of <u>non-White residents experienced 3.3 times higher rates of COVID-19 deaths</u> than facilities with the highest proportion of White residents... A CDC study found that <u>statewide mask mandates slowed</u> the rate of COVID-19 hospitalizations by up to 5.5 percentage-points in the three weeks after mandate implementation.

48 million COVID-19 <u>vaccine doses have been administered</u> in the US (1.62M/day over the last week)... KFF reported that only <u>29% of vaccine recipients in the first month were 65 or older</u>, despite the fact that the age group accounts for at least 75% of all COVID-19 deaths since the start of the pandemic... NIAID Director Anthony Fauci said that <u>20,000 pregnant women have received COVID-19 vaccines</u> without complications... CDC reported that <u>in December</u>, <u>49.1% of Americans polled intended to get vaccinated</u>, up from 39.4% in September.

Executive and Administrative Action

President Biden said it would <u>be "very difficult" to achieve herd immunity</u> in the US before the end of the summer due to vaccine rollout challenges... The Biden Administration is <u>considering a requirement that domestic air travelers</u> test negative for COVID-19... the Administration will launch <u>a public safety campaign focused on social distancing and mask wearing</u>, while delaying a campaign on vaccine awareness until more doses are available.

CDC recommended <u>wearing a cloth mask over a medical mask or adjusting a mask to fit more snuggly</u> in order to <u>prevent the spread of COVID-19</u>... CDC guidance states that individuals exposed to COVID-19 <u>more than two weeks after receiving their final vaccine dose are no longer required</u> to quarantine... CDC is <u>expected to release guidance</u> today recommending phased reopening of schools based on community spread levels.

President Biden unveiled the White House COVID-19 Health Equity Task Force that includes 12 non-federal members; the task force will meet for the first time on February 26.

The Defense Department <u>approved deployment of more than 1,900 active duty troops</u> to help with COVID-19 vaccine delivery.

Healthcare Regulatory News

The FDA granted emergency use authorization to Eli Lilly's COVID-19 combination (bamlanivimab and etesevimab) monoclonal antibody therapy and <u>Visby Medical's rapid point-of-care</u> COVID-19 test.

Healthcare Law, Business, and Policy News

A <u>survey from The Conference Board</u> found that 19% of workers haven't decided if they will take the COVID-19 vaccine and 6% do not plan to take the vaccine; only 67% of lower-ranking workers plan to take the vaccine, compared to 85% of CEOs... 28% of respondents to an Axios/Ipsos poll <u>have resumed in-person gatherings outside the home</u>; 66% believe returning to a pre-COVID life is a moderate or large risk, the highest rate since October... Littler Mendelson reported that <u>less than 1% of employers currently mandate COVID-19 vaccinations</u> for employees, and only 6% plan to do so once vaccines are readily available and fully approved by FDA.

Johns Hopkins Center for Health Security <u>released recommendations for how to equitably distribute</u> vaccines.

Uber and Walgreens will partner to offer communities of color free rides to vaccination sites.

The House Energy and Commerce Oversight and Investigations subcommittee will hold <u>a hearing</u> February 23 with officials from Pfizer, Moderna, Johnson & Johnson, AstraZeneca, and Novavax over COVID-19 vaccination production.

Surveillance, Testing, and Treatment

President Biden announced that the <u>federal government secured deals for another 200 million</u> COVID-19 vaccine doses, and that the country would have enough vaccines for 300 million people by the end of July... The Administration will also <u>increase weekly vaccine shipments to states, tribes, and territories from 10.5 million to 11 million</u> and <u>launch a community health center vaccination program</u>, beginning with 250 centers and growing to potentially 1,400 sites... CDC is planning <u>a three-day virtual event</u> to bolster public confidence in COVID-19 vaccines... Anthony Fauci said that by <u>April it will be "open season" for vaccines</u>, as "everybody, anybody, in any category, could start to get vaccinated."

The Administration is <u>finalizing contracts</u> with six companies to produce 61 million at-home COVID-19 tests by the end of the summer... NIH will <u>fund studies</u> on long-term symptoms of COVID-19.

The World Health Organization (WHO) <u>recommended</u> AstraZeneca-Oxford's <u>vaccine for emergency use</u> and <u>expressed confidence that that the vaccine</u> can prevent severe cases, hospitalizations, and death... A University of Oxford <u>study concluded</u> that its COVID-19 vaccine developed with AstraZeneca is effective against a new virus strain first identified in Britain; meanwhile, <u>South Africa halted rollout of the vaccine</u> after a small clinical trial found that it "provides minimal protection" against mild to moderate cases caused by a strain originating in that country... AstraZeneca is <u>developing an adapted vaccine</u> to combat new virus variants, which it hopes to have ready by the fall... AstraZeneca is addressing issues with manufacturing of its vaccine and <u>expects to double monthly production</u> to 200 million doses by April.

Pfizer expects to <u>reduce production time for a batch</u> of its COVID-19 vaccine from 110 days to roughly 60 days.

Teva is in conversation with other drug manufacturers to co-produce some existing COVID-19 vaccines, while Merck is discussing with governments about also supporting vaccine production.

Dermapharm hopes to <u>begin producing Pfizer-BioNTech's COVID-19 vaccine at a second site</u> in Germany beginning in May.

The asthma and COPD drug inhaled budesonide <u>reduces hospitalizations</u> for COVID-19 in a clinical trial... A UK trial found that <u>the rheumatoid arthritis drug tocilizumab could reduce the risk of death</u> in severely ill COVID-19 patients.

A WHO investigative team said it is "extremely" unlikely the virus leaked from a Chinese lab and that it probably jumped to humans via an animal or animal product.