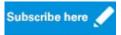


## May 14, 2021 | Issue 172

Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare</u> <u>Regulatory Insight</u> 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 <u>subscribe to our mailing list here</u>.

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

<u>President Biden</u> and <u>HHS announced</u> that one million Americans have signed up for ACA coverage through the special enrollment period.

A <u>CMS interim final rule</u> requires long-term care facilities to educate/offer the COVID-19 vaccine to residents, clients, and staff and to <u>provide weekly</u>

<u>reports</u> of vaccination rates... CMS <u>guidance details</u> how states can receive a temporary 10% Medicaid FMAP increase for home- and community-based services.

CMS <u>warned hospitals failing to report</u> payer-negotiated rates and gave them 90 days to correct issues... CMS <u>encouraged stakeholders</u> to respond to an RFI on advancing equity for underserved communities.

FTC is sending 51,875 payments <u>totaling \$59.1M to victims of a Reckitt</u> <u>Benckiser-Indivior scheme</u> to thwart competition to Suboxone.





## Healthcare law and policy news

The Senate <u>confirmed Andrea Palm</u> as HHS Deputy Secretary... The Senate <u>advanced Chiquita Brooks-LaSure's nomination</u> as CMS Administrator, a final vote is expected soon.

HHS <u>urged the Supreme Court to uphold</u> Trump Administration rules on site neutrality and 340B reimbursement cuts.

HHS will enforce healthcare-related protections for LGBTQ Americans.

Missouri Governor Mike Parson ended plans to expand Medicaid in the state following legislative resistance... An NBER paper found that increases in premiums resulted in beneficiaries dropping out of Michigan's Medicaid program... 32 hospitals in Medicaid non-expansion states sued HHS for additional DSH payments.

Dignity Health and University of Miami will pay \$10M and \$22M, respectively, to settle Medicare fraud allegations... Anthem was sued \$50M over holding back post-acquisition escrow payments... Alvotech alleged in a lawsuit that Abbvie deployed a "patent thicket" to prevent biosimilar competitors to Humira.

Allergan Aesthetics <u>will acquire Soliton (\$550M)</u>... St. Francis Medical Center <u>intends to join Capital Health</u>... Ginkgo Bioworks will <u>go public through a \$17.5B SPAC</u> merger... Cedar <u>acquired OODA Health</u> (\$425M)... Amedisys plans to <u>take over Visiting Nurse Association's</u> home health and hospice services... Mayo Clinic and Kaiser Permanente <u>will invest \$100M in Medically Home's</u> hospital-at-home model.

10 moderate House Democrats <u>urged Speaker Pelosi to pursue bipartisan</u> drug pricing reform.

World Health Organization and the International Coalition of Medicines Regulatory Authorities <u>urged drug manufacturers to make clinical trial data public</u> with redactions... National Funeral Directors Association and CDC estimated that the average "cost of dying" in the US is \$19,566.





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.



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## COVID-19 by the Numbers

There are now over 32.8 million confirmed COVID-19 cases in the US, with a <u>death toll of nearly 585,000</u>... The US averaged <u>fewer than 40,000 confirmed COVID-19 cases/day over the past week</u>, down 21% from the week before and the lowest point since September; cases declined in 37 states, while cases did not increase in any state... Deaths from COVID-19 are at <u>their lowest point (600/day) since July.</u>

267 million COVID-19 <u>vaccine doses have been administered</u> in the US (2.09M/day over the past week)... 154.6 million Americans (58.9% of Americans 18 and older and 84% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 119 million Americans are fully vaccinated (45.6% of Americans 18 and older)... CDC reported on <u>demographic and social disparities</u> with COVID-19 vaccination rates... AP reported that several states have asked the federal government to <u>send them just a fraction of allotted</u> COVID-19 vaccine doses.

Eight members (players and staff) of the New York Yankees <u>tested positive for COVID-19 more than 14 days after being fully vaccinated</u>, prompting serious questions from public health experts.

### Executive and Administrative Action

CDC updated guidance to say that <u>fully vaccinated Americans can gather indoors or outdoors</u> with other individuals without masks, even if some in the group are unvaccinated.

HHS Secretary Xavier Becerra told the House Energy and Commerce Committee that the department is considering extending the deadline for providers to use Provider Relief Fund allocations and that it will demand accountability and transparency from recipients of the remaining \$25 million... The Administration plans to open applications for billions in hospital COVID-19 grants before the end of May.

Treasury Department launched <u>a \$350 billion state</u>, local, territorial, and tribal aid program to offset economic damages from the pandemic... The Administration <u>announced \$7.4 billion in funding to expand the public health workforce</u> to conduct vaccinations, testing, contact tracing, and community outreach.

# Healthcare Regulatory News

Administration for Children and Families <u>issued guidelines to states</u>, <u>territories and tribes</u> on how to distribute \$24 billion in relief funds for child care providers.

## Healthcare Law, Business, and Policy News

Kaiser Health News reported on how some <u>hospitals and providers are profiting off COVID-19 test</u> through price gouging, because the CARES Act requires insurers to pay the full billed charge to the provider unless there is a negotiated rate.

An AP-NORC poll found that 71% of Americans approve of President Biden's handling of the pandemic.... An Axios/Ipsos poll found that for the first time, less than half (43%) of Americans say returning to their "normal" pre-pandemic lives would pose a large or moderate risk... 61% of respondents to a STAT-Harris poll believe that the Biden Administration is correct to support a waiver of intellectual property rights in order to broaden access to COVID-19 vaccines in low and middle income countries... 74% of young adults (age 18-29) believe COVID-19 vaccination should be required to return to work or campus.

KFF reported that Hispanic Americans are roughly twice as likely as White adults to say they want to get a COVID-19 vaccine as soon as possible, suggesting the need for increased outreach and access... CDC reported that over 40% of Hispanic adults have reported symptoms of depression during the pandemic.

Uber and Lyft will offer free rides to and from COVID-19 vaccine sites through the 4th of July.

18 international scientists <u>criticized the World Health Organization's (WHO) investigation</u> into the origin of the pandemic and called for a more extensive review.

# Surveillance, Testing, and Treatment

FDA <u>revised the emergency use authorization</u> for Pfizer and BioNTech's COVID-19 vaccine to permit its use in children ages 12 to 15; CDC's Advisory Committee on Immunization Practices (ACIP) <u>recommended the expanded use</u> and CDC Commissioner Rochelle Walensky approved it... CDC will also amend its clinical guidance to <u>allow COVID-19 vaccines and other childhood vaccines to be coadministered</u> on the same day or within 14 days of each other.

BioNTech said that <u>there is "no evidence" to support the need to adapt</u> the COVID-19 vaccine developed with Pfizer to improve effectiveness against emerging variants.

David Kessler, chief science officer of COVID-19 response at HHS, told a Congressional committee that <u>a</u> <u>COVID-19 vaccine booster will likely be needed</u> and that the federal government is planning to have doses available for all Americans.

States won't receive any doses of Johnson & Johnson's COVID-19 vaccine next week... CDC has identified just 28 people who have developed rare but serious blood clotting issues after receiving Johnson & Johnson's COVID-19 vaccine, out of roughly 8.7 million doses administered... meanwhile, the US government is considering joint production of the Johnson & Johnson COVID-19 vaccine with India, including arranging for necessary raw materials.

WHO <u>authorized China's Sinopharm COVID-19 vaccine</u> for emergency use, the sixth vaccine to receive WHO authorization.

AstraZeneca could skip asking FDA for emergency use authorization for its COVID-19 vaccine and pursue <u>full marketing approval instead</u>...Novavax said that it will not seek regulatory authorization for its COVID-19 vaccine <u>until July at the earliest</u> and that it is behind in meeting production targets.

The COVID-19 vaccine produced by China's Sinovac Biotech was <u>94% effective at protecting against symptomatic infection</u> in a real-world study.

Eli Lilly <u>signed licensing agreements with three Indian generic drug manufacturers</u> (Cipla, Lupin, and Sun Pharma) to make and sell its baricitinib arthritis drug in the country for treating Covid-19 patients.