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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</u> <u>here</u>.

We welcome your feedback. Let us know if KPMG can help. Please <u>reply</u> 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**

ONC and The Sequoia Project <u>published</u> the <u>Trusted Exchange</u> <u>Framework</u> and <u>Common Agreement</u> to accelerate <u>electronic health</u> information exchange.

FTC and Department of Justice are <u>seeking comment on bolstering</u> <u>merger oversight</u>.





## Healthcare law and policy news

President Biden <u>acknowledged Democrats may have to break up Build</u> <u>Back Better</u> for passage.

Francisco Health will acquire IBM's Watson Health data and analytics business... DaVita acquired MedSleuth... GlaxoSmithKline rejected Unilever's most recent offer to buy its consumer health business (\$68B)... UCB will acquire Zogenix (\$1.9B)... Encompass Health is spinning off its home health/hospice business.

Teva Pharmaceuticals <u>will pay \$420M to settle</u> generic drug price fixing allegations... Endo International <u>will pay up to \$68M to resolve opioid-related claims</u> in Florida... Gilead alleged a network of drug suppliers/distributors <u>sold counterfeit versions</u> of its HIV treatments... Sanofi asked an appeals court to <u>revive antitrust claims against Mylan over allegedly creating/holding</u> a monopoly for EpiPen.

Bristol Myers Squibb became the 12<sup>th</sup> drug manufacturer to <u>restrict</u>
340B discounts to contract pharmacies... Mark Cuban Cost Plus Drug
Company launched <u>its online pharmacy with 100 generic</u> drugs.

A <u>CBO analysis found</u> average net prescription prices fell 2009-2018 in Medicare (\$57 to \$50) and Medicaid (\$63 to \$48), largely attributable to increased generic use (75% to 90%)... National Health Interview Survey <u>data show 5.3M Medicare beneficiaries</u> had difficulty affording medications in 2019; Black and Latino adults reported 1.5 to 2 times higher difficulty than whites.

CBO reported greater market power leads to higher physician/hospital prices for commercial insurers, as compared to Medicare fee-for-service... Altarum found health care prices grew just 2.3% year-over-year in December, well below CPI (7%).

MedPAC reported 46% of Medicare beneficiaries are enrolled in Medicare Advantage (MA)... Axios reported roughly three-quarters of MA beneficiaries are covered by six plans... A Nature study found just 6% of biologic medicine-related patents cover active ingredients, suggesting widespread use of patent "thickets" to prevent biosimilar competition... A Health Affairs study found Black patients were 2.54 times likelier than white patients to be described with stigmatizing terms in EHRs.

A record 41,354 Americans underwent an organ transplant in 2021.

A House Oversight subcommittee gave HHS <u>a "D" grade on cybersecurity.</u>





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

# 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

Nearly 70 million COVID-19 cases have been documented in the US, with a death toll over 860,000... The country is now averaging roughly 745,000 cases/day over the past week, down from nearly 800,000/day a week ago; COVID-related deaths are averaging approximately 1,800/day over the past 7 days.... 461 out of every 1 million COVID-19 patients in the country were hospitalized as of January 18.

Over 530 million COVID-19 <u>vaccine doses have been administered</u> in the US (just over 300,000/day over the past week)... Roughly 250 million Americans (<u>85% of Americans 12 and older</u>) have received at least one COVID-19 vaccine dose; roughly 210 million Americans are fully vaccinated (72% of Americans 12 and older); over 80 million Americans have received a booster or additional dose... CDC data show that <u>only 19% of children ages 5 to 11</u> are fully vaccinated; 28% have received at least one dose... CDC data show that <u>unvaccinated adults 65 and older who are infected with COVID-19 are 49 times more likely to be hospitalized</u> than those in the same group who are vaccinated and have gotten a booster dose.

## **Executive and Administrative Action**

HHS Secretary Xavier Becerra <u>extended the public health emergency declaration</u> by another 90 days, effective January 16.

The Biden Administration <u>launched a website</u> for Americans to request rapid COVID-19 tests be shipped to their home addresses.

CDC <u>updated its masking guidance</u> to encourage more Americans to wear N95 and KN95 masks to help reduce spread of COVID-19... The Administration unveiled a <u>plan to distribute hundreds of millions of free, high-quality masks</u>, beginning with 400 million non-surgical N95s, through pharmacies and community sites.

The Administration <u>formed the Pandemic Innovation Task Force</u> to prepare new countermeasures for the emergence of future COVID-19 variants and other pandemic threats.

A federal court <u>dismissed a lawsuit filed by Texas</u> challenging the Administration's healthcare worker vaccine mandate, effectively making the requirement enforceable across the country. Health care workers in the state <u>must by fully vaccinated by March 21</u>.... Following last week's Supreme Court decision lifting the injunction, CMS <u>guidance gives medical facilities in two dozen states until March 15</u> to get their employees fully vaccinated against COVID-19. Medical facilities in the remaining 25 states that did not challenge the mandate must meet the vaccine requirement by February 28.

GAO <u>made 5 recommendations on improving transition</u> of Countermeasures Acceleration Group (formerly Operation Warp Speed) responsibilities, including vaccine activities, over to HHS.

## Healthcare Law, Business, and Policy News

A KFF analysis found that <u>just six of the country's 13 largest health insurers directly cover the cost</u> of rapid at-home COVID-19 tests (i.e., no upfront costs for enrollees).

CDC data show that both vaccination and prior infection offered strong protection against COVID-19 during the Delta variant wave, but individuals who had previously recovered from COVID-19 were less likely to be infected or hospitalized than those who were vaccinated alone... A CDC study found Hispanic patients received COVID-19 monoclonal antibody therapy 54% less often than non-Hispanic patients, while Black, Asian, or other race patients received the treatment 22%, 48%, and 47% less often, respectively, than did White patients from November 2020 through August 2021.

An NIH-funded study found that COVID-19 vaccines do not appear to hinder fertility.

A Morning Consult poll found that <u>56% of adults and 55% of private sector workers support employer vaccine</u> mandates.

## Surveillance, Testing, and Treatment

White House Chief Medical Advisor and NIAID Director Anthony Fauci said the FDA <u>could authorize</u> Pfizer-BioNTech's COVID-19 vaccine for children under age 5 in the next month.

The FDA plans to <u>participate in an internationally coordinated program</u> to decide if, when, and how to update COVID-19 vaccines... FDA Biologics Center Director Peter Marks predicted <u>that individuals will need to receive an annual booster COVID-19 vaccine</u>, similar to the flu vaccine.

An Israeli study found a fourth dose of Pfizer-BioNTech's COVID-19 vaccine <u>raised antibody levels</u>, <u>although not enough to prevent infection</u> with the Omicron variant.

<u>A pre-print study on mix-and-matching</u> COVID-19 vaccines found that most combinations appeared to increase antibodies against the Omicron variant, <u>except two doses of Johnson & Johnson's</u> vaccine.

Covax has <u>now delivered 1 billion COVID-19 vaccine doses to 144 lower-income countries</u>; 88 of the 194 World Health Organization's member countries have vaccinated less than 40% of their population... Covax plans to deliver the <u>next 1 billion doses twice as fast</u>.

Pfizer reported that its <u>antiviral pill was effective against the Omicron variant</u> in three separate lab tests.

Merck and Ridgeback Biotherapeutics <u>signed an agreement with UNICEF to supply up to 3 million</u> <u>courses of their antiviral pill</u> for distribution in 100 low- and middle-income countries... A group of 27 generic drug manufacturers also <u>reached an agreement with the Medicines Patent Portal to manufacture the antiviral</u> for low- and middle-income countries.