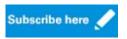


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Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare Regulatory</u> <u>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 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 <u>COVID-19 news for the week in this special supplement</u>.

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Healthcare regulatory news

FDA <u>approved/tentatively approved 776 generic drug applications</u> in 2021, down from 2020 (948) and 2019 (1,014) totals.

FTC failed (2-2) to pass a motion to probe PBMs' business practices.

HHS <u>awarded \$55M to 29 HRSA-funded health centers</u> to increase virtual care access/quality.

CMS is seeking comments on Medicaid/CHIP access/coverage.

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Healthcare law and policy news

The Senate <u>confirmed</u> (50-46) Robert Califf as FDA Commissioner; Califf <u>tweeted his</u> <u>priorities</u>... Senate <u>passed a continuing resolution</u> funding the federal government through March 11.

VillageMD acquired Healthy Interactions... ChristianaCare will acquire Crozer Health... BCBS Louisiana must face class action claims it violated state antitrust laws by honoring negotiated rates from other BCBS affiliates... A class action suit alleges Hartford Health engaged in anticompetitive behavior; Hartford denied the allegations.... FTC sued to block the Lifespan-Care New England merger.

STAT reported more than one-in-four biotech firms that went public in 2020 are trading below cash.

A <u>district court ruled</u> HHS violated procedural rules in <u>demanding AstraZeneca provide</u> <u>340B discounts</u> to contract pharmacies... Bristol Myers Squibb became the 14th drug manufacturer to <u>restrict such 340B discounts</u>... A federal appeals court <u>upheld a ruling</u> prohibiting <u>Teva's use of generic "skinny labels</u>"; Teva will appeal to the Supreme Court.

A <u>NBER working paper estimated</u> drug copay coupons increase negotiated prices for multiple sclerosis drugs by 8% and increase spending on couponed drugs without generics by up to 30%.

Modern Healthcare reported <u>state/federal funding to hospital/health systems doubled over</u> <u>the past two years</u>, as compared to historical averages... A CDC study found <u>41% of the</u> <u>59 million Part D antibiotic prescriptions in 2019 came from the top 10%</u> of prescribers... AHIP <u>reported costs for Medicare Part B drugs</u> administered in hospitals were an average of \$7,000 more than those purchased through specialty pharmacies.

A <u>JAMA study found</u> that remote clinical trials with online recruitment resulted in more racial, ethnic, and geographic diversity among study participants... Centivo reported <u>48%</u> and <u>37% of individuals</u> with the highest health insurance deductibles skipped/delayed specialist and primary care visits, respectively, due to costs.

"<u>Excess deaths</u>" in the US since the start of the pandemic <u>exceed 1 million per CDC</u>, including 13 non-COVID causes (e.g., heart disease, hypertension) higher than historical trend.

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

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COVID-19 News Supplement

Center for Healthcare Policy Insight



COVID-19 by the Numbers

<u>Over 78 million COVID-19 cases</u> have been documented in the US, with a death toll exceeding 930,000... The country <u>averaged just over 120,000 cases/day</u> over the past week, down from over 300,000/day just two weeks ago; however, COVID-related deaths remain above 2,000/day.

More than <u>10.4 billion COVID-19 vaccine doses have been administered across 184 countries</u>... Over 548 million COVID-19 <u>vaccine doses have been administered</u> in the US... Over 252 million Americans (<u>approximately 81% of Americans 5 and older</u>) have received at least one COVID-19 vaccine dose; roughly 214 million Americans are fully vaccinated (roughly 69% of Americans 5 and older); over 92 million Americans have received a booster or additional dose (just 43% of those fully vaccinated).

Executive and Administrative Action

HHS signaled to Congress that it <u>needs \$30 billion in additional COVID-19 funding</u> to keep its wideranging pandemic response efforts active, including meeting commitments to <u>increase access to COVID-19 vaccines</u> in low- and middle-income countries... The Administration will "<u>surge</u>" more than \$250 <u>million in COVID-19 vaccination support</u> to 11 sub-Saharan countries.

The White House announced it has <u>shipped 50 million free at-home COVID-19 tests to households</u>, about 85% of initial orders.

CDC could <u>update its indoor masking guidance</u> for states as soon as next week, with <u>a focus on COVID-19</u> <u>hospitalization rates</u>, not infections, as a guide for adjusting safety protocols... President Biden said it was <u>"probably premature" to relax indoor mask mandates</u>, but that "it's hard to say whether [governors] are wrong" to begin rolling back requirements.

The Biden Administration did not announce plans to let the public health emergency (PHE) declaration expire (suggesting that it would be extended again in April if they provide 60-days' notice as previously promised)... Meanwhile, More than 70 Republican members of Congress asked the <u>Biden Administration</u> to end the PHE due to the increased availability of vaccines and treatments "so our country can get back to normal;" the Federation of American Hospitals <u>urged HHS to renew the PHE</u>; Medicaid Health Plans of America urged appropriate notice for termination of the PHE (or Congressional action to delay maintenance of effort requirements) to allow adequate time to prepare for Medicaid coverage redeterminations; and eight lobbying organizations, including Medicaid Health Plans of America and AHIP, urged Congress to provide at least three months' notice before ending enhanced federal Medicaid funding.

The healthcare worker vaccine mandate <u>took effect in two dozen states</u> that challenged the policy in court.

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Healthcare Law, Business, and Policy News

Multiple states are <u>facing backlogs for healthcare workers to receive their licenses</u>, preventing additional clinicians from providing needed support to the strained healthcare system.

A CDC studies found <u>mRNA-based COVID-19 vaccination during pregnancy may prevent hospitalization</u> for infants (84% of infants who ended up in the hospital for COVID-19 were born to mothers who had not been vaccinated) and <u>hospitalizations rates (7.1 per 100,000)</u> among children and adolescents were four times higher at the Omicron variant's peak, as compared to Delta's peak... A <u>BMJ study found that</u> people who had COVID-19 were at increased risk of mental health disorders, including anxiety, depression, suicidal thoughts.

A Georgetown University report estimated that <u>6.7 million children could lose Medicaid coverage</u> when PHE-enhanced state Medicaid funding ends.

A <u>study found</u> pandemic-related unemployment led to a 2.6% decrease in medication adherence and 57.5M fewer prescriptions filled in 2020.

An economic and epidemiologic <u>model projected</u> that providing doses of an mRNA COVID-19 vaccine for every person living in lower-middle and low-income countries this year would avert 1.3 million deaths.

Anthem is partnering with Sidekick Health to create a COVID Concierge Care app.

19 House Democrats urged HHS to <u>collect better data on long COVID-19 in children and increase funding</u> <u>for treatments</u>.

An Axios/Morning Consult survey found <u>22% of healthcare workers considered leaving the industry in</u> <u>January</u>; more than 50% of healthcare workers treating COVID-19 patients reported their mental health had gotten worse during the pandemic and more than 60% said their stress level had worsened.

Surveillance, Testing, and Treatment

FDA cancelled a meeting of its vaccines advisory committee set to <u>consider authorization of</u> <u>Pfizer/BioNTech's COVID-19 vaccine in children under age 5</u> after the agency and companies indicated that they would wait until additional data was available on how well the vaccine worked after a third dose; the additional data is expected in early April, prompting FDA to urge parents to continue taking existing precautions to help prevent spread of the virus, such as masking.

FDA <u>awarded priority review vouchers to Moderna and BioNTech</u> for their FDA-approved COVID-19 vaccines, expediting the review process for future product applications.

BioNTech announced <u>plans for modular COVID-19 vaccine production hubs</u> in Africa... BioNTech's CEO said an Omicron-targeted COVID-19 vaccine <u>will not be ready until at least April</u>.

FDA granted emergency use authorization to Eli Lilly's monoclonal antibody treatment, bebtelovimab, believed to be effective against the Omicron variant, for patients with mild to moderate COVID-19.

AstraZeneca was awarded <u>a \$855M modification</u> for the manufacture, distribution, and storage of its monoclonal antibody, Evusheld, authorized as a COVID-19 pre-exposure prophylaxis for patients who are unable to receive COVID-19 vaccination, including those with a compromised immune system.