

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 <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> <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.

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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.

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FDA resumed standard domestic surveillance inspections... GAO called on FDA to overhaul its foreign inspection program.

CMS <u>expanded coverage of lung cancer screening</u> with low dose computed tomography.

CDC proposed updated clinical practice guidelines for prescribing opioids.

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Healthcare law and policy news

The Senate <u>will vote next week</u> on Robert Califf's nomination as FDA Commissioner.

The House <u>passed legislation</u> to fund the government through March 11, expected to be passed by the Senate, and <u>reached a "framework"</u> for FY2022 appropriations.

Senate Finance Committee is planning sweeping mental health legislation... Senators introduced bi-partisan legislation to <u>extend</u> <u>pandemic-related telehealth waivers by two years</u> and require a study on the waivers' impacts... House Energy and Commerce Committee <u>explored issues</u> related to the <u>proposed Advanced Research Projects</u> <u>Agency for Health (ARPA-H)</u>.

Teva reached a <u>\$225M opioid epidemic settlement with Texas</u>... The Commission on Combating Synthetic Opioid Trafficking <u>recommended</u> a "<u>nationwide and coordinated approach</u>" to combat the opioid crisis.

Yale New Haven Health <u>will acquire two health systems from Prospect</u> <u>Medical Holdings</u>... Signify Health <u>acquired Caravan Health</u> (\$250M)... Thirty Madison and Nurx <u>plan to merge</u>... CVS is partnering with Medable to <u>expand patient clinical trial access/engagement</u> at select MinuteClinics... Amazon Care will <u>expand its telehealth service</u> <u>nationwide</u> and open clinics in 20 US cities... Anthem <u>expanded virtual</u> <u>primary care services</u> to 11 new states... Banner/Aetna will <u>partner with</u> <u>Virtua Health to expand member access</u> to diabetes reversal services.

Health Affairs studies found (1) Black women are disproportionately employed in healthcare (6.9% of the country's workforce, but 13.7% of the healthcare workforce), particularly positions considered "menial" (e.g., direct care for older, disabled, and ill bodies); and (2) nonelderly Medicaid managed care enrollees in <u>racial/ethnic minority groups have</u> <u>significantly worse care experiences</u> than white enrollees... A study found just 12% of 162,428 individuals living with cystic fibrosis across <u>94 countries</u> are receiving a highly-effective, but expensive treatment, suggesting significant global care disparities.

A KFF-Epic Research analysis found <u>telehealth accounted for 8% of all</u> <u>outpatient visits March-August 2021</u>, down from 13% the year before... A Patient Rights Advocate <u>survey found only 14.3% of hospitals were</u> <u>fully compliant</u> with federal price transparency requirements.

Healthcare added 18,000 jobs in January, up from 14,300 in December.

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COVID-19 News Supplement

Center for Healthcare Policy Insight



COVID-19 by the Numbers

<u>Over 77 million COVID-19 cases</u> have been documented in the US, with a death toll over 910,000... The country is now <u>averaging roughly 215,000 cases/day</u> over the past week, down approximately 60% from two weeks ago; however, COVID-related deaths remain above 2,300/day.

More than <u>10.3 billion COVID-19 vaccine doses have been administered across 184 countries</u>... Over 545 million COVID-19 vaccine doses have been administered in the US... Over 251 million Americans (more than 80% of Americans 5 and older) have received at least one COVID-19 vaccine dose; roughly 213 million Americans are fully vaccinated (roughly 68% of Americans 5 and older); over 90 million Americans have received a booster or additional dose (just 42.5% of those fully vaccinated)... Fewer than 100,000 people are getting their first COVID-19 vaccine dose every day and fewer than 200,000 are getting a booster dose every day, the lowest rate since boosters were first recommended in September... CMS began posting COVID-19 vaccine booster dose data for nursing home residents and staff.

Executive and Administrative Action

HHS is working with hospitals across the country to improve COVID-19 data reporting, particularly recalculating the number of COVID-19 hospitalizations.

HHS <u>OCR guidance reinforces requirements</u> for providers to offer equitable COVID-19 care to individuals with disabilities, even as resources become scarce.

CDC is <u>considering updating guidelines on metrics that states should use</u> when contemplating lifting COVID-19 public health measures, such as masking requirements... CDC is <u>expanding monitoring of</u> <u>COVID-19 in sewage</u>, including <u>sharing virus wastewater trends on its public-facing COVID-19 website</u>, to better identify/predict potential changes in case rates.

At least <u>8 Democratic-leaning states</u> have <u>announced plans to loosen masking policies</u>, while acknowledging that COVID-19 will enter an endemic phase... CDC Director Rochelle Walensky <u>urged</u> <u>state officials to not end school mask</u> requirements.

A federal appeals court <u>declined to lift an injunction blocking</u> the Biden Administration from enforcing its federal worker vaccine requirement.

HHS awarded another <u>\$66.5 million for community-based vaccination</u> programs.

Healthcare Law, Business, and Policy News

CDC researchers <u>estimated that just under 11% of people infected with COVID-19</u> will develop new symptoms a month or more after diagnosis (long COVID), including fatigue, shortness of breath, heart rhythm changes, and type 2 diabetes.

AHIP <u>urged Congress to address price gouging of COVID-19 tests</u> by repealing a CARES Act provision requiring plans pay the "cash price" of out-of-network tests and instead base payments on median innetwork rates.

American Association of Cancer Research reported on pandemic-related disruption to cancer care, including nearly 10 million missed cancer screenings from January to July 2020 and an <u>11% increase in</u> <u>patients with inoperable or metastatic cancer</u> from March to December 2020 as a result of impaired referrals for preliminary cancer diagnoses.

A Morning Consult survey tracker found <u>support for vaccine requirements reached all-time lows</u> for schools (53%), employers (51%), and businesses (50%)... An <u>Axios/Ipsos survey found</u> that Americans are roughly split on the next steps for handling the pandemic: open up and get back to life as usual with no restrictions (21%), move toward opening up with some precautions (29%), mostly keep precautions and requirements in place (23%), or increase mask mandates and vaccine requirements (21%). Just 11% of respondents believe the country can eradicate COVID-19 in the next year... A Harris poll shared with Axios found that <u>73% of vaccinated parents plan to vaccinate their children under age 5</u>, while just 35% of unvaccinated parents plan to do so.

Surveillance, Testing, and Treatment

CDC Director Rochelle Walensky <u>endorsed ACIP's recommendation for use of Moderna's COVID-19</u> vaccine in individuals ages 18 and up.

CDC plans to <u>roll out 10 million doses of Pfizer-BioNTech's COVID-19 vaccine for young children</u> in three phases once it is authorized by the FDA, with states receiving shipments as early as February 21.

CDC <u>updated its clinical recommendations</u> to shorten the <u>booster interval between third and fourth</u> <u>doses</u> of mRNA COVID-19 vaccines from five months to three months for immunocompromised patients; those receiving the Johnson & Johnson vaccine are advised to get at third doses two months after their second dose. CDC also recommended that patients receiving monoclonal antibody treatment get their vaccinations at any time after treatment, rather than waiting 90 days.

A Johnson & Johnson plant in the Netherlands <u>temporarily stopped producing COVID-19 vaccines in late</u> <u>2021</u> to focus on vaccine production for another virus, potentially reducing overall supply of the vaccine by a few hundred million doses.

Novavax plans to seek authorization for use of its COVID-19 vaccine in teens ages 12 to 17.

Merck and Ridgeback Biotherapeutics announced they had <u>fulfilled their agreement to provide 3.1</u> <u>million courses of their oral COVID-19 antiviral</u> to the federal government, and plan to produce at least 20 million courses in 2022. The Biden Administration <u>ordered 600,000 courses (\$720 million) of an Eli Lilly monoclonal antibody</u> (<u>mAb</u>) that appears effective against the Omicron variant... A <u>preprint study</u> suggests the GlaxoSmithKline-Vir Biotechnology monoclonal antibody (mAb), sotrovimab, the only mAb currently being distributed by the federal government, <u>may not be effective against a "sister" variant</u> of Omicron; however, Vir research <u>suggests the mAb retains neutralizing activity against the subvariant</u>.