

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 <u>COVID-19 news for the week in this special supplement</u>.

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Healthcare regulatory news

HHS released its <u>Spring Regulatory Agenda</u> and <u>proposed rescinding</u> the Trump Administration requirement that community health centers pass insulin/epinephrine 340B discounts to patients.

HHS reported ACA special enrollment reached <u>1.2M enrollees</u> and more than 1M ACA consumers <u>pay \$10 or less/month in premiums</u>.

ONC <u>released draft data standards</u> for documenting <u>patient addresses</u> and announced <u>\$80M to strengthen public health IT</u>.

FDA established a <u>Generic Drug Cluster</u> to align global generic drug scientific/regulatory approaches.

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Healthcare law and policy news

The Supreme Court reversed and remanded (7-2) a lower court ruling on the ACA's constitutionality... Senate HELP Committee advanced nominations for ASPR and SAMHSA Directors.

Colorado <u>enacted legislation requiring insurers</u> to offer a standard plan that cuts premiums 15% over three years... Arkansas will <u>submit a revised</u> <u>Medicaid expansion plan</u> to CMS.

MedPAC <u>recommended</u> Medicare <u>streamline APMs</u> and eliminate/replace the SNF value-based purchasing program and reported that <u>Medicare Part</u> <u>D spending increased 26%</u> from 2013-2018.

A federal judge <u>denied HHS' request to dismiss</u> AstraZeneca's lawsuit over providing 340B discounts to contract pharmacies... The Justice Department <u>sued Paksn</u> for alleged physician kickbacks for SNF referrals... Mississippi <u>sued drug manufacturers/PBMs</u> over <u>insulin costs</u>... Centene will <u>pay \$143M to settle allegations</u> of overcharging for Medicaid drugs.

Spectrum and Beaumont <u>plan to merge</u>, creating a \$12B health system... Steward <u>will acquire five Tenet hospitals</u> (\$1.1B)... Humana <u>plans to</u> <u>acquire One Homecare Solutions</u>... Cano Health <u>acquired University</u> <u>Health Care</u> (\$600M)... Oschner <u>will acquire Rush</u>... Danaher <u>will acquire</u> <u>Aldevron</u> (\$9.6B)... GlaxoSmithKline will pay iTeos Therapeutics <u>up to</u> <u>\$2.1B to co-develop an immune therapy</u>.... Aetna, Cleveland Clinic, and HCSC <u>supported launch</u> of a startup using <u>blockchain to lower</u> <u>administrative costs</u> and improve interoperability... Anthem and Catalent <u>joined CivicaScript</u>.

AAMC projected a <u>17.800-48.000 primary care physician shortage</u> by 2034... Johns Hopkins researchers found <u>26 of the top 100 revenue</u> <u>hospitals</u> filed nearly 39,000 lawsuits against patients over unpaid medical bills between 2018 and mid-2020.

Altarum reported that <u>April healthcare spending was up 32.4%</u> from last year and estimated that Alzheimer's drug Aduhelm would <u>constitute more</u> than 1% of all national health spending and raise total prescription drug spending 8% by the mid-2020s.

A study found that <u>83% of hospitals were noncompliant</u> with price transparency requirements.

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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 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There are now over 33.5 million confirmed COVID-19 cases in the US, with a death toll of over 600,000.

315 million COVID-19 vaccine doses have been administered in the US (1.33M/day over the past week)... 176 million Americans (<u>62% of Americans 12 and older</u> and 87% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 148 million Americans are fully vaccinated (52% of Americans 12 and older)... In 15 states, at least 70% of adults have received at least one vaccination dose; <u>four states have vaccinated fewer than 50% of the population</u>, far short of President Biden's goal of reaching 70% vaccination rates by July 4... AMA reported that <u>96% of US physicians are fully</u> <u>vaccinated</u>... KFF projected that 65% of Americans 12 or older will have gotten at least one COVID-19 vaccine by July 4, including 70% of Asian individuals, 66% for White individuals <u>and just 63% and 51% of</u> <u>Hispanic and Black individuals</u>, respectively.

A study found that the delta COVID-19 variant first identified in India <u>doubles the risk of hospitalization</u> <u>from COVID-19</u>, as compared to the Alpha variant first identified in the UK... CDC classified the <u>delta</u> <u>variant as a "variant of concern."</u>

Executive and Administrative Action

HHS <u>revised reporting requirements</u> for providers receiving one or more payments exceeding, in aggregate, \$10,000 in Provider Relief Fund payments, while <u>extending deadlines for use of the funds</u> depending on when funds were received.

The US government <u>purchased an additional 200 million doses of Moderna's COVID-19 vaccine</u>, targeted for <u>use in children or as boosters</u>... the US will <u>donate an additional 1 million</u> Moderna doses to Canada.

HHS awarded <u>\$125 million in workforce grants</u> to 14 nonprofit organizations to accelerate COVID-19 vaccinations in underserved communities.

The EU is <u>easing restrictions on travel to Europe</u> from the United States.

Healthcare Regulatory News

CDC released <u>interim guidance on treating COVID-19 long-haulers</u>, including recommending that a <u>broad</u> <u>spectrum of symptoms be considered</u> and that patient-centered care approaches be used to address quality of life and function.

Healthcare Law, Business, and Policy News

FAIR Health found that <u>19% of patients with asymptomatic COVID-19 had at least one</u> post-COVID condition... AMA called for <u>policies to better diagnose and treat long-haul COVID-19</u>.

A study found that <u>organ transplant recipients who received a third dose of COVID-19 vaccine</u> had higher antibody levels than after getting just two standard doses.

KFF reported that <u>unvaccinated adults are more likely to be uninsured</u> and have lower income... An African American Research Collaborative-Commonwealth Fund <u>survey found that vaccine hesitancy is</u> <u>roughly similar</u> across White, Black, Native American, and Hispanic individuals (40%); two-thirds of those surveyed reported more than one barrier to getting vaccinated... A Morning Consult survey found that <u>20% of Americans don't plan to get vaccinated</u>, largely unchanged since March.

A Willis Towers Watson <u>survey found that 72% of businesses won't require COVID-19 vaccines</u> before employees can enter the workplace; of those business that will require vaccines, 56% will require documented proof of vaccination.

Amazon customers can <u>now purchase its COVID-19 test and access a diagnostic portal</u> previously available only to workers.

Surveillance, Testing, and Treatment

The FDA ordered Johnson & Johnson to <u>dispose of 60 million doses of its COVID-19 vaccine</u> made at Emergent BioSolutions' Baltimore facility; FDA <u>has authorized</u> roughly <u>25 million doses of the vaccine to</u> <u>be released for use</u> in the United States or exported to other countries ... Emergent BioSolutions <u>detailed quality improvement steps</u> to prevent future contamination.

Novavax reported that its <u>COVID-19 vaccine was 90% effective against confirmed, symptomatic COVID-19</u> infection in a phase 3 trial; Novavax plans to apply for emergency use authorization in Q3... CureVac reported that its <u>COVID-19 vaccine is just 47% effective</u> against COVID-19 of any severity.

Pfizer is examining "breakthrough" <u>cases of fully vaccinated people contracting COVID-19</u> to determine whether and when a booster vaccine may be necessary.

A University of Oxford study found that <u>Regeneron's COVID-19 monoclonal antibody (mAb) therapy</u> <u>reduced the risk of death by 20% among hospitalized COVID-19 patients</u> who do not generate their own antibody response; the mAb is currently not authorized for use in hospitalized patients, although Regeneron plans to seek expanded use authorization... AstraZeneca reported that its <u>monoclonal</u> <u>antibody therapy failed to prevent symptomatic COVID-19</u>.

The NIH will <u>spend \$3B to develop</u> COVID-19 antiviral therapies... Pfizer reported that its <u>Xeljanz oral</u> <u>rheumatoid arthritis drug reduced death or respiratory failure</u> in hospitalized COVID-19 patients with pneumonia in Brazil.

NIH researchers found additional evidence to <u>suggest that COVID-19 was circulating in the US as early as</u> <u>December 2019</u>.

Group of 7 leaders called for <u>a "timely, transparent, expert-led, and science-based" investigation</u> by the World Health Organization into the origins of the COVID-19 pandemic.