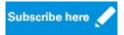


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Editor's note

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

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

HHS <u>proposed rescinding</u> the Trump Administration Most Favored Nation drug pricing model final rule.

Over <u>2.5M people have enrolled in ACA coverage</u> during the special enrollment period... CMS informed <u>Ohio</u>, <u>Utah</u>, and <u>South Carolina</u> it would not allow Medicaid work requirements.

Following court loss, FDA will begin regulating some drugs, including imaging agents, as devices.

The VA will not cover the Alzheimer's drug Aduhelm.

GAO <u>reported SNFs</u> with fewer registered nurses had higher patient rehospitalizations and recommended that HHS impose stronger penalties to prevent such incidents.





Healthcare law and policy news

President Biden <u>urged Congress to lower drug prices</u>, including through Medicare negotiation... Biden <u>nominated Samuel Bagenstos</u> as HHS General Counsel.

Senate passed a <u>budget resolution</u> (50-49), setting up Democrats' attempt at a \$3.5B budget reconciliation bill that would, among other things, <u>lower Medicare eligibility age</u>, <u>expand Medicare benefits</u>, extend enhanced ACA subsidies, and permit Medicare drug price negotiation.

A Missouri judge ruled <u>Medicaid expansion can advance</u> over the Governor's objection.

UnitedHealthcare will pay \$15.6M to settle mental health parity claims...

Takeda will pay \$1.85M to settle pay-for-delay claims related to a generic ADHD drug... A class action suit alleges four pharmaceutical manufacturers colluded by restricting sale of insulin to contract pharmacies under 340B... A class action antitrust lawsuit alleges that HCA raised prices and failed to comply with price transparency requirements...

Chamber of Commerce sued HHS to stop health plan price transparency requirements.; PCMA sued to invalidate plan requirements to publish historical prescription drug net prices.

EQRx will go public through a SPAC... Honor Technology acquired Home Instead... Aetna launched a virtual primary care solution... Pfizer will sell rights to a recently-discontinued glaucoma drug to Fera Pharmaceuticals.

62% of physicians surveyed by Google Cloud said the <u>pandemic forced</u> technology upgrades that would normally take years; 90% now use telehealth, up from 32% pre-pandemic... Telehealth use stabilized at <u>5% of claims</u> in May, after three months of decline... A Better Medicare Alliance-commissioned report <u>recommended that Medicare Advantage plans</u> improve data collection on social determinants of health... A *Journal of General Internal Medicine* study found a <u>hospital-at-home program boosted</u> inpatient capacity during the pandemic.

The US had a record 95,000 drug overdose deaths in 2020.





Questions or comments, please send to <u>us-hcinsight@kpmg.com</u>.

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COVID-19 by the Numbers

There have now been over 36.3 million confirmed COVID-19 cases in the US, with a death toll approaching 620,000... The country is averaging over 110,000 new cases/day over the past week, up from approximately 20,000 cases/day a month ago... American Academy of Pediatrics reported that there were nearly 94,000 cases among children last week (about 15% of all cases) and hospitalizations rates are rising.

354 million COVID-19 <u>vaccine doses have been administered</u> in the US (roughly 680,000/day over the past week)... 196 million Americans (69.2% of Americans 12 and older and 90.6% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 167 million Americans are fully vaccinated (59% of Americans 12 and older).

Executive and Administrative Action

Biden chief medical advisor, Anthony Fauci, urged more testing among those already vaccinated in order to better track breakthrough infections... Fauci and other senior Administration officials also urged vaccination mandates to be instituted at the local level, including at universities, businesses, and other organizations.

HHS will require its healthcare employees to get vaccinated for COVID-19.

Secretary of Defense Lloyd Austin <u>plans to make COVID-19 vaccine mandatory</u> for all 1.4 million service members by mid-September.

Healthcare Law, Business, and Policy News

A <u>KFF poll found</u> that 63% of parents thought that unvaccinated students 12 and older should be required to wear masks in schools, however, only 42% of parents feel comfortable with vaccine mandates.

More than 90 health systems have <u>adopted COVID-19 vaccination requirements</u> for employees.

Surveillance, Testing, and Treatment

FDA <u>authorized a third dose</u> of Pfizer-BioNTech and Moderna's COVID-19 vaccines for people with weak immune systems... CDC's Advisory Community on Immunization Practices will <u>meet today to discuss and vote</u> on whether COVID-19 vaccine booster shots are needed... Anthony Fauci hopes that <u>full FDA approval of one or more COVID-19 vaccines</u> will occur within the month of August.

Based on new confirmatory evidence, CDC <u>advised people who are pregnant, breastfeeding, or contemplating pregnancy</u> to get vaccinated against COVID-19.

A *NEJM* study <u>found that a third dose of Moderna's COVID-19 vaccine</u> substantially improved protection for organ transplant recipients who have weakened immune systems... An Israeli study found that 88% of individuals who received a booster shot of Pfizer-BioNTech's COVID-19 vaccine <u>had similar or fewer side effects</u> than they did after their second dose.

A <u>preprint study</u> found that Pfizer-BioNTech's COVID-19 vaccine was only <u>42% effective against infection</u> in July, suggesting that it may not be as effective against the Delta variant.

The European Medicines Agency is <u>investigating potential skin condition and kidney disorder side effects</u> resulting from the Pfizer-BioNTech and Moderna vaccines.

FDA <u>cleared AstraZeneca COVID-19 vaccine doses</u> for export overseas after delays resulting from investigation of contamination issues at the Emergent BioSolutions manufacturing plant... NIH animal studies found that <u>an intranasal version of AstraZeneca's COVID-19 vaccine</u> provided protection against serious disease.

Moderna will double enrollment in a trial of its COVID-19 vaccine in children under age 12.

World Health Organization (WHO) announced <u>a clinical trial in 52 countries to study three anti-inflammatory drugs</u> as potential COVID-19 treatments.

WHO also announced <u>new efforts to investigate origins of the pandemic</u>, encouraging countries to "depoliticize the situation and cooperate."