



# Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



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Editor's note

***ATW 360 will not be published on Friday, July 9th. We hope you enjoy the 4th of July holiday!***

*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 [reply 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.

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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](#).



**Healthcare regulatory news**

An [HHS-Treasury proposed rule](#) would [roll back Trump Administration ACA policies](#) and extend individual market open enrollment... CMS proposed increasing 2022 [home health payments](#) 1.8% and 2022 [ESRD payments](#) 1.2%, while [expanding the home health value-based purchasing model](#) and [revamping the ESRD Treatment Choices Model](#) to address health inequities... CMS released [Part 1](#) of the [surprise billing interim final rule](#).

CMS [transferred \\$11.7B](#) among insurers in 2020 ACA risk adjustment program payments.

DEA [eased requirements for addiction treatment mobile vans](#) to deliver methadone.

FDA [draft guidance](#) would provide drug manufacturers with drug trial safety reporting requirement flexibilities.

Justice Department opened a [record 580 False Claims Act healthcare fraud cases](#) last year.

OIG concluded that CMS [does not have adequate authority](#) to ensure accredited hospitals are [prepared for pandemics](#).



## Healthcare law and policy news

Daniel Tsai was named [Director of Center for Medicaid and CHIP Services](#).

Supreme Court [refused to review hospitals' challenge](#) to site-neutral payment policies.

Eight opioid manufacturers/distributors [went on trial in New York](#) for opioid epidemic-related claims; Johnson & Johnson will [pay \\$263M to settle](#) related lawsuits and [halt opioid sales](#)... Juul will [pay North Carolina \\$40M to settle](#) vaping-related claims; NC Attorney General [urged FDA to ban flavors and limit nicotine](#) in e-cigarettes... A federal judge [ruled that AstraZeneca's lawsuit against HHS over 340B contract pharmacy discounts](#) can proceed despite HHS withdrawing an associated advisory opinion.

Two House committees [launched investigations](#) of Biogen's Aduhelm approval/pricing... GAO reported that [Medicare and beneficiaries spent \\$324B on prescription drugs advertised to consumers](#) from 2016-2018, 58% of total Part B/D spending... GoodRx [reported that hospital chargemaster](#) generic drug prices are nearly 6,000% higher than pharmacy costs.

KPMG, EBG, and FP [reported that healthcare/life sciences deals](#) are up 70% year-to-date... University of Oklahoma and University Hospitals Authority and Trust [merged clinics and hospitals](#)... AccentCare [acquired Southeastern Health Care at Home](#)... Anthem [acquired MMM Holdings](#) and its affiliates... Amedisys [will acquire Contessa Health](#) (\$250M)... Sanofi will

[invest \\$447M/year in mRNA vaccine research](#)... Walmart collaborated with Novo Nordisk to [launch a private label insulin analog](#).

Physicians Advocacy Institute reported that [69.3% of physicians were employed by hospitals or corporations in January 2021](#), up from 62.2% in January 2020.



Questions or comments, please send to [us-hcinsight@kpmg.com](mailto:us-hcinsight@kpmg.com).

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# COVID-19 News Supplement

Center for Healthcare Regulatory Insight



## COVID-19 by the Numbers

There are now [over 33.6 million confirmed COVID-19 cases](#) in the US, with a death toll of approximately 605,000... Cases are [up roughly 10% over the past week](#), after several weeks of declining rates... CDC Director Rochelle Walensky said that roughly [one-in-four new COVID-19 cases are attributable to the highly transmissible Delta variant](#) and that cases are rising the fastest in communities where people remain unvaccinated.

328 million COVID-19 [vaccine doses have been administered](#) in the US (1.12M/day over the past week)... 181 million Americans ([64% of Americans 12 and older](#) and 88% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 156 million Americans are fully vaccinated (55% of Americans 12 and older).

CDC Director Walensky [expressed continued support for the CDC's guidance](#) on mask-wearing despite the World Health Organization (WHO) suggesting that vaccinated people continue to wear masks; meanwhile, LA County [urged vaccinated individuals to continue wearing masks](#) as the Delta variant continues to spread.

## Executive and Administrative Action

General Gus Perna will [retire this summer from the Countermeasures Acceleration Group](#), formerly known as Operation Warp Speed.

The Biden Administration [fell short of meeting its goal of distributing 80 million COVID-19 vaccine doses](#) by the end of June; the US has shipped 24 million doses to 10 countries so far, with 40 million more doses expected to ship in the coming days.

Politico reported on [continuing challenges with filling the US Strategic National Stockpile](#) reserves with medical supplies needed for response to the current and future pandemics.

HHS [rejected an AHA request to delay](#) spending deadlines for some Provider Relief Funds recipients.

## Healthcare Regulatory News

Bloomberg reported that [OSHA's emergency workplace standards was initially intended](#) to cover all workers, not just those in healthcare... OSHA [issued inspection guidelines](#) for the emergency standards... AHA [asked OSHA to delay compliance](#) of the standards by 6 months.

FDA [revoked emergency use authorizations](#) for respirator decontamination systems and certain masks due to increased domestic supply of N95 respirators.

## Healthcare Law, Business, and Policy News

A CDC survey found that [53% of public health employees reported mental health symptoms](#) last Spring as a result of the pandemic... Just 41% of respondents to an Axios-Ipsos survey believe [attending a Fourth of July celebration is a large or moderate risk](#)... A KFF survey found that [just 3% of unvaccinated adults plan to get a COVID-19 vaccine](#) as soon as possible; 76% of adults are optimistic that the US is nearing the end of the pandemic.

A Resolve to Save Lives survey found that [32% of unvaccinated individuals were more likely to consider getting vaccinated](#) after having long-COVID symptoms described to them.

## Surveillance, Testing, and Treatment

FDA granted emergency use authorization for [Genentech's arthritis drug Actemra in hospitalized COVID-19 patients](#) who are receiving supplemental oxygen, mechanical ventilation, systemic steroids or extracorporeal membrane oxygenation.

Moderna's COVID-19 vaccine [produced neutralizing antibodies to protect against the Delta, Beta, and Eta variants](#) in a lab study.

A [Nature study found](#) that Pfizer-BioNTech and Moderna's vaccines [prompt a strong immune response that could potentially protect](#) against COVID-19 for years.

A University of Oxford study found that a [longer gap of about 10 months between doses of AstraZeneca's COVID-19 vaccine](#), and a third shot, can boost antibody levels and immune response... Another study found that [alternating doses of Pfizer-BioNTech's and AstraZeneca's COVID-19 vaccine](#) provided a stronger immune response than two doses of AstraZeneca's vaccine.

Johnson & Johnson (J&J) said that its [COVID-19 vaccine protects against the Delta variant](#) and that the immune response generated by the vaccine has lasted eight months... J&J [plans to conduct four clinical trials](#) of its COVID-19 vaccine in children ranging from under 2 years to 17 years old.

CureVac announced final clinical trial data show that [its COVID-19 vaccine had an efficacy of only 48%](#).

COVAX urged Western countries to [recognize equally all WHO-approved](#) COVID-19 vaccines.

HHS [paused distribution of Eli Lilly's combination monoclonal antibody \(mAb\) treatment](#) for patients with mild to moderate COVID-19 at high-risk of developing severe symptoms due to the growing prevalence of virus variants against which the treatment does not appear effective.

Five Indian generic drug manufacturers will [jointly conduct a clinical trial testing Merck's antiviral drug](#) to treat mild COVID-19 in on-hospitalized patients.

An NIH study [concluded that rapid antigen COVID-19 tests are as effective](#) as laboratory PCR tests in detecting COVID-19.