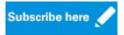


## August 20, 2021 | Issue 185

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 here</u>.

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**

CMS <u>will give states a year</u>, up from six months, after the COVID-19 public health emergency ends to redetermine Medicaid enrollee eligibility... CMS is <u>not yet penalizing hospitals</u> that are non-compliant with price transparency requirements... Texas <u>refused</u> a CMS <u>offer to continue a DSRIP program</u> that pays Texas providers billions for another year after CMS recently rejected the state's Medicaid waiver request.

HHS <u>invested \$19M to expand telehealth</u> in rural/underserved communities.

HHS could <u>recommend common billing codes for biosimilars</u> and their brand biologics.

OIG <u>reported that CMS paid new hospitals three times</u> more for capital costs than it would have under the IPPS and recommended removing the existing capital cost exemption.





## Healthcare law and policy news

US Court of Appeals for the DC Circuit overturned a lower court decision, ruling that <u>actuarial equivalence did not apply to a Medicare Advantage</u> overpayment rule.

UnitedHealth and Change Healthcare <u>agreed to not complete their \$8B merger</u> until 120 days after both companies certify compliance with Justice Department (DOJ) requirements... Humana <u>completed its acquisition of Kindred at Home</u>... Illumina <u>closed its \$8B acquisition of Grail</u>, despite lacking FTC or EU clearance... Inovalon <u>will go private</u> in a \$7.3B deal... Verily <u>will acquire SignalPath</u>... SSM Health and Medica <u>plan to form a strategic partnership</u>... Cigna and Fresenius <u>extended their value-based kidney care partnership</u> through 2023... In a letter to HHS, DOJ, and FTC, the AHA argued that hospital mergers present no competitive issues.

Merck plans to withdraw 340B discounts to most contract pharmacies... Eli Lilly is splitting its Bio-Medicines unit into neuroscience and immunology units.

States must <u>decide by Saturday whether to join</u> a \$26B opioid-related settlement.

A <u>Pediatric study found</u> that almost half of children/adults under age 21 given opioid prescriptions fit high-risk patterns known to increase overuse/overdose risks... A KFF analysis found that <u>per-enrollee spending in Medicare Advantage</u> is higher and growing faster than fee-for-service Medicare... A KFF/Epic Health Research Network analysis found <u>hospital admissions have not rebounded as expected</u> in early 2021... Altarum reported that <u>healthcare employment is approaching</u> pre-pandemic highs... A <u>JAMA study found</u> that healthcare spending on White Americans accounted for 72% of all spending from 2002-2016, despite accounting for just 61% of the population.





Questions or comments, please send to ushcinsight@kpmg.com.

# Succeeding in the new reality

Visit the COVID-19 resource center for KPMG analysis, insights, and perspectives.



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## COVID-19 by the Numbers

There have now been over 37.3 million confirmed COVID-19 cases in the US, with a death toll over 625,000... The country is averaging over 130,000 new cases/day over the past week... Cases rose in nearly every state over the past week, with no state seeing a decline in cases... Wall Street Journal reported that COVID-19 hospitalizations among people in their 30s hit a record high (2.5 per 100,000 individuals)... NIH Director Francis Collins warned that the Delta variant is "going up steeply with no signs of having peaked."

360 million COVID-19 <u>vaccine doses have been administered</u> in the US (roughly 823,000/day over the past week)... Nearly 200 million Americans (70.4% of Americans 12 and older and 91.1% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 169.6 million Americans are fully vaccinated (59.8% of Americans 12 and older)... More than <u>one million Americans received a dose of a COVID-19 vaccine on Thursday</u> for the first time in nearly seven weeks.

### **Executive and Administrative Action**

The Biden Administration <u>recommended a third dose of Pfizer-BioNTech and Moderna's COVID-19</u> <u>vaccines</u> eight months after a second dose, and will start offering booster shots on September 20<sup>th</sup> to all vaccinated US adults.

CDC <u>provided \$47 million to the nonprofit Task Force for Global Health</u> to expand access to COVID-19 and influenza vaccines in developing nations.

The Transportation Security Administration will extend the mask mandate for air travelers and passengers on public transit to January 18, 2022.

The CDC launched a Center for Forecasting and Outbreak Analytics.

## Healthcare Regulatory News

CMS, in collaboration with CDC, will <u>issue an emergency regulation requiring all nursing homes to vaccinate their staff</u> against COVID-19 or risk losing Medicare and Medicare funding; the requirement could take effect as soon as September.

## Healthcare Law, Business, and Policy News

A KFF analysis found that <u>72% of the two largest health insurers in each state and DC</u> have stopped waiving cost-sharing requirements for COVID-19 treatment.

The World Health Organization (WHO) Access to Covid-19 Tools Accelerator <u>launched a \$11.5 billion</u> <u>appeal</u> for COVID-19 tests, treatments, and vaccines... WHO and Unitaid urged Roche to ensure existing doses of Actemra, which is being used to treat COVID-19 patients, <u>are equally available to low- and middle-income</u> countries.

An Axios/Ipsos poll found that <u>69% of Americans support mandating masks in schools</u>, while 64% support state and local government mandates requiring mask wearing in public areas.

Association for Accessible Medicines <u>urged COVID-19 vaccine manufacturers to license</u> <u>generic/biosimilar companies</u> to manufacture the vaccines in order to help meet global demand.

AMA has <u>created new billing codes to reimburse providers</u> for administering a third dose of Moderna's or Pfizer-BioNTech's vaccine.

## Surveillance, Testing, and Treatment

The CDC Advisory Committee on Immunization Practices <u>unanimously voted in favor</u> of recommending that immunocompromised individuals receive a third COVID-19 shot... The <u>committee postponed a meeting scheduled for next week</u> to discuss booster shots for all Americans.

Pfizer-BioNTech <u>submitted early stage clinical trial data to the FDA</u> on the safety and efficacy of a third dose of their COVID-19 vaccine... An Israeli study found that a <u>booster shot of Pfizer-BioNTech's COVID-19</u> vaccine can improve immunity for those aged 60 and above.

A UK study found that the <u>Pfizer-BioNTech COVID-19 vaccine loses effectiveness over time</u>, dropping from preventing 85% of infections to 75% after 90 days.

Federal officials are exploring reports that <u>Moderna's COVID-19 vaccine may be linked to a higher risk of heart inflammation</u> in younger adults than previously thought.

CDC released studies finding that with respect to effectiveness of preventing infection, <a href="Pfizer-BioNTech's and Moderna's COVID-19">Pfizer-BioNTech's and Moderna's COVID-19 vaccines dropped</a> from 75% among nursing home residents in March-May to 53% in June-July; that the effectiveness of those vaccines <a href="did not change significantly from March to July">did not change significantly from March to July</a> at 21 hospitals; and that effectiveness of Pfizer-BioNTech's, Moderna's, and Johnson & Johnson's vaccines <a href="dropped from 92% in early May to 80% at the end of July">dropped from 92% in early May to 80% at the end of July</a>, but effectiveness against hospitalization remained stable.

A *Health Affairs* study concluded that <u>early uptake of COVID-19 vaccines saved nearly 140,000 lives</u> across the US through early May... A <u>pre-print study suggests that the Lambda variant could be vaccine resistant</u>.

AstraZeneca reported that its <u>monoclonal antibody treatment was 77% effective at preventing</u> symptomatic COVID-19 in high-risk individuals and that it plans to seek emergency use authorization.