



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

Center for Healthcare Regulatory Insight



July 16, 2021 | Issue 180

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 [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

CMS [proposed](#) decreasing the FY2022 physician fee schedule conversion factor by 3.75% and [covering certain additional Medicare telehealth services](#) through 2023.

CMS opened [a national coverage determination](#) for the Alzheimer's drug Aduhelm... FDA approved [Bayer's treatment for kidney disease associated with diabetes](#).

HHS reported [2.1M individuals have enrolled in ACA special enrollment period coverage](#); Medicaid/CHIP enrollment reached 81M... CMS [announced \\$15M to help states](#) provide Medicaid beneficiaries with community-based mobile crisis intervention services... HRSA [awarded \\$144M](#) to HRSA Health Center Program look-alikes (LALs).

OIG reported that the VA [underreported EHR modernization project](#) costs by \$2.5B.



Healthcare law and policy news

President Biden [nominated Rahul Gupta](#) as Director of the Office of National Drug Control Policy.

Philip Morris [will acquire Vectura Group \(\\$1.24B\)](#), which specializes in inhaled therapeutics... Eli Lilly [will acquire Protomer Technologies](#) (\$1B)... Intelerad Medical Systems will [acquire Heart Imaging Technologies](#)... MSP Recovery [will go public \(\\$32.6B\) through a SPAC](#)... Microsoft and Teladoc are [collaborating on a clinician "unified practice experience"](#)... Digital health funding [reached a record \\$15B](#) in Q1/Q2 2021.

A federal judge [dropped antitrust claims against Eli Lilly, Sanofi, Novo Nordisk, and three PBMs](#) over insulin pricing, but did not dismiss racketeering claims... A Teva subsidiary accused Amicus Therapeutics of [failing to provide drug samples](#) in order to prevent generic competition.

Tennessee Department of Health [ended vaccine outreach to teenagers](#).

Senate Democrats announced [a \\$3.5T budget reconciliation plan](#), including [Medicare dental, hearing, and vision benefits](#); expanded home/community-based services; and extension of enhanced ACA subsidies... [Drug pricing reforms will likely be used](#) to offset costs... Democrats are also [considering options for expanding coverage](#) in Medicaid non-expansion states... Nearly 40 employer/health organizations [urged Congress to advance legislation permitting Medicare](#) to negotiate drug prices.

McKinsey reported that telehealth use has [stabilized at 38 times higher](#) than pre-pandemic, or 13-17% of visits... [JAMA study found that 77.2% of telemedicine visits](#) in the second half of 2020 were for long-term diagnoses, compared to just 2.7% for preventive care.

Lown Institute reported that [72% of nonprofit hospitals spent less on charity care/community benefit](#) than they received in tax breaks.

CDC reported [93,331 drug overdose deaths in 2020](#), up from 70,890 in 2019, the largest increase in 50 years.

We did not publish last week, so here is our summary... in less than 180 Words

President Biden [signed an Executive Order](#) to spur competition, including through boosting generics/biosimilars markets; directing FDA to work with states/tribes on prescription drug importation; encouraging FTC to ban “pay for delay” arrangements; recommending closer scrutiny of healthcare/life sciences mergers; and creating standardized health plan options.

Meena Seshamani was named [Director of Center for Medicare](#).

ONC [updated EHR data standards](#) to include patient [social determinants of health, sexual orientation, and gender identity](#) data.

FDA [revised guidance to recommend that the Alzheimer’s drug Aduhelm](#) only be used for individuals with mild cognitive impairment or mild dementia... Acting FDA Commissioner Janet Woodcock [called for a federal investigation](#) into approval of the drug.

Supreme Court agreed to hear cases on [340B payment cuts](#) and [DSH payment calculation](#) methodology.

A [WSJ analysis](#) found that hospitals often charge cash-paying patients higher prices than negotiated insurer rates... House Oversight Committee reported that the [top 14 drug companies spent \\$577B on stock buybacks and dividends](#) from 2016-2020.

Moderna is [testing a seasonal flu vaccine](#) using mRNA technology.

15 states [signed onto a bankruptcy plan](#) for Purdue Pharma.



Questions or comments, please send to 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 [nearly 34 million confirmed COVID-19 cases](#) in the US, with a death toll over 605,000... The country is [now averaging over 25,000 cases/day](#), more than double the daily rate the week of June 22 (11,300 cases/day); cases are up in 48 states... States with lower vaccination rates reported an [average of 6 new daily cases/100,000](#), compared to 2.2 new daily cases/100,000 in states with higher vaccination rates... A Belgian woman died of COVID-19 after [simultaneously contracting two variants of the virus](#), the first documented dual infection.

335 million COVID-19 [vaccine doses have been administered](#) in the US (548,000/day over the past week)... 185 million Americans ([65% of Americans 12 and older](#) and 89% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 160 million Americans are fully vaccinated (56% of Americans 12 and older)... Axios reported that [more than half of unvaccinated Americans](#) live in households that make less than \$50,000 annually, including 22% in households making less than \$25,000 annually.

Executive and Administrative Action

CDC indicated that [schools should allow students to return to in-person learning this fall](#), regardless of vaccination status and case rates... CDC and FDA [jointly stated](#) that Americans who have been fully vaccinated do not need a vaccine booster “at this time.”

The White House will move its [COVID-19 Task Force calls with governors](#) from weekly to biweekly.

The Strategic National Stockpile is [seeking a company capable of producing 127 million disposable surgical masks](#) over the next year.

Healthcare Regulatory News

OSHA extended by 30 days (until August 20) [the comment period](#) for its COVID-19 emergency protection standard.

Healthcare Law, Business, and Policy News

Seven healthcare professional organizations [released a consensus statement](#) recommending that COVID-19 vaccination be a condition of employment for healthcare workers.

The American Healthcare Association and National Center for Assisted Living [urged HHS to release the remainder of Provider Relief Funds](#) to help long term care facilities remain financially solvent.

Honeywell and Premier [will expand domestic production of exam gloves](#).

Commonwealth Fund [estimated that rapid rollout of COVID-19 vaccines](#) saved 279,000 lives and prevented 1.25 million hospitalizations in the US... A *Lancet* study concluded that the pandemic [disrupted routine childhood vaccines for at least 17 million children](#) globally... A *Health Affairs* study found that COVID-19 case rates at nursing homes [with the most unique staff members were 92% higher](#) than facilities with fewer staff.

Surveillance, Testing, and Treatment

After announcing plans to [seek emergency use authorization](#) to distribute its COVID-19 vaccine as a booster shot, Pfizer [briefed government officials](#) on the possible need for a booster... US health leaders said [more data is needed before regulators can determine](#) whether booster shots will be necessary.

FDA added [a warning to Johnson & Johnson's \(J&J\) COVID-19 vaccine](#) about a [risk of Guillain-Barré Syndrome](#), a rare immune system disorder, in some vaccine recipients... The CDC Advisory Committee on Immunization Practices [will meet July 22](#) to discuss the possible risk, as well as boosters for immunocompromised individuals... J&J also reported that its vaccine [maintains strong and stable effectiveness](#) against COVID-19 variants, including Delta.

AstraZeneca, J&J, and the University of Oxford are [conducting early-stage research on whether modified versions of their COVID-19 vaccines](#) could reduce or eliminate the risk of serious blood clots.

A [Lancet study found](#) that BioNTech's vaccine [produced 10 times the level of antibodies](#) as compared to the Sinovac vaccine.

Gavi [signed advance purchase agreements](#) for 60 million doses of Sinopharm COVID-19 vaccines and 50 million doses of Sinovac COVID-19 vaccines to supply COVAX.

The World Health Organization [recommended a combination regimen of corticosteroids](#) with Roche's tocilizumab or Sanofi's sarilumab, two anti-inflammatory monoclonal antibodies, for the treatment of severe or critical COVID-19.