



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ATW 360 will not be published on Friday, July 8th. 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

CMS [proposed conditions of participation](#) (CoPs) for [rural emergency hospitals](#) and updates to [critical access hospital CoPs](#)... CMS [updated](#) long-term care [facility safety/quality guidance](#), including [using payroll data to assess staffing compliance](#), requiring infection prevention staff, and encouraging room occupancy limits.

CMMI [announced](#) the [Enhancing Oncology Model](#), launching July 2023 to [replace the Oncology Care Model](#).

CMS [approved](#) Vermont's 1115 demonstration extension, allowing for [continuation of some pandemic flexibilities](#) beyond public health emergency expiration.

HHS is [seeking comment](#) on [strengthening primary care](#)... OCR [will seek comment from HIPAA-covered entities](#) on [improving health IT data breach reporting](#).

FDA [proposed requirements](#) for prescription drugs with an additional condition for non-prescription use to switch to over-the-counter status... A federal appeals court [issued an emergency order](#) blocking FDA's ban of Juul's e-cigarettes [pending a full appeal](#).

HRSA [warned UCB it was violating the 340B statute](#) by restricting access to drugs at contract pharmacies.

The Biden Administration [plans to expand access to monkeypox vaccines](#) for at-risk individuals.



Healthcare law and policy news

The Supreme Court (1) unanimously ruled [doctors must “knowingly and intentionally” violate opioid prescribing standards](#) to be convicted of unlawful distribution; and, (2) [declined to hear a lawsuit](#) that alleged an ERISA fiduciary obligation for a plan/PBM to lower drug prices.

Oklahoma [reached a \\$250M settlement](#) with AmerisourceBergen, Cardinal, and McKesson over their role in the opioid epidemic... Gilead reached [a \\$33M settlement](#) with a health clinic accused of a “dangerous and fraudulent scheme” to [exploit an HIV medicine patient assistance program](#).

KPMG-EBG-FPP reported May healthcare/life sciences [deal volume \(154\) was the lowest of any month this year](#).

Sanofi will [cap out-of-pocket insulin costs for uninsured patients](#) at \$35/30-day supply... Pfizer and Roivant Sciences [formed a company to develop](#) anti-inflammatory drugs.

Kaufman Hall reported May [median hospital operating margins were up 18.9%](#), but down 45.6% from May 2021... Willis Towers Watson reported [40% of employees deferred medical care over the past year](#); roughly half cited affordability (25%) or cost uncertainty (23%) as the cause.

[OIG](#), [GAO](#), and [MedPAC](#) officials urged the House Energy and Commerce [Oversight Subcommittee](#) to [increase Medicare Advantage plan oversight](#).

Democratic leaders reportedly [agreed to include prescription drug pricing provisions](#) in a possible reconciliation package.





Questions or comments, please send to
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COVID-19 News Supplement

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COVID-19 by the Numbers

Over [87.4 million COVID-19 cases](#) have been documented in the US, with the death toll exceeding 1.01 million... As of June 29, 2022, the current 7-day moving average of [daily new cases](#) (109,930) increased 12% compared with the previous week's 7-day moving average (98,217); the current 7-day moving average of [new deaths](#) (317) has increased 9.6% compared with the previous week's 7-day moving average (289).

As of June 25, the BA.2.12.1 variant [accounted for 42% of COVID-19 cases](#), down from 53% the previous week, while BA.5 and BA.4 accounted for 37% and 16%, respectively, both up from the previous week (25% and 12%).

More than [12.1 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 594 million COVID-19 [vaccine doses have been administered](#) in the US... Over 259.4 million Americans ([approximately 83% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 222 million Americans are fully vaccinated (71.1% of Americans 5 and older); over 105 million Americans have received a booster or additional dose (just 47.3% of those fully vaccinated).

Executive and Administrative Action

FDA plans to [use a hybrid inspection model](#) to help ease out of the pandemic through combining record requests and remote interactive evaluations with onsite inspections.

Federal health officials urged parents, including [through social media](#) and [a PSA](#), to vaccinate their children under age 5 against COVID-19 and [encouraged early childhood educators to support efforts to increase vaccination](#).

US Patent and Trademark Office [extended through December 31 a pilot program to prioritize review](#) of patents related to COVID-19 therapies.

Healthcare Law, Business, and Policy News

A [JAMA study found relative maternal mortality rates increased 33.3%](#) during the first year of the pandemic, with a disproportionate increase among Hispanic (74.2%) and non-Hispanic Black (40.2%) women, as compared to non-Hispanic White women (17.2%).

Surveillance, Testing, and Treatment

FDA's [vaccine advisory committee recommended \(19 to 2\)](#) that the agency authorize new COVID-19 vaccine boosters that include Omicron and other growing virus subvariant components. The committee did not formally vote on whether to make boosters bivalent (including both the original COVID-19 strain and Omicron strain) or whether to include BA.4 and BA.5 variants of Omicron in the booster but

appeared supportive of both approaches... Later in the week, FDA's CDER Director said that vaccine manufacturers [should develop modified vaccines that add the Omicron BA.4/BA.5 spike protein component to the current vaccine](#) composition to create a bivalent vaccine.

HHS will pay [\\$3.2 billion for 105 million doses of Pfizer and BioNTech's COVID-19 vaccine](#) targeting Omicron, with options for up to 300 million doses.

Pfizer and BioNTech reported that [two versions of their updated COVID-19 booster vaccine prompted significant increases](#) in antibodies to combat the Omicron BA.1 variant.

Pfizer and BioNTech [will partner on clinical trials](#) for a [pan-coronavirus vaccine](#) that protects against the broader family of viruses and mutations.

The federal government will [purchase 150,000 additional doses of Eli Lilly's bebtelovimab](#), the only monoclonal antibody drug for treating non-hospitalized patients that's effective against Omicron, for \$275 million.

Pfizer asked FDA [for full approval of its antiviral pill Paxlovid](#) in high-risk patients with COVID-19.