



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

Center for Healthcare Regulatory Insight



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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 [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](#).

Beginning next week we will discontinue the special supplement and summarize COVID-19 news for the week in a special section within the body of ATW 360.



Healthcare regulatory news

An [FDA final rule](#) allows sale of [over-the-counter hearing aids](#) as soon as mid-October.

FDA [approved the first cell-based gene therapy for beta thalassemia](#), bluebird bio's [Zynteglo \(\\$2.8M/patient\)](#).

CDC Director Rochelle Walensky [announced an “ambitious” overhaul](#) of the agency’s structure/operations, including improving the [speed/quality of communication of information](#) to the public.

CMS [proposed](#) mandatory [Medicaid/CHIP quality reporting](#)... CMS announced [actions to strengthen/expand](#) healthcare access for children... CMS approved [12-month postpartum Medicaid/CHIP coverage](#) in Hawaii, Maryland, and Ohio... CMS will [allow states flexibility to adjust final ACA rates](#) due to the IRA... CMS will [no longer require provider](#) certificate of medical necessity and DME information forms starting in 2023.

Citing a [forthcoming study](#) finding hospitals increased prices 39%-51% following repeal/expiration of certificates of public advantage (COPAs), [FTC warned](#) states to [avoid COPA legislation](#) aiming to [exempt hospital mergers from antitrust](#) challenges.

OIG found [just 35 of 72 NIH-funded clinical trials in 2019/2020](#) reported timely results per federal requirements, and recommended NIH improve procedures/enforcement.

The White House [announced new actions to combat](#) monkeypox.



Healthcare law and policy news

President Biden [signed](#) the [Inflation Reduction Act](#) into law and [touted its impacts](#).

Endo International [filed for bankruptcy](#) due to opioid lawsuits... A federal judge [ordered CVS, Walgreens, and Walmart to pay two Ohio counties \\$650.5M](#) for contributing to the opioid epidemic.

Humana [will acquire Includa](#)... Merck will [develop mRNA-based vaccines/therapies](#) with Orna Therapeutics (\$3.75B investment)... Mount Sinai and Regeneron [plan to sequence/study 1M patients’ genomes](#)... Brainstorm Cell Therapeutics [will seek FDA approval of its ALS treatment](#) despite [past agency opposition](#).

NextGen Healthcare [intends to become a qualified health information network](#) under TEFCA.

The Joint Commission will [add health equity accreditation standards](#) January 1.

A [JAMA study found](#) only 20 of 63 NCI-designated cancer centers were fully compliant with federal price transparency requirements.

HRSA [data show](#) prescription drug purchases through the [340B program reached \\$43.9B in 2021](#), up 15.6% from 2021... A [Reuters’ analysis found the median price](#) of 13 FDA-approved novel chronic disease drugs in 2022 is \$257,000, up from [\\$180,000 for 30 drugs in the first half of 2021](#).

ONC reported just [12% of office-based physicians electronically exchanged](#) health information with public health authorities in 2019.



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

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COVID-19 by the Numbers

Over [93.3 million COVID-19 cases](#) have been documented in the US, with the death toll of approximately 1.039 million... As of August 17, 2022, the current 7-day moving average of [daily new cases](#) 95,652 decreased 9.9% compared with the previous week's 7-day moving average (106,115); the current 7-day moving average of [new deaths](#) (394) has decreased 10.6% compared with the previous week's 7-day moving average (441)... The 7-day [moving average of hospitalizations](#) with a confirmed case of COVID-19 was 5,845 for the week ending August 15, down 3.5% from the previous week.

As of August 13, the BA.5 variant [accounted for 88.8% of COVID-19 cases](#), up from 87.1% the previous week.

More than [12.5 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 606 million COVID-19 [vaccine doses have been administered](#) in the US... Approximately 262.3 million Americans ([approximately 83.7% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 223.6 million Americans are fully vaccinated (71.5% of Americans 5 and older); over 108.2 million Americans have received a booster or additional dose (just 48.4% of those fully vaccinated)... Approximately 941,750 children under age 5 have received at least one vaccine dose, out of [nearly 20 million eligible](#) recipients.

Executive and Administrative Action

HHS Secretary Xavier Becerra [did not provide 60-days' notice that the COVID-19 public health emergency \(PHE\) would end October 13](#), suggesting that it will be extended again.

The Biden Administration plans to [stop paying for COVID-19 vaccines and treatments](#), eventually transitioning to commercial distribution with costs being passed to insurers and consumers. A planning session for the transition, which will take months, is scheduled for August 30.

CMS [released resources](#), including provider-type-specific fact sheets on current applicable waivers and other flexibilities, to help providers prepare for the end of the PHE.

CDC will [retake control of COVID-19 hospital data](#), with hospitals resuming reporting to the CDC in mid-December as the federal government's contract with TeleTracking Technologies expires December 31.

Healthcare Law, Business, and Policy News

A [study found people infected with Alpha, Delta, and Omicron](#) COVID-19 variants [expel higher amounts of the virus](#) than those infected with other variants.

A [Lancet study found](#) people who have had COVID-19 are at increased risk of neurological and psychiatric conditions (e.g., brain fog, psychosis, and dementia) up to two years after infection.

Surveillance, Testing, and Treatment

White House COVID-19 Response Coordinator, Ashish Jha, said [next-generation, bivalent COVID-19 vaccines that offer protection from multiple virus variants](#) will likely be available in September.

The UK became the [first country to approve](#) Moderna's [revamped bivalent COVID-19 vaccine targeting the Omicron variant](#) as a booster shot.

Novavax is [seeking FDA authorization for use of its COVID-19 vaccine as a booster dose](#) in people who have either received its shot or a different vaccine.

STAT [reported that Eli Lilly is charging \\$2,100 for each dose](#) of its COVID-19 monoclonal antibody treatment bebtelovimab on the commercial market, up from approximately \$1,800/dose it charged the federal government; HHS ASPR indicates [providers can bill Medicare \\$2,394/treatment](#).