



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 Supplements: 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](#).

Also, since we did not publish on July 8th, we've included a brief roundup of significant news from the week of July 4th.



Healthcare regulatory news

CMS [released](#) a ten-year [framework for health equity](#).

ONC reported [65% of physicians engaged in electronic exchange \(sending, receiving, querying\) of patient health information](#) in 2019; 75% of those physicians reported quality, patient safety, or efficiency benefits.

CMS approved 1332 reinsurance waiver extensions for [Alaska](#), [Oregon](#), and [Minnesota](#).

FDA issued two [warning letters to companies selling unauthorized non-tobacco nicotine e-liquid products](#) and 107 warning letters to companies selling non-tobacco nicotine products to minors.



Healthcare law and policy news

A [district court approved](#) a \$264M settlement over [alleged EpiPen price-gouging by Mylan](#)... Teva and Allergan will [pay \\$54M in cash and overdose reversal drugs](#) to settle a San Francisco opioid epidemic-related lawsuit... Endo is [considering filing for bankruptcy](#) without settling opioid-related claims.

Teva [asked the Supreme Court](#) to [hear a case](#) over use of generic “skinny labels”... Department of Justice (DOJ) [joined a whistleblower suit alleging Fresenius](#) performed [thousands of unnecessary vascular procedures](#).

Vertex [will acquire ViaCyte](#) (\$320M)... Molina plans to [acquire My Choice Wisconsin](#) (\$150M)... Nomi Health [acquired Everyone Health and Sano Surgery](#) (\$26.5M)... Rock Health reported US [digital health startups raised \\$10.3B](#) across 329 deals through the first half of 2022, [down from \\$15B](#) (384 deals) in the first half of 2021... Optum and Red Ventures [formed a consumer health joint venture](#), RVO Health.

Modern Healthcare analysis found [approximately 20M patients had personal/health information breached](#) in the first half of 2022.

Wall Street Journal reported [one-in-six calls to the National Suicide Prevention Lifeline](#), which is transitioning to the “988” dialing code on Saturday, were abandoned/disconnected before reaching a counselor from 2016-2021.

A Mercer survey found [52% of employers will offer virtual behavioral healthcare](#) in 2023.

BMJ and *JAMA* studies found that patients with darker skin are more likely to receive inaccurate pulse oximeter readings, resulting in them [receiving less supplemental oxygen](#) in ICUs than white patients... A *Health Affairs* [study found high-acuity patients](#) were charged, on average, [\\$1,218 more for cash price facility fees at for-profit emergency departments](#) than at not-for-profit facilities.

The Uniform Law Commission approved [model legislation to harmonize telehealth regulation](#), including licensure, across states.

While overall CPI increased 9.1% year-over-year in June, [medical care service prices increased just 4.8%](#).

In Case you Missed It: Highlights from the Week of July 4th

- CMS [proposed](#) cutting the physician [fee schedule conversion factor by 4.4% to \\$33.08](#), [adjusting Medicare Shared Savings Program \(MSSP\)](#) policies, expanding [coverage of certain dental services](#) related to covered clinical services, expanding access to mental health services, and implementing the statutory extension of certain telehealth services to 151 days after the end of the COVID-19 public health emergency

- Senate Finance Committee Democrats released [an updated prescription drug pricing bill](#), for possible inclusion in a reconciliation package, including Medicare [negotiation of prescription drugs beginning in 2023 \(effective in 2026\)](#), a \$2,000 Medicare Part D drug cost out-of-pocket cap and other Part D redesign, and Parts B and D inflation rebates; CBO projected the package could [cut the deficit by \\$287.6B over a decade](#)
 - FDA [paused its ban on sale of Juul e-cigarettes](#)
 - HHS and DOJ [negotiated/recovered a record \\$5B+](#) in 2021 healthcare fraud cases.
 - A federal judge dismissed claims that AmerisourceBergen, Cardinal, and McKesson [caused a public nuisance by shipping millions of opioids](#) to a vulnerable West Virginia community
 - AstraZeneca [will acquire TeneoTwo](#) (\$1.3B) and Merck is [in advanced talks to acquire Seagen](#)
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COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

Over [89.2 million COVID-19 cases](#) have been documented in the US, with the death toll exceeding 1.02 million... As of July 13, 2022, the current 7-day moving average of [daily new cases](#) (124,048) increased 16% compared with the previous week's 7-day moving average (107,174); the current 7-day moving average of [new deaths](#) (351) has increased 13% compared with the previous week's 7-day moving average (312)... The 7-day [moving average of hospitalizations](#) with a confirmed case of COVID-19 was 5,775 for the week ending July 11, up 12% from the previous week.

As of July 9, the BA.5 variant [accounted for 65% of COVID-19 cases](#), up from 54% the previous week; the BA.2.12.1 strain, which represented approximately half of cases on June 18, now accounts for just 17% of cases.

More than [12.2 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 598 million COVID-19 [vaccine doses have been administered](#) in the US... Over 260 million Americans ([approximately 83.2% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 222.4 million Americans are fully vaccinated (71.2% of Americans 5 and older); over 106 million Americans have received a booster or additional dose (just 47.9% of those fully vaccinated)... Approximately 2.67 million children under age 5 have received at least one vaccine dose, out of [nearly 20 million eligible](#) recipients.

A White House Council of Economic Advisers analysis found that excess mortality varied significantly across states during the pandemic, [ranging from 5.7% above expected deaths in Hawaii to 27.4% in Texas](#), and was correlated with a state's uninsured rate. Specifically, a 10-percentage point increase in the uninsured rate in 2019 was associated with a 4.8 percentage point increase in excess mortality not directly attributable to COVID-19 during the pandemic.

Executive and Administrative Action

HHS Secretary Xavier Becerra is expected to renew the COVID-19 public health emergency declaration, [set to expire today](#).

The White House COVID-19 Team [outlined a strategy for managing the BA.5 subvariant](#).

During [an event](#), White House Coronavirus Response Coordinator Ashish Jha said the [country will not have enough COVID-19 vaccines and tests](#) for the next wave of the pandemic this fall and winter without additional funding from Congress.

Due to rising case numbers and spreading variants, senior Biden Administration officials are [considering allowing a second round of COVID-19 booster doses](#) for all adults.

GAO reported CDC's air travel contact tracing system for public health purposes, including COVID-19 spread, [needs "substantial improvement."](#)

Department of Labor, CDC, and the Surgeon General are [seeking input from employers and others on supporting workers](#) suffering from long COVID.

Updated EEOC guidance states that [employers must show that mandatory screening of employees for COVID-19 is "job-related and consistent with business necessity"](#) based on relevant facts such as community transmission levels, vaccination status of employees, and the accuracy and speed of processing tests.

Healthcare Law, Business, and Policy News

A JAMA study found COVID-19 was the [third leading cause of death in the US from March 2020 to October 2021](#), accounting for one-in-eight deaths.

CDC [reported antimicrobial-resistant hospital-onset infections and deaths](#) increased 15% during the first year of the pandemic as antibiotic use increased.

A JAMA study found the [share of overdose deaths involving methadone declined from 4.5% in January 2019 to 3.2% in August 2021](#), likely driven by a pandemic policy allowing certain patients to take their medicine at home rather than under supervision at methadone clinics.

The World Health Organization (WHO) will likely [wind down its ACT-Accelerator program](#) this fall to accelerate production of COVID-19 vaccines, diagnostics, and therapeutics.

Wall Street Journal reported on the [slow development and lack of focus on therapeutics](#) to address long-COVID and other post-viral illness.

Airfinity [estimated 1.1 billion COVID-19 vaccines have been wasted](#) since the start of the pandemic.

Politico reported on [developments of a global pandemic preparedness agreement](#), including [a working draft](#).

WHO and UNICEF data show [childhood vaccination rates worldwide dropped to their lowest level in 30 years](#), driven in part by the pandemic.

Surveillance, Testing, and Treatment

FDA [granted emergency use authorization](#) to Novavax's protein-based COVID-19 vaccine as a two-dose primary series for individuals 18 and older... HHS secured [3.2 million doses of Novavax's COVID-19 vaccine](#)... Novavax plans to [provide a COVID-19 vaccine targeting Omicron in the fourth quarter](#) of the year, and expects to have preclinical data in late summer or fall.

FDA granted approval to [Pfizer and BioNTech's COVID-19 vaccine for individuals ages 12 to 15](#).

FDA [revised the emergency use authorization](#) for Pfizer's Paxlovid to [allow state-licensed pharmacists to prescribe the antiviral](#).