



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 the attached special supplement.



Healthcare regulatory news

CMS [proposed](#) a 2.7% (\$6.2B) increase for 2023 [hospital outpatient payments](#) and [policies to improve care access for rural communities](#); CMS also seeks comment on [data to assess impacts of provider mergers/acquisitions](#)... CMS will address [340B drug payment rates](#), accounting for budget neutrality, in the final rule.

OMB is reviewing a [final rule establishing a regulatory pathway](#) for over-the-counter hearing aids... CMS is [planning a rule on Medicare coverage of innovative medical devices](#) by year-end.

ASPR will be [elevated to an operating division](#) of HHS and renamed the [Administration for Strategic Preparedness and Response](#).

OCR announced [enforcement actions against 11 entities](#) for failing to provide patient access to health records under the HIPAA Right of Access Initiative... NIST released [updated guidance on implementing/complying with the HIPAA Security rule](#).

FDA Commissioner Robert Califf announced an [external evaluation of the agency's food and tobacco programs](#)... FDA [approved the first at-home treatment](#) for vitiligo.

VA OIG [found the new Cerner EHR system piloted at Mann-Grandstaff Medical Center failed](#) to deliver [approximately 11,000 orders to appropriate locations](#) and resulted in 149 patient adverse events.

Department of Justice [charged 36 individuals with more than \\$1.2B in healthcare fraud](#), including telemedicine, genetic testing, and DME schemes. .



Healthcare law and policy news

Biogen will [pay \\$900 to settle whistleblower allegations of kickbacks](#) to boost sales of MS drugs.

Amazon will [acquire One Medical](#) (\$3.9B)... GlaxoSmithKline [completed spinoff of Haleon](#), its consumer health business... Novartis will [decide the future of its Sandoz generic unit by year-end](#)... Pfizer will [invest \\$470M to expand mRNA vaccine research facilities](#).

UnitedHealth Group [will eliminate out-of-pocket costs](#) for five emergency-use drugs, [including insulin, for fully insured group plan members](#)... Yale, Morehouse, and Vanderbilt [launched a PhRMA-funded initiative](#) to increase clinical trial diversity.

181 [House members urged OIG to fine drug manufacturers](#) that [restrict 340B discounts](#).

McKinsey projected healthcare industry [EBITDA could grow 6% post-COVID](#), adding \$31B in profits from 2021-2025... A [KFF analysis found](#) ACA insurers in 13 states and DC are planning median premium increases of 10% next year.

CDC reported [drug overdose deaths among Black and American Indian/Alaska Native individuals](#) increased 44% and 39%, respectively, between 2019-2020, compared to 30% population-wide and 22% among White individuals.



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

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COVID-19 by the Numbers

Over [90 million COVID-19 cases](#) have been documented in the US, with the death toll exceeding 1.02 million... As of July 20, 2022, the current 7-day moving average of [daily new cases](#) (125,827) remained largely flat with the previous week's 7-day moving average (125,185); the current 7-day moving average of [new deaths](#) (347) has decreased 1% compared with the previous week's 7-day moving average (384)... The 7-day [moving average of hospitalizations](#) with a confirmed case of COVID-19 was 6,180 for the week ending July 19, up 5% from the previous week.

As of July 16, the BA.5 variant [accounted for 78% of COVID-19 cases](#), up from 69% the previous week.

More than [12.2 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 599 million COVID-19 [vaccine doses have been administered](#) in the US... Over 260.7 million Americans ([approximately 83.3% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; over 222.7 million Americans are fully vaccinated (71.3% of Americans 5 and older); over 107 million Americans have received a booster or additional dose (just 48.1% of those fully vaccinated)... Approximately 400,000 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 [renewed the COVID-19 public health emergency \(PHE\) declaration](#), effective July 15, for another 90 days.

Healthcare Law, Business, and Policy News

Families USA, UnidosUS, and First Focus on Children [reported the country will see its largest one-year drop in children's Medicaid coverage](#) if states do not expand electronic and "administrative" renewals in preparation for the end of the PHE, with disproportionate impact on Latino and Black children.

A [JAMA study found](#) the odds of dying following major inpatient surgery between March 1 and May 31, 2020 was 38% higher at hospitals with very high COVID-19 burden as compared to hospitals with low COVID-19 burden; odds were greater among patients requiring urgent and emergency surgery than among those requiring elective procedures. However, the findings suggest the pandemic did not exacerbate the mortality gap between patients with no insurance or Medicaid and patients with commercial insurance.

An Axios-Ipsos survey found, among other things, [78% of Americans "strongly" or "somewhat" agree](#) that we will never be fully rid COVID-19 in their lifetime; 46% report they have had or suspect they had COVID-19; and 74% of vaccinated individuals are likely to get a COVID-19 booster shot if recommended annually.

Congressional Democrat leaders are pushing for [inclusion of additional COVID-19 pandemic funding](#) in a reconciliation bill.

Surveillance, Testing, and Treatment

CDC's vaccine advisory committee unanimously [recommended use of Novavax's COVID-19 vaccine](#) as a primary series option for adults ages 18 and older; CDC Director Rochelle Walensky [endorsed the recommendation](#).