



## 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 the [attached special supplement](#).



### Healthcare regulatory news

CMS finalized 2023 payment increases for [inpatient rehabilitation facilities \(3.2%\)](#), [inpatient psychiatric facilities \(2.5%\)](#), and [hospice \(3.8%\)](#).

CMS is [seeking comment](#) on [improving Medicare Advantage](#).

HHS [proposed](#) reinstating [civil rights protections against LGBTQ health discrimination](#)... HHS [withdrew a rule preventing agencies from using standards solely from guidance documents](#) for civil enforcement action... CMS [delayed \(July 2023\) a decision](#) on finalizing a rule easing long-term care administrative burden.

CMS [released](#) its [Maternity Care Action Plan](#); approved [12-month postpartum Medicaid coverage](#) in Connecticut, Massachusetts, and Kansas; and [launched](#) its enhanced [Nursing Home Five-Star Quality Rating System](#).

OIG [reported CMS collected only 55% of \\$498M in Medicare overpayments](#) identified by audits October 2014-December 2016 and recommended HHS strengthen nursing home [infection prevention/control requirements](#).

WHO declared [monkeypox a public health emergency of international concern](#)... White House will [name a monkeypox coordinator](#), while HHS [considers declaring a public health emergency](#).

FDA guidance documents 1) clarify generic [product applications could be withdrawn for failing to address deficiencies](#) within one year; 2) detail unique device identifier [compliance dates](#) for class I/unclassified devices; and 3) recommend including [patients with non-curative cancers](#) in clinical trials.

NIH [seeks comment](#) on [incorporating EHR data into the All of Us program](#).



## Healthcare law and policy news

Senate Democrats released [updated reconciliation legislation](#) that would, among other things, allow limited Medicare drug price negotiation and [extend enhanced ACA subsidies through 2025](#).

An appeals court [upheld a lower-court ruling](#) that [Pfizer's copay assistance program violated anti-kickback law](#)... Teva will [pay \\$4.3B in cash/medications to settle opioid-related claims](#) with local/state governments and tribes; Allergan will [pay \\$2B+ to settle similar claims](#)... New York's Attorney General [sued CVS Health](#) for allegedly violating antitrust law by requiring safety net hospitals use a CVS-owned company to process 340B subsidy claims.

Humana is [restructuring operations into two units](#): health insurance and CenterWell for care delivery... 3M will [spin off its healthcare business](#) as a public company.

Viizient projected [pharmaceutical prices to rise 3.26% in 2023](#), continuing [a downward trend](#).

[Morgan Health-NORC reported](#) on [racial/ethnic, socioeconomic, and sexual orientation health disparities](#) among employer-sponsored insurance enrollees.

CDC [reported](#) 8% of Americans (26.4 million) were uninsured in Q1 2022, down from 9.5% (30.8 million) in Q1 2021.



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# COVID-19 News Supplement

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## COVID-19 by the Numbers

Over [91 million COVID-19 cases](#) have been documented in the US, with the death toll exceeding 1.02 million... As of July 27, 2022, the current 7-day moving average of [daily new cases](#) (126,272) remained relatively flat with the previous week's 7-day moving average (127,478); the current 7-day moving average of [new deaths](#) (364) has decreased 0.5% compared with the previous week's 7-day moving average (382)... The 7-day [moving average of hospitalizations](#) with a confirmed case of COVID-19 was 6,509 for the week ending July 25, up 6.1% from the previous week.

As of July 23, the BA.5 variant [accounted for 82% of COVID-19 cases](#), up from 76% the previous week.

More than [12.3 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 261.4 million Americans ([approximately 83.4% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; nearly 223 million Americans are fully vaccinated (71.4% of Americans 5 and older); over 107.4 million Americans have received a booster or additional dose (just 48.2% of those fully vaccinated)... Approximately 544,000 children under age 5 have received at least one vaccine dose, out of [nearly 20 million eligible](#) recipients. KFF reported, as of July 20, [the share of children under age 5 with at least one dose](#) ranged from 0.4% in Mississippi to 14.4% in DC.

## Executive and Administrative Action

HRSA is [setting up a dispute and appeals process for providers](#) whose Provider Relief Fund payments have been recouped.

FDA guidance proposes [increasing use of remote assessments across all products to supplement in-person inspections](#) and other activities after the public health emergency expires.

## Healthcare Law, Business, and Policy News

A [JAMA study found](#) 5.8% of children who tested positive for COVID-19 in the emergency department (ED) had post-COVID-19 ("long") symptoms 90 days after testing, including 9.8% of children who were admitted to the hospital from the ED; [factors associated with long COVID included](#) having seven or more symptoms during initial illness, being hospitalized for more than two days, and being 14 years and older.

A [BMJ study found](#) 12 million individuals could have persistent taste loss and 15 million individuals could have smell loss as a result of COVID-19.

A [PLOS Science study concluded](#) that "vaccine deserts" in Black neighborhoods and rural and low-income areas were more to blame than mistrust in the medical establishment for low vaccine uptake rates among the most vulnerable populations.

Commonwealth Fund projected [an aggressive fall COVID-19 booster campaign could prevent](#) as many as 160,000 deaths and more than 1.7 million hospitalizations, while averting \$109 billion in direct medical costs.

A KFF survey found [43% of parents with young children will “definitely not” get their children vaccinated](#) for COVID-19; 64% of Republicans and unvaccinated parents will “definitely not” vaccinate their children... A STAT-Harris Poll survey found [71% of Americans credit the pharmaceutical industry](#) with helping to contain COVID-19, higher than credit given to the CDC (66%), International Health Organizations, such as WHO (64%), FDA (63%), the White House/President (53%), among others.

The [House passed \(426-12\)](#) legislation [extending pandemic-related telehealth flexibilities/waivers through 2024](#); Senate passage is uncertain.

### Surveillance, Testing, and Treatment

The Biden Administration is [pausing plans for a second round of COVID-19 booster doses for individuals younger than 50](#) as focus shifts to developing reformulated doses that target Omicron subvariants... The Administration plans to [begin offering updated COVID-19 boosters](#) from Pfizer-BioNTech and Moderna in September.

The White House [held an event on Tuesday to discuss approaches to accelerate development](#) of next-generation COVID-19 vaccines, including formulations delivered through nasal mist or skin patch; funding for development of these products remains unclear.

BioNTech and Pfizer [sued CureVac](#) arguing its COVID-19 [vaccine did not infringe on CureVac patents](#) and alleging that CureVac is trying to profit from the success of the BioNTech-Pfizer vaccine.