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Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare Regulatory Insight</u> 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 <u>subscribe to our mailing list here</u>.

We welcome your feedback. Let us know if KPMG can help. Please <u>reply here to me</u>, **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

HHS <u>declared</u> monkeypox <u>a public health emergency</u>... The White House named <u>a national monkeypox coordinator</u>.

HHS reported the uninsured rate reached an all-time low (8.0%) in Q1 2022.

HHS and Department of Justice (DOJ) <u>released guidance</u> on <u>federal non-discrimination laws and telehealth</u>.

CMS finalized 2023 payment increases for <u>skilled nursing homes 2.7% (\$904M)</u>, <u>inpatient hospitals 4.3% (\$2.6B)</u>, and long-term care hospitals <u>2.3% (\$71 billion)</u>, and <u>a birthing-friendly hospital</u> designation.

CMS projected average 2023 Medicare Part D monthly premiums will drop 1.8% to \$31.50.

FDA <u>approved the first biosimilar</u> interchangeable across all five Lucentis indications... FDA ordered 88,000 synthetic nicotine products off the market.

Federal agencies can opt into Carequality's interoperability framework.





Healthcare law and policy news

The Senate will begin consideration of Democrats' reconciliation bill tomorrow.

West Virginia cities/counties reached a \$400M settlement with McKesson, AmerisourceBergen, and Cardinal Health over epidemic-related claims... A federal appeals court rejected Sanofi's claims that Mylan schemed to block EpiPen competition... A federal appeals court declined to revive a lawsuit alleging Abbvie used "patent thickets" to thwart Humira competition... A federal court jury ordered Eli Lilly to pay \$61M for intentionally underpaying Medicaid drug rebates.

KPMG, EBG, and FPP reported <u>healthcare deals through Q2 are down 23% year-over-year</u>, but on pace to exceed historical trends... Ochsner Health closed its <u>merger with Rush Health System</u>... Amgen <u>will acquire ChemoCentryx</u> (\$4B)... CVS plans to <u>invest in or acquire a provider</u> organization by year-end.

CivicaRx <u>launched its first generic product....</u> Optum will <u>offer a 30-day supply of Sanofi insulins for</u> \$35 to uninsured individuals with diabetes.

Senate Finance Committee reported <u>70 organ recipients died January 2008-September 2015 from donor-derived diseases</u> due to testing failure... A separate government review recommended overhaul of the UNOS organ transplant system due to technology issues.

Altarum reported health spending <u>declined year-over-year in Q1 for the first time</u> in 60+ years... Health Affairs studies found <u>dialysis provider consolidation</u> led to <u>Medicare Advantage plan cost markups</u> and annual patient <u>out-of-pocket spending ranges</u> across states from \$7,250 (Utah) to \$14,500 (Alaska)... JD Power reported customers are <u>increasingly comfortable/interested in receiving routine healthcare services at pharmacies.</u>

West Health/Gallup found 38% of Americans skipped/delayed healthcare in the last 6 months due to costs.



Questions or comments, please send to <u>us-hcinsight@kpmg.com</u>.

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COVID-19 by the Numbers

Over 91.8 million COVID-19 cases have been documented in the US, with the death toll exceeding 1.03 million... As of August 3, 2022, the current 7-day moving average of <u>daily new cases</u> (117,350) decreased 7% compared with the previous week's 7-day moving average (126,536); the current 7-day moving average of <u>new deaths</u> (377) has decreased 5% compared with the previous week's 7-day moving average (397)... The 7-day <u>moving average of hospitalizations</u> with a confirmed case of COVID-19 was 6,321 for the week ending August 1, down 1.7% from the previous week.

As of July 30, the BA.5 variant accounted for 86% of COVID-19 cases, up from 82% 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 261.6 million Americans (approximately 83.5% of Americans 5 and older) have received at least one COVID-19 vaccine dose; over 223 million Americans are fully vaccinated (71.5% of Americans 5 and older); over 107.9 million Americans have received a booster or additional dose (just 48.4% of those fully vaccinated)... Approximately 632,000 children under age 5 have received at least one vaccine dose, out of nearly 20 million eligible recipients.

Executive and Administrative Action

HHS released a report on <u>services and supports</u> for long COVID and a <u>national research action plan</u> for long COVID, which includes creation of the Office of Long COVID Research... Assistant Secretary for Health Rachel Levine will serve as long COVID coordinator and <u>laid out the Administration's plans</u>.

CDC could <u>issue updated COVID-19 community guidance as soon as today</u>, which is expected to relax quarantine requirements for those exposed to the virus and deemphasize social distancing measures and regular testing in schools.

Healthcare Law, Business, and Policy News

A <u>JAMA</u> study found hospital workers receiving a fourth dose of Pfizer-BioNTech's COVID-19 vaccine were far less likely to have a breakthrough infection (6.9%) as compared to individuals with three doses (19.8%).

A *Lancet* study <u>estimated the prevalence of long COVID at 1 in 8 adults</u> (12.7%) testing positive for COVID-19.

Surveillance, Testing, and Treatment

HHS agreed to purchase <u>66 million doses (\$1.74B) of Moderna's bivalent COVID-19 vaccine</u> updated with the Omicron subvariant for the fall/winter.

FDA does not plan to authorize a <u>second booster dose of the original COVID-19 mRNA vaccines for</u> <u>people ages 18 to 49</u> and will wait until booster doses are available that target BA.4 and BA.5 Omicron subvariants.

Eli Lilly will <u>sell its COVID-19 monoclonal antibody, bebtelovimab, commercially</u> as the government's supply of the product comes close to depletion.

HHS data show that July marked the <u>first month that more than 1 million courses of Pfizer's Paxlovid</u> were prescribed.