



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.



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](#).



Healthcare regulatory news

HHS [delayed until September 22](#) a Trump Administration rule requiring departmental review of rules every 10 years.

HHS-Labor-Treasury will [redo guidance/provide revised training](#) on *No Surprises Act* billing arbitration.

ONC [received 274 information blocking complaints as of 2/28](#).

FDA [approved a CAR-T therapy](#) for multiple myeloma... FDA [guidance describes how](#) researchers can account for patients' physical/intellectual barriers in [drug trial data collection](#) and [aims to speed oncology clinical trials](#).

NIH [ordered a review of federal biosecurity policies](#) for experiments involving potentially dangerous pathogens.



Healthcare law and policy news

During the [State of the Union](#), President Biden called for [Medicare drug price negotiation and caps on insulin](#) prices and laid [out nursing home reforms](#) and [strategies to address the mental health crisis](#).

US PTO [ruled CRISPR technology belongs to Broad Institute of Harvard/MIT](#), not UC Berkley, thereby [requiring new technology licenses](#)... Viatris will [settle \(\\$246\) a class action suit alleging anticompetitive behavior](#) to delay EpiPen generics... the Sackler [family will pay \\$6B to settle Purdue Pharma opioid-related claims](#).

KPMG, EBG, and FocalPoint [reported 274 announced/closed healthcare and life sciences deals](#) in January... Biocon Biologics [will acquire Viatris' biosimilar business \(\\$3.3B\)](#)... Tenet [will not spin off](#) Conifer Health... Teladoc and Amazon will [offer on-demand medical care](#) through Amazon's Alexa... CivicaRx [plans to make/distribute insulin](#) for no more than \$30/vial or \$55/box of five pen cartridges... Dario Health [will partner with Sanofi \(\\$30M\) to extend](#) its digital therapeutics' reach... Allscripts will [sell its hospital/large physician practices](#) business.

An [NBER study found](#) receiving care from higher-priced hospitals is associated with lower mortality in less concentrated markets; care from expensive hospitals in concentrated markets may increase spending with no detectable mortality effect... A [JAMA study](#) found physician management companies with private equity funding charged 16.5% higher prices for outpatient anesthesia than those without.

KFF reported price increases [outpaced inflation for half of all Medicare-covered drugs](#) in 2020... AMA estimated [\\$979M in excess healthcare spending annually](#) from primary care physician turnover... A [Kaiser Permanente study found increased screening](#) reduced colorectal cancer [racial disparities](#).

CDC data show US suicide rate peaked in 2018, [before falling 3%](#) from 2019-2020.

The [National Academies urged changes](#) to the US organ [transplant system to improve equity](#).



Questions or comments, please send to us-hcinsight@kpmg.com.

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COVID-19 News Supplement

Center for Healthcare Policy Insight



COVID-19 by the Numbers

[Over 79 million COVID-19 cases](#) have been documented in the US, with a death toll of approximately 955,000... The country [averaged under 60,000 cases/day](#) over the past week; COVID-related deaths are still averaging more than 1,500/day over the past week... CDC data based on blood antibody tests suggest [more than 140 million \(43%\) of Americans](#) have had COVID-19... World Health Organization [reported on Tuesday that the number of COVID-19 cases fell 16% worldwide](#) in the previous week, while deaths dropped 10%.

More than [10.8 billion COVID-19 vaccine doses have been administered across 184 countries](#)... Over 554 million COVID-19 [vaccine doses have been administered](#) in the US... Nearly 254 million Americans ([approximately 81% of Americans 5 and older](#)) have received at least one COVID-19 vaccine dose; roughly 216 million Americans are fully vaccinated (69% of Americans 5 and older); over 94.5 million Americans have received a booster or additional dose (just 44% of those fully vaccinated... CDC reported COVID-19 vaccine coverage with a first dose was [lower in rural \(58.5%\) than in urban \(75.4%\)](#) counties.

Executive and Administrative Action

The White House released a wide-ranging [National COVID-19 Preparedness Plan](#) with four goals: protecting against and treating COVID-19; preparing for new variants; preventing economic and educational shutdowns; and continuing to lead efforts to vaccinate the world... Among other things, the plan calls for boosting vaccination manufacturing by 1 billion doses per year, accelerating R&D on a vaccine for all known COVID-19 variants, maintaining a network for delivering vaccines, and adding at-home COVID-19 tests, antivirals, and masks to the Strategic National Stockpile for the first time.

During the [State of the Union address](#), President Biden said “[COVID-19 need no longer control our lives](#)” while the Administration remains “on guard”; said that individuals who have already ordered four free at-home COVID-19 tests can [request an additional four](#) tests (it was reported earlier in the week only [46% of the 500 million COVID-19 tests made available](#) had been claimed); announced the [Test to Treat initiative](#) allowing individuals testing positive for COVID-19 at a pharmacy to receive antiviral pills on the spot at no cost; and announced the [appointment of a Justice Department prosecutor to focus on fraud](#) related to the pandemic.

The White House is [considering whether masks will continue to be mandated](#) on public transit and airplanes; the current TSA mandate will expire on March 18.

The Administration [asked Congress for \\$22.5B](#) in pandemic-related funding as members work through a broader government funding bill needed by March 11 to avoid a government shutdown.

HHS [outlined efforts](#) to make the public health supply chains and biological preparedness industrial base more resilient, diverse, and secure, including establishing a new office focused on domestic manufacturing and [launching a Defense Production Act program](#) to provide financial assistance through loans and grants.

CMS guidance [provides states with 14 months, up from 12 months, to complete](#) all pending actions related to Medicaid coverage redetermination (initiated within the first 12 months) at the end of the public health emergency and warns states to [comply with the full timeline and reporting requirements](#) to ensure individuals are not inappropriately made ineligible.

CMS said that it [would not release statistics on hospital worker vaccination rates](#) until the agency has a full year of data in October.

CMS reopened the Merit-based Incentive Payment System (MIPS) [extreme and uncontrollable circumstances hardship exemption](#) tied to the COVID-19 pandemic.

GAO estimated that “long COVID” has [affected 7.7 million to 23 million Americans](#).

Healthcare Law, Business, and Policy News

[Preprint studies support the theory](#) that COVID-19 [originated at a market or markets in Wuhan, China](#) where is spread from animals to humans, not a laboratory.

A [KFF survey found](#), among other things, 62% of Americans believe the worst of the pandemic is behind us; 61% believe lifting pandemic restrictions will put immune-compromised people at increased risk, while 65% believe keeping pandemic restrictions will negatively impact kids’ and teenagers’ mental health; and just 38% believe the country’s pandemic response has been “excellent” (3%) or good (35%). The “economy and inflation” is the issue most likely be considered “very important” (65%) or “somewhat important” (24%) by voters.

An [Axios/Ipsos survey found](#) 58% of respondents think the Biden Administration has done an excellent or good job supporting the development and distribution of COVID-19 vaccines, while just 41% believe the Administration has communicated clearly with the American public about the state of the pandemic and 43% trust President Biden to provide them with accurate information about the virus, down from 54% a year ago.

Surveillance, Testing, and Treatment

A [preprint study](#) based on New York State Department of Health data found that the Pfizer-BioNTech COVID-19 vaccine did not perform as well at preventing infection and hospitalization in children aged 5 to 11 as compared to children aged 12 to 17... however, [a CDC study indicates](#) although effectiveness of the vaccine wanes in children as a result of the Omicron variant, protection against severe illness remains strong in both age groups.

A [NEJM study](#) found a booster dose of either Pfizer-BioNTech’s or Moderna’s COVID-19 vaccine [restored protection against symptomatic illness](#) from the Omicron variant, while two doses was only minimally effective.

Arbutus Biopharma and Genevant Sciences [sued Moderna for allegedly infringing on their patent rights](#) for a technology used to develop their mRNA COVID-19 vaccine.

Kaiser Health News-reported data from several states show [Medicare enrollees are receiving COVID-19 vaccines at far lower rates](#) than the general population.

WHO announced that [NIH will license certain government-developed technologies](#) to the COVID-19 Technology Access Pool (C-TAP) for potential licensing through the Medicines Patent Pool.

WHO [endorsed Merck's antiviral COVID-19 pill](#) for patients in the early stages of the disease who are at high risk for hospitalization.

Pfizer plans to [provide 10 million courses of its COVID-19 antiviral pill](#) to low- and middle-income countries this year.

Eli Lilly and Incyte's rheumatoid arthritis drug baricitinib [reduced the risk of death from COVID-19](#) in a large UK-based study.