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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.



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

CMS Actuaries estimated 4.2% growth in 2021 national healthcare spending, down from 2020 (9.7%); spending is forecasted to average 5.1% growth 2021-2030, reaching \$6.8T (19.6% of GDP).

CMS proposed increasing FY2023 payment rates for hospice 2.7% (\$580M); inpatient rehabilitation facilities 2% (\$170M); and inpatient psychiatric facilities 1.5% (\$50M).

CMS announced \$110M to expand access to home and community-based services (HCBS).

OMB completed review of an <u>RFI on sharing civil monetary penalties/settlements</u> with HIPAA violation victims.

An FDA Advisory committee recommended (6-4) against approval of Amylyx's ALS treatment.

HHS announced that ARPA-H will sit <u>within NIH</u>, but its <u>leader will report to the HHS</u> <u>Secretary</u>.





Healthcare law and policy news

The President's FY2023 Budget <u>requests a 26.8% increase</u> in HHS discretionary funding to \$127.3B.

Senate Finance Committee <u>released a bipartisan report</u> on the state of mental health and possible policy reforms... The House <u>passed legislation (232-193)</u> capping patient out-of-pocket insulin costs at \$35/month; Senate passage is uncertain.

Department of Justice (DOJ) <u>joined a whistleblower lawsuit against Modernizing Medicine</u> related to illegal kickbacks... DOJ is <u>investigating an alleged counterfeit HIV drug-trafficking</u> network.

Teva, Allergan, CVS, and Endo Health Solutions <u>settled (\$870M) opioid-related claims in Florida</u>.

KPMG, EBG, and FPP reported <u>volume of announced/closed healthcare and life sciences deals in February</u> (186) was the lowest since November 2020... UnitedHealth Group's Optum <u>will acquire LHC</u> (\$5.4B).

Biogen submitted to FDA a study protocol for a confirmatory clinical trial for Aduhelm.

A <u>JAMA study concluded</u> the number of children with prediabetes increased from more than 11% to 28% between 1999 and 2018... A <u>JAMA study found</u> US physicians using EHRs spend an average of 1.84 hours/day completing documentation outside work hours.

Kauffman Hall reported hospital operating margins were negative for the second consecutive month in February... FAIR Health reported hospitals increased median charges for evaluation/management services by 7% and related negotiated rates by 5% between November 2020-November 2021, outpacing all other medical price categories... An SSR Health analysis found wholesale drug prices increased 4.4% in Q4 2021, but fell 2.3% when accounting for inflation; net prices decreased 0.7% overall or 5.4% after accounting for inflation.

A KFF survey found 58% of Americans are very/somewhat worried about paying unexpected medical bills.





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

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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 athome COVID-19 tests, antivirals, and masks to the Strategic National Stockpile for the first time.

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

The White House is <u>considering whether masks will continue to be mandated</u> on public transit and airplanes; the current TSA mandate will expire on March 18.

The Administration <u>asked Congress for \$22.5B</u> in pandemic-related funding as members work through a broader government funding bill needed by March 11 to avoid a government shutdown.

HHS <u>outlined efforts</u> 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 <u>launching a Defense Production Act program</u> to provide financial assistance through loans and grants.

CMS guidance <u>provides states with 14 months</u>, <u>up from 12 months</u>, <u>to complete</u> 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 <u>comply with the full timeline and reporting requirements</u> to ensure individuals are not inappropriately made ineligible.

CMS said that it <u>would not release statistics on hospital worker vaccination rates</u> until the agency has a full year of data in October.

CMS reopened the Merit-based Incentive Payment System (MIPS) <u>extreme and uncontrollable</u> <u>circumstances hardship exemption tied to the COVID-19 pandemic.</u>

GAO estimated that "long COVID" has affected 7.7 million to 23 million Americans.

Healthcare Law, Business, and Policy News

<u>Preprint studies support the theory</u> that COVID-19 <u>originated at a market or markets in Wuhan, China</u> where is spread from animals to humans, not a laboratory.

A <u>KFF survey found</u>, 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 <u>Axios/Ipsos survey found</u> 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 <u>preprint study</u> 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, <u>a CDC study indicates</u> 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 <u>NEJM study</u> found a booster dose of either Pfizer-BioNTech's or Moderna's COVID-19 vaccine <u>restored</u> <u>protection against symptomatic illness</u> from the Omicron variant, while two doses was only minimally effective.

Arbutus Biopharma and Genevant Sciences <u>sued Moderna for allegedly infringing on their patent rights</u> for a technology used to develop their mRNA COVID-19 vaccine.

Kaiser Health News-reported data from several states show <u>Medicare enrollees are receiving COVID-19</u> vaccines at far lower rates than the general population.

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

WHO <u>endorsed Merck's antiviral COVID-19 pill</u> for patients in the early stages of the disease who are at high risk for hospitalization.

Pfizer plans to <u>provide 10 million courses of its COVID-19 antiviral pill</u> to low- and middle-income countries this year.

Eli Lilly and Incyte's rheumatoid arthritis drug baricitinib <u>reduced the risk of death from COVID-19</u> in a large UK-based study.