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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 <u>COVID-19 news for the week in this special supplement</u>.

Breaking News: Supreme Court Decisions

The Supreme Court released decisions in a number of important cases this morning, including: 1) *Dobbs v. Jackson Women's Health Organization, et al.*, in which the Court overturned *Roe v. Wade* and *Planned Parenthood of Southeastern Pa. v. Casey*, ruling "the <u>Constitution does not confer a</u> right to abortion...and the authority to regulate abortion is returned to the [states];" and, 2) *Becerra v. Empire Health Foundation*, in which the <u>Court upheld</u> HHS' hospital DSH payment methodology.



HHS' <u>Spring Regulatory Agenda</u>, includes, among others, planned rules on <u>nicotine limits in</u> <u>cigarettes</u>, <u>over-the-counter hearing aid</u> regulations, <u>direct-to-consumer drug advertising</u>

restrictions, <u>Medicaid/CHIP eligibility/enrollment</u> streamlining, and <u>340B administrative dispute</u> resolution improvement.

CMS proposed cutting FY2023 home health payments <u>4.2% (or \$810M)</u> and <u>increasing</u> FY2023 <u>ESRD facility payments 3.1%</u> to \$8.2B... CMS <u>approved a Colorado 1332 waiver</u> amendment to <u>create a public insurance option</u>.

FDA <u>ordered</u> <u>Juul e-cigarettes be removed</u> from the market... FDA <u>draft guidance details</u> considerations for rescinding breakthrough therapy designation.

IRS is seeking comment on medical necessity criteria for mental health parity requirements.

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The Supreme Court (SCOTUS) ruled an <u>employer health plan did not violate federal</u> law or discriminate against ESRD patients by offering out-of-network provider reimbursement for outpatient dialysis... SCOTUS <u>declined to hear UnitedHealth Group's challenge</u> of a CMS rule allowing recoupment of Medicare Advantage overpayments.

HCA <u>abandoned plans to acquire five Steward hospitals</u> in Utah (<u>applauded by FTC</u>)... A UnitedHealth Group unit <u>will acquire EMIS Group (\$1.5B</u>)... Pfizer <u>will buy 8.1% stake (\$95M) in</u> <u>Valneva</u> to pursue a Lyme disease vaccine... Merck is <u>considering purchasing Seagen</u> to enhance its cancer drug portfolio.

Three House Republicans <u>asked GAO to study PBMs' role</u> in drug pricing... Senate Commerce Committee <u>advanced legislation</u> to increase <u>FTC enforcement authority against</u> unfair/deceptive PBM practices... Senators Shaheen (D-NH) and Collins (R-ME) <u>introduced legislation</u> to <u>reduce insulin prices and cap monthly copays</u> for commercial/Medicare plans; Senate Majority Leader Schumer <u>pledged a floor vote "very soon."</u>

The House passed (1) <u>legislation authorizing</u> ARPA-H <u>outside of NIH</u> and (2) broad <u>mental health</u> <u>legislation</u>, including to authorize/increase associated <u>program/grant funding and expand access</u> to care... <u>Gun safety</u> legislation <u>passed by the Senate</u> would <u>expand access to community behavioral</u> <u>health services</u> and require CMS <u>guidance to states</u> on expanding telehealth behavioral health access under Medicaid/CHIP.

An <u>Annals of Internal Medicine study</u> concluded Medicare could have saved up to \$3.6B in 2020 by paying Mark Cuban Cost Plus Drugs Company prices on 77 prescription drugs... Altarum reported national health spending grew 6.5% year-over-year in April but accounted for 18.1% of GDP, down 0.06% from December... A Commonwealth Fund commission issued recommendations to improve the country's public health system.

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

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COVID-19 by the Numbers

Over <u>86.6 million COVID-19 cases</u> have been documented in the US, with the death toll exceeding 1.01 million... As of June 22, 2022, the current 7-day moving average of <u>daily new cases</u> (97,430) decreased 5.6% compared with the previous week's 7-day moving average (103,175); the current 7-day moving average of <u>new deaths</u> (255) has decreased 10.5% compared with the previous week's 7-day moving average (285)... World Health Organization reported global cases decreased 4% last week.

As of June 18, the BA.2.12.1 variant <u>accounted for 56% of COVID-19 cases</u>, down from 63% the previous week, while BA.5 and BA.4 accounted for 24% and 11%, respectively, both up from the previous week (13% and 8%).

More than <u>12 billion COVID-19 vaccine doses have been administered across 184 countries</u>... Over 592 million COVID-19 <u>vaccine doses have been administered</u> in the US... Over 259 million Americans (<u>approximately 83% of Americans 5 and older</u>) have received at least one COVID-19 vaccine dose; over 221.9 million Americans are fully vaccinated (71% of Americans 5 and older); over 104.7 million Americans have received a booster or additional dose (just 47.2% of those fully vaccinated).

Executive and Administrative Action

NIH's real-world data program, All of Us, announced that <u>health data from nearly 20,000 individuals who</u> <u>have had COVID-19 are now available to researchers</u>, including nearly 6,000 whole genome sequences and 600 Fitbit records.

Healthcare Law, Business, and Policy News

A <u>Lancet study concluded</u> that COVID-19 vaccinations prevented 14.4 million deaths in the first year of the pandemic; accounting for all excess deaths potentially attributable to COVID-19, the estimate increased to 19.8 million.

A CDC survey found <u>18.9% of adults who've ever had COVID-19 are currently experiencing long COVID</u> symptoms and 35.1% of those who've had COVID-19 experienced long COVID symptoms at some point.

Surveillance, Testing, and Treatment

Following <u>a final CDC recommendation</u>, children as young as 6 months began receiving COVID-19 vaccines this week from Pfizer-BioNTech and Moderna... CDC's ACIP <u>unanimously recommended</u> Moderna's COVID-19 vaccine for children ages 6 to 17.

World Health Organization <u>supports study of updated COVID-19 vaccines</u> to better address the Omicron variant.

Moderna's CEO said the company's COVID-19 <u>vaccine targeting new variants should be ready to ship</u> in August.

CDC <u>reported dispensing rates of COVID-19 antiviral pills in high vulnerability zip codes</u> (35.7 per 100,000) are roughly half those in low (77.4 per 100,000) and medium vulnerability (70 per 100,000) zip codes.... Another <u>CDC study found emergency room visits or hospitalizations</u> for COVID-19 occurred in less than 1% of patients previously treated with Pfizer's Paxlovid.

Enanta Pharmaceuticals <u>alleged in a lawsuit</u> that Pfizer's Paxlovid <u>violates a patent</u> of its own COVID-19 drug still in development.