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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</u> <u>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 this special supplement.





Healthcare regulatory news

FTC voted unanimously to <u>investigate Pharmacy Benefit Managers</u> (PBMs) role in access and affordability of prescription drugs.

CMS announced the <u>launch of its National Quality Strategy</u>, with stakeholder listening sessions beginning this summer.

The House passed <u>FDA user fee legislation</u> including provisions to increase generic drug competition, enhance clinical trial diversity, and reform FDA's accelerated approval pathway.

CMS proposes to <u>suppress public access to key hospital safety data</u>, citing impact of COVID-19.

CMS <u>held a forum for the general public</u> to present information regarding HCPCS coding requests for new <u>products</u>, <u>supplies and services for Medicare</u> beneficiaries.





Healthcare law and policy news

States will have an additional year to use American Rescue Plan funds to strengthen home care workforce and expand access to services.

A <u>Supreme Court ruling</u> allows states to seek reimbursement from Medicaid beneficiaries' injury settlements.

<u>Oracle</u> completed its \$28.4B acquisition of Cerner...<u>Eagle Pharmaceuticals</u> (NJ) acquired Britain-based Acacia Pharma for \$104M...<u>Singing River Health Systems'</u> board voted to pursue sale or merger.

A clinical trial for a <u>rectal cancer treatment</u> found 100% of patients achieved complete remission... Cancer treatment <u>Enhertu</u> was found to reduce risk of death by 36% in patients with advanced breast cancer with chemotherapy... <u>Adicet Bio</u> reported a 75% overall response rate and complete response in a Phase 1 trial for a potential treatment for aggressive Non-Hodgkin's Lymphoma.

A JAMA study found only <u>6% of hospitals comply with the federal Hospital Price</u>
<u>Transparency rule, hospitals in highly concentrated markets are even less likely to comply...</u>CMS issued its first fines to two GA hospitals for <u>failure to comply with the rule.</u>

A *JAMA* study found the <u>median launch price of new prescription drugs has increased 20% per year from 2008-2021.</u>

A Survey found 8 in 10 <u>Black patients with metastatic breast cancer would consider</u> <u>participating in a clinical trial but are not offered the chance</u>.

Teladoc is facing a <u>shareholder class-action lawsuit</u> over allegedly downplaying challenges to their mental health and chronic care businesses and violating federal securities laws...HCA Healthcare faces a second antitrust <u>class-action lawsuit</u> over price inflation allegations following its acquisition of Mission Health.

A Shields Health Care Group data breach impacted two million individuals and 50 facilities in March 2022.





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

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COVID-19 by the Numbers

Approximately <u>85.2 million COVID-19 cases</u> have been documented in the US, with the death toll exceeding 1 million... As of June 8, 2022, the current 7-day moving average of daily new cases (109,032) increased 7.5% compared with the previous 7-day moving average (100,915); meanwhile, the current 7-day moving average of new deaths (306) has increased 15.7% compared with the previous 7-day moving average (258)...global cases and deaths were down 27% and 17%, respectively, over the past two weeks.

The BA.2.12.1 variant now <u>accounts for 62% of COVID-19 cases</u>, while BA.2 accounts for up to 24% of cases and BA.5 accounts for 7% of cases.

More than 12 billion COVID-19 vaccine doses have been administered across 184 countries... Over 590 million COVID-19 vaccine doses have been administered in the US... Over 258 million Americans (approximately 82.9% of Americans 5 and older) have received at least one COVID-19 vaccine dose; over 221.5 million Americans are fully vaccinated (70.9% of Americans 5 and older); over 103.9 million Americans have received a booster or additional dose (just 47% of those fully vaccinated).

Executive and Administrative Action

The Biden Administration has <u>shifted \$10B in federal COVID-19 funds</u> from test procurement to secure an additional round of vaccines and treatments.

The Biden Administration has set aside <u>10 million doses of Pfizer and Moderna COVID-19 vaccines for children under five</u> to be shipped as early as June 20th, pending FDA authorization.

Healthcare Law, Business, and Policy News

CDC is investigating 100 deaths that may be attributed to long-COVID-19.

CMS ended <u>the pandemic-related Temporary Nursing Assistant (TNA) hiring flexibility</u> for nursing homes... American Health Care Association survey found <u>87% of nursing homes face moderate or high staffing shortages</u>, and 73% expressed closure concerns over staffing challenges.

CMS released <u>new guidance</u> for states with ten priority actions to prepare for the Public Health Emergency (PHE) unwinding. <u>KPMG</u> recently published a primer on the top 5 health care issue to watch during the unwinding.

A preprint study found <u>independent laboratories may be inflating costs of COVID-19 tests</u>, which may be passed on through higher consumer health premiums.

Surveillance, Testing, and Treatment

An <u>FDA advisory panel recommended Novavax COVID-19 vaccine</u> for emergency use authorization in adults.

Pfizer will <u>invest \$120M</u> in a Michigan plant to manufacture ingredients for its COVID-19 treatment, Paxlovid.

A study found that Moderna's <u>bivalent COVID-19 booster</u>, which targets the omicron variant and the original coronavirus, produces a stronger immune response in adults than its current vaccine.

CDC data shows <u>U.S. has wasted 82 million COVID-19 vaccine doses</u> (11% of federally distributed doses) since December 2020.