October 8, 2021 | Issue 192

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.

Subscribe here

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 issued approximately 100 more warnings to hospitals deemed to be noncompliant with price transparency requirements… 18% of hospitals (down from 20% in FY2021) will be penalized more than 1% under the Hospital Readmission Reduction Program in FY2022.

New Mexico, Kentucky, and Maine transitioned from federally-run to state-based ACA exchanges.

An FDA de novo classification final rule aims to expedite the approval pathway for new, low-risk medical devices… FDA updated draft guidance for drug compounding, including removing a policy preventing distribution to facilities outside of a 1 mile radius of the compounding pharmacy.

HRSA ordered Boehringer Ingelheim to comply with 340B drug discount program requirements.

World Health Organization (WHO) approved the first-ever malaria vaccine and recommended its use for children in sub-Saharan Africa and other at-risk regions.

GAO reported on provider complaints with the Merit-Based Incentive Payment System.

Healthcare law and policy news

Francis Collins will retire as NIH Director by year-end.

President Biden's plan for an Advanced Research Projects Agency for Health has reportedly been removed from reconciliation legislation.

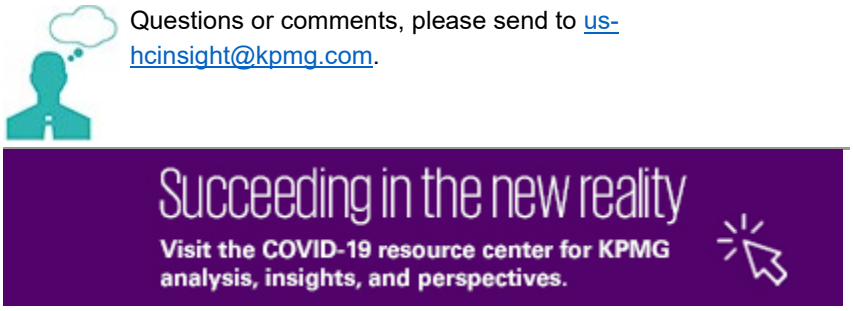
A district court denied Pfizer's lawsuit to permit programs subsidizing the cost of heart medications, ruling they would violate federal kickback law… Taro Pharmaceutical ($213.2M), Sandoz ($185M), and Apotex ($49M) will pay $447.5M to resolve price fixing allegations.

A WHO committee recommended formation of a working group to explore policies for bringing down essential medicine prices.

Jefferson Health and Einstein Healthcare Network finalized their merger, forming an 18-hospital system… Rock Health reported digital health funding topped $6.7B in Q3… Intermountain, Presbyterian, and SSM launched a digital transformation company.

A Commonwealth Fund/Urban Institute analysis found that permanently extending enhanced ACA subsidies and using subsidies in the Medicaid "gap" would cover 7M individuals and cost $33B over 10 years… Willis Towers reported that health benefit costs are expected to increase 5.5% in 2021 and 5.2% in 2022… A JD Power survey found that although 36% of patients used telehealth June 2020 to July 2021, overall consumer satisfaction has declined… PhRMA reported that 41% of Americans who take a prescription drug have skipped a dose over the last year, many due to costs (high-deductible health plans)… Antibiotic-resistant infections caused 11,852 deaths among adults 65 and older in 2017.

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



kpmg.com/socialmedia

Privacy | Legal

COVID-19 by the Numbers

There have now been roughly 44.2 million confirmed COVID-19 cases in the US, with a death toll over 710,000… The country averaged 102,000 new cases per day, down 22% over the past two weeks; deaths are also down 13% from the previous week to roughly 1,800 per day.

400 million COVID-19 vaccine doses have been administered in the US (roughly 950,000/day over the past week)… Over 216 million Americans (76.2% of Americans 12 and older) have received at least one COVID-19 vaccine dose; 186.6 million Americans are fully vaccinated (65.8% of Americans 12 and older); 6.8 million Americans have received a booster dose.

White House Chief Medical Advisor Anthony Fauci said that the US is "turning the corner" on the latest surge in COVID-19 cases, but more people must get vaccinated to keep infections on a downward trend.

California will institute a COVID-19 vaccination mandate for schoolchildren once the vaccine gains final approval for different age groups.

Executive and Administrative Action

The Administration announced that it will buy another $1 billion of rapid at-home COVID-19 tests, quadrupling the number of available tests to Americans by December.

Moderna is resisting pressure from the Administration to increase domestic production of its COVID-19 vaccine given existing commitments in other countries, including investing up to $500 million to build a factory in Africa to make up to 500 million of mRNA vaccines, including for COVID-19.

BARDA purchased $339M worth of anthrax vaccines for the Strategic National Stockpile from Emergent Biotechnologies.

Healthcare Regulatory News

FDA granted emergency use authorization to Flowflex's at-home COVID-19 test and Labcorp's home collection kit for combined COVID-19 and influenza A/B detection.

OMB guidance outlines specific medical conditions that warrant an exemption from federal worker COVID-19 vaccine requirements.

CMS guidance states that employers cannot deny benefits to employees who do not get vaccinated for COVID-19, but can offer premium discounts to those who are vaccinated.

Healthcare Law, Business, and Policy News

A *Wall Street Journal* analysis found that the cost of similar COVID-19 treatments can vary by tens of thousands of dollars per patient, even within the same hospital, based on insurance provider.

A forecast projects that if 10 states were to immediately increase their daily COVID-19 vaccinations by 50% they could collectively prevent 19,500 hospital stays and 6,900 deaths during the next six months... A Premier analysis found that hospitals are paying $24 billion more for labor annually due to pandemic-driven staffing shortages and increased patient demand.

KFF data show 59% of unvaccinated individuals are Republicans, 64% are white, and 46% have a high school education or less; 38% of unvaccinated individuals are age 30 to 49, the most of any age group.

Surveillance, Testing, and Treatment

Pfizer and BioNTech formally requested that FDA authorize their vaccine for children ages 5 to 11.

A *Lancet* study found that the Pfizer-BioNTech COVID-19 vaccine remains nearly 90% effective at preventing hospitalization for as long as six months; however, protection against "breakthrough" infections fell to 47% after five months.

Johnson & Johnson applied for emergency use authorization for a booster dose of its COVID-19 vaccine.

The European Medicines Agency recommended that immunocompromised individuals receive a booster dose of Pfizer-BioNTech's or Moderna's COVID-19 vaccine 28 days after their second dose; they also advised healthy adults could receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine six months after their second dose, but left it up to EU member states to make their own decision.

Moderna will ask a federal circuit court to invalidate two patents belonging to Arbutus Biopharma Corp. that deal with drug-delivery technology and could make its COVID-19 vaccine vulnerable to infringement lawsuits.

FDA's Vaccines and Related Biological Products Advisory Committee will meet October 14th and 15th to vote on whether to authorize booster doses of Moderna and Johnson & Johnson's COVID-19 vaccines for people age 18 and up; it will also explore data on mixing vaccine doses from different manufacturers.

Merck and Ridgeback Biotherapeutics will seek emergency use authorization for their oral antiviral COVID-19 therapy as soon as possible… The European Medicines Agency will consider whether to launch a rolling review of the drug in the coming days… Axios reported that the drug was developed with $35 million in taxpayer grants and that the federal government paid $712 per treatment course in a June $1.2B purchase agreement.

RedHill Biopharma reported its oral antiviral treatment reduced mortality for moderately severe COVID-19 patients by 62%.

AstraZeneca is seeking emergency use authorization for its COVID-19 antibody injection treatment to prevent COVID-19 in people with chronic diseases and conditions that make vaccines less effective.

A *JAMA* study concluded that there is little clinical value in treating seriously ill COVID-19 patients with convalescent plasma from recovered patients.