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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.

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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

CMS formalized a delay in enforcement of payer-to-payer data exchange requirements pending future rulemaking.

A CMMI-commissioned evaluation found the Independence at Home model reduced total Medicare spending only 1% per beneficiary per

month in 2019; many practices failed to meet required quality standards.

Nearly 4.6 million individuals have enrolled in 2020 ACA coverage.

The Biden Administration issued a call to action to address the country's high maternal mortality rate.

FDA guidance documents aim to accelerate targeted gene therapy studies.

The Patient-Centered Outcomes Research Institute (PCORI) Board of Governors approved $23.5M in awards to support three mobile health and telehealth research studies.

Healthcare law and policy news

Congress voted to delay Medicare sequestration, physician fee schedule, and PAYGO cuts impacting providers; President Biden is expected to sign the legislation… the Senate parliamentarian met with Democrats to review permissibility of health care provisions in the Build Back Better Act.

Senate HELP Committee will consider Robert Califf's nomination as FDA Commissioner on December 14.

AMA, AHA, and others sued HHS challenging its interpretation of how to calculate fair payment amounts in arbitration under the No Surprises Act.

HealthEquity will buy 87,000 HSAs from HealthSavings Administrators ($60M)… City of Hope will acquire Cancer Treatment Centers of America ($390M)... Merck sold $8B of bonds to fund its acquisition of Acceleron… Roche and Recursion Pharmaceuticals will partner on using machine learning to find new neuroscience and cancer drugs.

A jury decided UnitedHealthcare must pay TeamHealth $62.65M for underpayments to clinicians…
Allergan will pay up to $200M to NY State and two counties to settle opioid epidemic-related claims.

HHS data show Medicare fee-for-service telehealth visits totaled nearly 52.7M in 2020, up from 840,000 in 2019; total Part B clinician visits were down 11% in 2020… AMA analysis found Medicare physician services spending fell $13.9B (14%) below expected levels in 2020… A PBM Accountability Project report found PBM gross profits increased 12% between 2017 and 2019... KFF analysis found premiums for 2022 ACA silver benchmark plans are decreasing 3.1% across the country…

Pediatrics study estimated the number of underinsured children grew by 2.4M from 2016 to 2019, reaching 23.7M (34% of children).

House Oversight Committee released its final Drug Pricing Investigation report.

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

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COVID-19 by the Numbers

There have now been roughly 49.7 million confirmed COVID-19 cases in the US, with a death toll of nearly 795,000… Cases are averaging approximately 120,000/day up 26% over the past two weeks, with deaths averaging over 1,300/day, up 14% over the past two weeks.

477 million COVID-19 vaccine doses have been administered in the US (roughly 2.1 million/day over the past week)… More than 237 million Americans (82% of Americans 12 and older) have received at least one COVID-19 vaccine dose; nearly 201 million Americans are fully vaccinated (70.1% of Americans 12 and older); nearly 50 million Americans have received a booster or additional dose.

Executive and Administrative Action

The US shipped 11 million COVID-19 vaccine doses to other countries last Friday, the most in a single day since shipments began.

USAID will invest an additional $400 million to support vaccine delivery in low- and middle-income countries, local vaccine manufacturing, and Rapid Response Surge Support to areas with surges in COVID-19 hospitalizations.

A Georgia district court issued a nationwide injunction to put on hold the Biden Administration's requirement that federal contractors get vaccinated against COVID-19.

Healthcare Law, Business, and Policy News

A KFF survey found that only 43% of parents are confident that the COVID-19 vaccines are safe for children ages 5 to 11; 39% of parents are taking a "wait and see" approach on getting their kids in that age group vaccinated.

Surveillance, Testing, and Treatment

FDA authorized Pfizer-BioNTech's COVID-19 booster vaccine for 16 and 17 year old children; CDC recommended booster doses for the age group.

Johnson & Johnson reported that preliminary study results show that a booster of its COVID-19 vaccine administered six months after a two-dose regimen of Pfizer-BioNTech's vaccine raised both antibody and T-cell responses.

Pfizer and BioNTech reported that their COVID-19 vaccine is most effective as a three-dose regimen, given recent laboratory data showing the first two doses may not provide enough protection against the Omicron variant.

Early data reported by the South African Medical Research Council suggest the Omicron variant may cause less severe disease (patients hospitalized for COVID-19 have been less likely to require supplemental oxygen).

FDA reported that molecular COVID-19 tests developed by Thermo Fisher Scientific, Verily Life Sciences, and nearly two dozen other companies may be able to detect the Omicron variant.

FDA expanded emergency use authorization for Eli Lilly's combination monoclonal antibody therapy to include patients under age 12 who have mild to moderate COVID-19 and are at high risk of progression to serious illness.

FDA granted emergency use authorization to AstraZeneca's long-acting monoclonal antibody therapy for prevention of COVID-19 infection in patients who are immunocompromised or unable to receive an authorized vaccine.

GlaxoSmithKline and Vir Biotechnology reported their COVID-19 antibody therapy retained effectiveness against the Omicron variant in lab studies.

Merck announced a deal with Thermo Fisher Scientific to manufacture its antiviral pill molnupiravir for distribution in Canada, the United Kingdom, and markets in the European Union, Asia Pacific, and Latin America… Knowledge Ecology International is attempting to create a path for generic manufacturers to sell Pfizer's COVID-19 antiviral pill in the Dominican Republic, which was excluded from a previous licensing deal to make the product available in 95 low- and middle-income countries.

Wall Street Journal reported on growing concerns among public health experts and patient advocates that COVID-19 antiviral pills being considered for emergency use authorization are likely to be delayed in reaching low- and middle-income countries.

Novartis is continuing development on COVID-19 treatments, particularly a pill that could work broadly against coronaviruses, not just the one that causes COVID-19.

Gilead recalled two lots (55,000 vials) of its COVID-19 therapy remdesivir over contamination from glass particles.

The World Health Organization advised against using convalescent plasma to treat patients with COVID-19, citing increasing evidence that it does not improve survival or reduce the need for mechanical ventilation.

The European Commission recommended use of Roche's arthritis treatment Actemra for adults who are severely ill with COVID-19.