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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: 9 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 revoked a 10-year Texas Medicaid 1115 waiver approved by the Trump Administration… NIH reversed Trump Administration fetal tissue research restrictions and HRSA rescinded a Trump Administration vaccine injury compensation rule… CMS approved Georgia's Medicaid waiver

extending postpartum coverage to six months… An HHS interim rule extends higher medical equipment rates for rural areas until May 11.

HHS announced $80M in plan year 2022 ACA Navigator grants… HHS is considering administrative enforcement measures for 340B program rules.

The White House is considering requiring reduced cigarette nicotine levels.

FDA approved a GlaxoSmithKline endometrial cancer treatment.

OIG recommended that Humana repay CMS $197.7M in Medicare Advantage overpayments identified in a risk score audit.

Healthcare law and policy news

Senator John Cornyn (R-TX) placed a hold on Chiquita Brooks-LaSure's nomination as CMS Administrator; Senate Finance Committee appears split on advancing her nomination, which would necessitate Senate Majority Leader Chuck Schumer to intervene… CMMI Director Liz Fowler detailed efforts to reevaluate the Center's value-based care portfolio.

A California trial began over Johnson & Johnson, Teva, Allergan, and Endo's role in the opioid epidemic… An Ohio federal court concluded that Walmart must comply with discovery requests in ongoing opioid litigation.

Advocates sued to overturn the Trump Administration's approval of a Tennessee Medicaid funding cap… A class action suit alleges that Health First created an acute care monopoly.

Global healthcare investment reached a record $31.6B in Q1… University Hospitals finalized its acquisition of Lake Health… Evernorth completed its acquisition of MDLIVE… Molina will acquire Cigna's Texas Medicaid plans… Vertex will pay CRISPR Therapeutics $900M to change terms of their collaboration on gene-editing therapies… Oscar Health launched a tech-enabled payer and provider platform.

House Democrats reintroduced sweeping drug pricing reform legislation… KFF reported that the top-selling 250 drugs (7% of all covered products) with one manufacturer and no generic/biosimilar competitors accounted for 60% of 2019 Medicare Part D spending… Overall drug spending grew 4.9% to $535.3B in 2020.

Urban Institute estimated that making enhanced ACA subsidies permanent would increase marketplace coverage by 5.1M… A *Health Affairs* study found that patients with an acute respiratory infection were more likely to obtain follow-up care after telehealth visits (10.3%) than in-person visits (5.9%) 2016-2019.

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COVID-19 by the Numbers

There are now over 31.9 million confirmed COVID-19 cases in the US, with a death toll over 570,000… The country averaged 64,814 new confirmed cases/day over the past week, roughly the same as at the end of February (65,686 cases/day); however, deaths/day have fallen to roughly 700, down from a peak of 3,500… the American Academy of Pediatrics and the Children's Hospital Association reported that children's share of cases topped 20% in the US for the first time.

219 million COVID-19 vaccine doses have been administered in the US (2.95M/day over the last week)… 134 million Americans (52% of Americans 18 and older and 80.7% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 34.4% of Americans 18 and older are fully vaccinated… As of Thursday, daily COVID-19 vaccinations had dropped 11% in the last week… Politico reported on the supply of COVID-19 vaccines beginning to exceed demand in certain areas of the country; while KFF projected that the US will run out of adults enthusiastic about getting a COVID-19 vaccine within the next two to four weeks.

Executive and Administrative Action

President Biden announced that the country had administered 200 million COVID-19 vaccine doses, ahead of his previously stated goal of doing so within his first 100 days… the Administration also announced a new tax credit to encourage businesses with fewer than 500 employees to give paid time off to workers to get vaccinated (up to $511 per day of paid or sick leave that employees take to get a COVID-19 vaccine or recover from its side effects).

HHS announced $145 million in American Rescue Plan funding to support roughly 100 Health Center Program look-alikes in responding to COVID-19.

The State Department will release travel warnings aimed at reducing visits to approximately 80% of countries worldwide due to "unprecedented risk to travelers" from COVID-19.

NIH is investing $33 million in research projects to help officials safely reopen schools serving vulnerable and underserved populations.

GAO concluded that HHS did not appropriately follow "plans or guidance delineating their roles and responsibilities" when returning US citizens to the country from Wuhan, China and the Diamond Princess cruise ship at the outset of the pandemic last year.

Healthcare Regulatory News

FDA announced a streamlined approach for COVID-19 test developers to receive emergency use authorization for use of tests on pooled nasal specimens, so long as the developer has self-validated its test for pooling.

OSHA released employer FAQs on COVID-19 vaccines, including guidance on when employers must record adverse reactions in the workplace… In a letter to employer groups, Equal Employment Opportunity Commission said it would be updating guidance for employers on when they can provide COVID-19 vaccine incentives to employees without violating federal anti-discrimination laws.

Healthcare Law, Business, and Policy News

CVS, Walgreens, and other retailers began selling at-home COVID-19 tests from Abbott, Ellume, and other companies.

Washington Post reported on people buying, making, and selling fake COVID-19 vaccination cards.

A de Beaumont Foundation poll found that 32% of Americans would never get a Johnson & Johnson (J&J) COVID-19 vaccine… A STAT-Harris poll found that 74% of Americans "agree" or "strongly agree" that the US government should only start donating COVID-19 vaccine doses to other countries once everyone in the US who wants vaccine has received one; 48% agree that the US should not donate vaccines to other countries.

Democratic Congressional members are investigating Emergent BioSolutions to determine whether it improperly received $628 million in federal contracts to manufacture COVID-19 vaccines… Apiject Systems has yet to produce any syringes to support COVID-19 vaccine rollout roughly a year after it was granted a $1.3 billion contract to do so.

Surveillance, Testing, and Treatment

All 50 states, plus DC and Puerto Rico, met President Biden's April 19 deadline for making all US adults over age of 16 eligible for COVID-19 vaccines… Chief Science Officer for COVID Response, David Kessler, told the House Select Subcommittee on the Coronavirus Crisis that the Administration is in the process of securing booster COVID-19 doses in the likely event that they are needed.

CDC Director Rochelle Walensky said that the Administration was evaluating a "handful of cases" of blood clots related to J&J's COVID-19 vaccine… No additional adverse events have been reported since the vaccine's use was paused.

The CDC's Advisory Committee on Immunization Practices will reconvene today to discuss whether the recommended pause in the use of J&J's COVID-19 vaccine should be lifted… NIAID Director Anthony Fauci said he expected that the pause would be lifted and that the vaccine would continue to be used with "some sort of warning or restriction or risk assessment"… Meanwhile, the Administration reportedly is no longer planning to rely on the vaccine to meet demand … The European Medicines Agency concluded that although blood clots are a very rare side effect of the vaccine, the benefits outweigh the risks; as a result, J&J resumed distribution of the vaccine in the European Union.

Production of material for J&J's COVID-19 vaccine at an Emergent remains on hold following an FDA inspection that found multiple problems; FDA indicated that additional batches of J&J vaccine, beyond the 15 million already identified, could have been contaminated.

Pfizer identified in Mexico and Poland the first confirmed instances of counterfeit versions of its COVID-19 vaccine developed with BioNTech.

A *NEJM* study found no evidence that the Pfizer-BioNTech or Moderna COVID-19 vaccines posed any serious risks to pregnant women… Preprint studies found that the Pfizer-BioNTech and Moderna appears effective against serious illness from the virus variant first identified in New York.

The National Institute of Allergy and Infectious Diseases will study the impacts of mixing COVID-19 vaccine doses from different manufacturers (i.e., receiving one type of authorized COVID-19 vaccine, followed by a booster of another).

Following a request by Eli Lilly, FDA revoked emergency use authorization for Lilly's COVID-19 monoclonal antibody therapy bamlanivimab when used as a single therapy.

Adagio Therapeutics raised $336 million in new funding to develop a COVID-19 antibody therapy for prevention and treatment of current and future coronaviruses.

NIH will provide $155M in Phase 3 clinical trial funding to test several existing prescription and over-the-counter medications for use as COVID-19 treatments.

Public Citizen asked FDA to convene an external advisory panel to evaluate whether approval of remdesivir should be rescinded based on inconclusive clinical trial results.