October 29, 2021 | Issue 195

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

HHS proposed withdrawing a Trump Administration rule requiring review of all department regulations every 10 years.

CMS opened healthcare.gov for "window shopping" ahead of November 1st open enrollment… CMS will cut payments to 47%

(2,499) of hospitals, through the Hospital Readmissions Reduction Program.

HHS announced a federal overdose prevention strategy.

FDA and Canadian/UK regulators issued guiding principles for AI and machine-learning-enabled medical devices… FDA, NIH, 10 pharmaceutical companies, and five nonprofits launched a $76M five-year consortium to accelerate rare disease gene therapy development.

A Justice Department (DOJ) official said the Administration is likely to increase enforcement of white collar crimes.

Healthcare law and policy news

President Biden announced a framework for Congressional Democrats' scaled-back reconciliation package, including temporary extension of enhanced ACA subsidies, ACA tax credits for those in the Medicaid "coverage gap," a new Medicare hearing benefit, $150B for home and community-based services, and repeal of the Trump Administration drug rebate rule… Notably, the framework does not include any prescription drug pricing provisions.

Boehringer Ingelheim sued HHS alleging that HRSA's interpretation of the 340B program has expanded the program inconsistent with statutory text to include for-profit pharmacies… DOJ alleges that Kaiser Permanente defrauded Medicare out of $1B through diagnosis coding… Johnson & Johnson will pay $297M to resolve opioid epidemic-related claims in Texas… UnitedHealthcare is suing TeamHealth, alleging that it fraudulently billed for services inconsistent with actual care provided.

23andMe plans to acquire Lemonaid Health ($400M)… Bristol Myers Squibb is reportedly interested in acquiring Aurinia Pharmaceuticals… Novartis is considering the sale/spinoff of Sandoz, its generic drug business… Takeda will acquire GammaDelta… Mark Cuban and the Purchaser Business Group each launched new PBMs… Centene is evaluating proposals for a PBM to manage its $30B annual drug spending…FTC will require DaVita to divest three dialysis clinics, avoid no-poach agreements, and limit future acquisitions in Utah.

Cigna will expand access to virtual-first primary, dermatology, behavioral, and urgent care services for select employers… Aetna announced a network focused on coverage of expensive gene therapies… Premier and Resilinc expanded their collaboration to mitigate supply chain disruptions.

Modern Healthcare reported that hospitals continue to charge vastly different prices for the same procedure even with new price transparency requirements.

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COVID-19 by the Numbers

There have now been roughly 45.8 million confirmed COVID-19 cases in the US, with a death toll over 740,000… The country is averaging roughly 70,000 new cases per day over the past week, down 20% over the past two weeks; deaths per day are down 15% to roughly 1,400... According to HHS data, daily pediatric hospital admissions with confirmed COVID-19 have fallen 56% since the end of August.

416 million COVID-19 vaccine doses have been administered in the US (roughly 756,000/day over the past week)… More than 221 million Americans (78% of Americans 12 and older) have received at least one COVID-19 vaccine dose; over 191 million Americans are fully vaccinated (67.4% of Americans 12 and older); 15.4 million Americans have received a booster dose.

Executive and Administrative Action

The Biden Administration will ease air travel restrictions for fully vaccinated foreign nationals as of November 8 and said that it would not dictate a standard for airlines to verify vaccination status.

The federal government purchased an additional 50 million pediatric doses of the Pfizer-BioNTech COVID-19 vaccine, set to be delivered by the end of April.

CMS guidance clarifies that state Medicaid program and the Children's Health Insurance Program (CHIP) are required to cover treatments for COVID-19, including preventive therapies and treatment for "long COVID," without cost-sharing.

HHS announced actions to increase access to over-the-counter (OTC) COVID-19 tests, including FDA permitting developers of COVID-19 serial tests to apply for their product to be authorized as single-use OTC tests without submitting additional data, FDA authorization of an additional OTC rapid antigen test, and an NIH investment of $70 million to expedite high-quality at-home tests to the market in coordination with FDA.

FDA and Aetion will collect real-world evidence (RWE) on inpatient COVID-19 therapies and attempt to prove how a platform-based approach can help accelerate regulatory knowledge on the use of RWE and be applied to consideration of therapies for future pandemics.

EEOC guidance stated that workplace anti-bias laws requiring exemptions from COVID-19 vaccine requirements do not extend to non-religious concerns, such as political, social, or personal objections.

GAO issued its eighth report on the federal government's response to the pandemic, which included new recommendations in several areas, including provider aid oversight, unemployment insurance fraud, worker safety, and COVID-19 testing.

Healthcare Law, Business, and Policy News

A *JAMA* study found that hospitals that received the most federal COVID-19 relief funds were disproportionately academic-affiliated and had higher pre-pandemic assets; however, those hospitals were also more likely to have higher COVID-19 case numbers… An Urban Institute analysis estimated that there is $26.8B left in COVID-19 relief funds.

CDC reported that 17.1 million children globally did not receive their first diphtheria, tetanus, and pertussis (DTP) doses in 2020 due to the pandemic.

An Axios-Ipsos survey found that just 44% of Americans are confident the Biden Administration can ensure the economy recovers quickly after the COVID-19 pandemic, an eight percentage point drop since late January… A KFF poll found that 27% of parents would seek out vaccinations for their children ages 5 to 11 immediately after authorized.

Surveillance, Testing, and Treatment

FDA's Vaccines and Related Biological Products Advisory Committee voted (17-0 with one abstention) in favor of authorizing Pfizer-BioNTech's COVID-19 vaccine for children ages 5 to 11, although some committee members expressed concerns about the lack of sufficient data and the possibility of vaccine mandates in schools… FDA documents posted in advance of the Committee's meeting concluded that the benefits of the Pfizer-BioNTech vaccine far outweigh the potential risks, including myocarditis, for children ages 5 to 11… FDA is expected to grant emergency use authorization for use of the vaccine in that age group, with shipments beginning as early as this weekend… Pfizer also reported that the vaccine is 90.7% effective in children ages 5 to 11.

Moderna reported that its COVID-19 vaccine induced a strong antibody response in children ages 6 to 11.

White House Chief Medical Advisor Anthony Fauci said that millions of children under the age of 12 could begin getting COVID-19 vaccines "within the first week or two of November".

BioNTech plans to expand COVID-19 vaccine production and share know-how with local companies in Africa, while Moderna agreed to boost vaccine donations to Africa; some critics expressed the need for additional support to ensure appropriate access to African countries.

CDC updated guidelines to say that adults who are "moderately to severely immunocompromised" and have received three doses of an mRNA vaccine may get a fourth shot (Pfizer-BioNTech, Moderna, or Johnson & Johnson) at least six months after getting their third mRNA dose.

Merck granted a royalty-free license for its COVID-19 antiviral pill to the Medicines Patent Pool, a UN-backed nonprofit, to allow companies to manufacture and cheaply sell the product in 105 lower- and middle-income, primarily African and Asian, countries… Merck said that is it ready to produce and distribute ten million doses of the antiviral pills to higher-income countries by the end of this year and more than double that next year, assuming the drug is authorized by the FDA.

Brazilian researchers reported that the antidepressant fluvoxamine reduced the risk of hospitalization for COVID-19 patients by 32%.