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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 will increase 2022 payments to hospital-based ESRD (3.3%) and freestanding ESRD facilities (2.5%), home health (2.6%); and outpatient services (2.0%)... CMS will allow a temporary 3.75% payment increase for physician services to expire and increase penalties for hospitals non-compliant with price transparency requirement (upwards of $5,500/day or $2M per year).

FDA issued medical device software draft guidance on pre-market application documentation requirements, based on device and software risk level.

Healthcare law and policy news

Senate Democrats announced an agreement on drug pricing reform, including allowing Medicare to negotiate prices for 20 drugs by 2028; penalizing drug manufacturers for raising drug prices faster than inflation; and capping Medicare Part D out-of-pocket spending ($2,000/year)… Based on CBO analysis, the White House estimated the drug pricing provisions would save $100B, while repeal of the Trump Administration rebate rule would save $150B… The House is expected to vote on the $1.75T reconciliation bill and infrastructure package today.

The Texas Medical Association sued HHS over the interim final rule to implement the *No Surprises Act*… A federal court ruled that HHS was "arbitrary and capricious" in asserting enforcement penalty authority over drug manufacturers that do not pass on 340B discounts to contract pharmacies… A California superior court ruled that several manufacturers did not mislead doctors and patients about their opioid products… Geisinger settled $18.5M in Medicare hospice and home health billing false claims… TeamHealth filed 10 lawsuits against UnitedHealth alleging underpayment of tens of millions of dollars.

Novartis plans to sell its voting stake in Roche back to the company ($20.7B)… Jefferson Health acquired the remaining 50% stake in Health Partners Plans from Temple University Health System ($305M)…
CVS plans to launch physician-staffed primary care practices...
Moderna's CEO said that early data on its flu vaccine could be available in a few weeks.

HHS data show that the rate of uninsured Americans in 2020 remained relatively stable (between 8.6% to 9.7%) in 2020.

FAIR Health reported telehealth use among privately-insured individuals increased 12.9% from July to August in the South and 2.4% nationally… An MGMA survey found that 91% of physician group practice executives believe overall regulatory burden increased over the past 12 months, up from 86% in 2019.

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COVID-19 by the Numbers

There have now been roughly 46.3 million confirmed COVID-19 cases in the US, with a death toll over 750,000… 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 roughly 1,400, the same as last week... The global death toll from COVID-19 passed 5 million… CMS data show that the number of COVID-19 hospitalizations among older Americans dropped significantly since vaccine rollout.

425 million COVID-19 vaccine doses have been administered in the US (roughly 1.13 million/day over the past week)… More than 222.6 million Americans (78.4% of Americans 12 and older) have received at least one COVID-19 vaccine dose; over 193 million Americans are fully vaccinated (68.1% of Americans 12 and older); 21.5 million Americans have received a booster dose.

Executive and Administrative Action

A CMS interim final rule requires over 17 million eligible staff at healthcare facilities participating in Medicare and Medicaid to get vaccinated against COVID-19 by January 4… An OSHA emergency temporary standard requires private employers with 100 or more employees to mandate COVID-19 vaccinations or at least weekly testing for all workers by January 4… the Administration delayed the vaccine mandate deadline for federal contractors from December 8 to January 4.

Guidance from the Safer Federal Workforce Task Force states that federal contractors subject to vaccine COVID-19 requirements will be in charge of determining and enforcing employee enforcement.

CMS clarified that the Pfizer-BioNTech will be covered for children ages 5 to 11 under Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and in the commercial market without cost sharing.

BARDA and Emergent BioSolutions mutually agreed to end a contract under which Emergent set aside manufacturing capacity to rapidly supply vaccines during public health and pandemic threats.

Surveillance, Testing, and Treatment

Last Friday, FDA granted emergency use authorization to Pfizer-BioNTech's COVID-19 vaccine for children ages 5 to 11… On Tuesday, CDC Director Rochelle Walensky endorsed a unanimous recommendation from the CDC Advisory Committee on Immunization Practices (ACIP) for vaccinating children in that age group with the COVID-19 vaccine.

Moderna will delay seeking FDA authorization for its COVID-19 vaccine in children ages 6 to 11, after FDA notified the company that it would need additional time to review approval of its vaccine in

children ages 12 to 17 due to potential risks of rare heart inflammation; FDA review may not be completed until January… Moderna scaled back the number of COVID-19 vaccines it plans to deliver this year to between 700 and 800 million, down from upwards of 1 billion.

World Health Organization (WHO) granted emergency use authorization to Bharat Biotech's COVID-19 vaccine Covaxin.

The federal government bought 614,000 additional doses ($1.29B) of Eli Lilly's combo COVID-19 monoclonal antibody treatment; 400,000 doses will be delivered by December 31, with the rest to be provided by January 31… Meanwhile, Eli Lilly retracted a request for European Union approval of its monoclonal antibody treatment, citing a lack of demand from EU member states.

UK regulators authorized Merck's antiviral pill molnupiravir for use in patients at high-risk of developing severe COVID-19 requiring hospitalization… WHO is seeking additional data from Merck about its antiviral pill and hopes to issue guidance soon on its use for patients with mild to moderate cases.

Pfizer reported that its experimental antiviral pill reduced the risk of death and hospitalization by 89% in patients newly diagnosed with COVID-19.

NIH is supporting a four-year study of potential long-term effects from COVID-19 in pregnant women and children who contract the disease during pregnancy.