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Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare</u> <u>Regulatory Insight</u> 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 <u>subscribe to our mailing list here</u>.

We welcome your feedback. Let us know if KPMG can help. Please <u>reply</u> <u>here to me</u>, **Larry Kocot**, principal and national leader, KPMG Center for Healthcare Regulatory Insight or simply reply to this email with any comments or requests.



# 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 <u>end the Part D Payment Modernization Model</u> on December 31 due to low participation.

939,575 individuals have <u>signed up for ACA plans</u> during the special enrollment period through April 30.

FDA approved a <u>naloxone nasal spray</u> with double the typical dose for opioid overdose treatment... FDA <u>withdrew</u> a Trump Administration policy <u>requiring annual drug review timeline reports</u>.... The FDA issued <u>a report on its oversight activities</u> during the pandemic.





#### Healthcare law and policy news

President Biden signed legislation <u>extending the ban on fentanyl analogues</u> into October.

A federal <u>trial began over McKesson, AmerisourceBergen, and Cardinal Health's</u> roles in the opioid epidemic... Delaware's supreme court <u>rejected Cigna's attempt</u> to <u>collect a \$1.85B termination fee</u> from Anthem over their failed merger.

Roivant Sciences will go public through a SPAC (\$7.3B)... HCA sold four hospitals to Piedmont Healthcare (\$960M)... Myriad sold assets, including its rheumatoid arthritis disease test Vectra, to LabCorp (\$150M)... R1 RCM will acquire VisitPay (\$300M)... Walmart plans to acquire MeMD.

A \$100M CVS venture fund will invest in digital health startups... Medline invested \$1.5B in the domestic healthcare supply chain... Incyte will settle kickback allegations (\$12.6M).

50% of Americans want <u>Congress to pass legislation bringing down</u> <u>prescription drug</u> costs; 53% of <u>Americans</u> fear healthcare costs will become unaffordable... House <u>Energy and Commerce</u> and <u>Education and Labor Committees</u> discussed drug pricing reform bills.

Health Affairs studies found that "pharmacy deserts" are more common in Black and Hispanic neighborhoods; that hospital acquisitions of physician practices were associated with higher rates of inappropriate MRI referrals and diagnostic and lab tests; that PE firms are more likely to acquire hospitals with larger operating margins; and that SNF patients could be discharged to the home sooner without compromising quality... Lown Institute ranked hospitals on delivery of low-value tests/procedures.

A JAMA study found that rising wholesale drug prices led to higher out-of-pocket expenses for 57.3% of insured patients... FAIR Health reported that telehealth utilization among privately-insured individuals fell 15.7% from January to February, the first month-to-month decline since September... AMA reported that for the first time less than half of physicians (49.1%) work in private practice... A JAMA study found that Medicaid enrollment increased 5.2M January 2019-September 2020.





Questions or comments, please send to <u>ushcinsight@kpmg.com</u>.

# Succeeding in the new reality

Visit the COVID-19 resource center for KPMG analysis, insights, and perspectives.



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## COVID-19 by the Numbers

There are now over 32.6 million confirmed COVID-19 cases in the US, with a <u>death toll over 580,000</u>... New confirmed COVID-19 cases in the United States are <u>at the lowest point in seven months</u> (48,000 new cases/day over the past week); 20 states had fewer cases than the week before... As of Monday, children <u>made up 22.4% of new COVID-19 cases</u> in the past week, up from <u>just 3% of new cases</u> a year ago... CDC projected that US COVID-19 <u>cases could see a sharp decline by July</u> and that the pandemic could be brought under control if nationwide vaccination efforts and safety measures continue.

University of Washington scientists <u>estimated that 6.9 million people have died from COVID-19</u> worldwide, more than twice the official number, and that 905,000 have died in the US, 38% higher than the CDC tally.

252 million COVID-19 <u>vaccine doses have been administered</u> in the US (2.09M/day over the last week, <u>down from 3.37M/day</u> three weeks ago)... 149.5 million Americans (<u>57% of Americans 18 and older</u> and 83% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 108 million Americans are fully vaccinated (41.9% of Americans 18 and older).

### **Executive and Administrative Action**

President Biden set a goal of <u>having 70% of Americans receive at least one COVID-19 vaccine</u> dose by July 4; as soon as Pfizer-BioNTech's vaccine is authorized for children ages 12 to 15, the Administration also plans to launch a comprehensive plan to vaccinate as many as many adolescents as possible by July 4<sup>th</sup>.

The Biden Administration will <u>begin reallocating COVID-19 vaccines</u> that go unclaimed by states... The Administration <u>launched a website</u>, <u>text-message tool</u>, <u>and phone hotline</u> to help Americans find COVID-19 vaccines available near them and is <u>supporting Pfizer's efforts to begin exporting</u> US-made doses of its COVID-19 vaccine.

U.S. Trade Representative Katherine Tai announced that the White House supports the waiver of intellectual property protections for COVID-19 vaccines for the duration of the pandemic; the Administration is moving forward on discussions with the World Trade Organization on waiving the protections.

HHS announced \$1 billion in American Rescue Plan funding to <u>strengthen COVID-19 response efforts and increase vaccinations</u> in rural communities and \$250 million in American Rescue Plan funding to develop and support a community-based workforce charged with increasing COVID-19 vaccinations in

underserved communities... HHS also announced a <u>COVID-19 Coverage Assistance Fund to cover COVID-19 vaccine administration costs</u> for patients in health plans that do not cover the costs or require patient cost-sharing.

The Administration <u>restricted travel from India</u> (not impacting citizens, permanent citizens, and others with exemptions) starting at midnight on Tuesday (May 4).

CMS increased <u>national average payment rates</u> for COVID-19 monoclonal antibodies from \$310 to \$450 in most health care settings and to \$750 when administered at the beneficiary's permanent residence or temporary lodging, like a hotel or motel, cruise ship, hostel, or homeless shelter.

GAO reported on access-related issues for mental health and addiction treatment during the pandemic...

## Healthcare Regulatory News

FDA <u>revoked the emergency use authorization</u> for Battelle's respiratory decontamination system following a voluntary request from the company.

## Healthcare Law, Business, and Policy News

The American Hospital Association <u>requested that HHS extend</u> the provider relief funds spending deadline from June 30 until the end of the public health emergency.

A federal judge <u>vacated the nationwide ban on evictions</u> during the pandemic, ruling that the <u>CDC</u> <u>exceeded its authority</u> in issuing the moratorium.

A Harris poll found that 10% of Americans will get a COVID-19 vaccine "whenever I get around to it;" 21% will wait and see before getting the vaccine, and 14% will not get the vaccine at all... Only 52% of parents responding to an Axios/Ipsos survey are likely to vaccinate their children under the age of 18 as soon as they are eligible... An Ipsos survey found that 57% of all Americans continue to wear a mask "at all times" when leaving the house; just 47% of unvaccinated adults wear a mask "at all times"... 55% of respondents to a VeryWell survey believe individuals should have to prove they've been vaccinated to do things such as board an airplane or enter a restaurant for indoor dining.

Dell will collaborate with i2b2 transSMART Foundation to create and study "digital twins" or virtual models of tens of thousands of long-haul COVID-19 patients.

# Surveillance, Testing, and Treatment

FDA is expected to clear <u>Pfizer's COVID-19 vaccine for children aged 12 to 15</u> as early as <u>next Wednesday</u>.

Pfizer will <u>distribute smaller packages of its COVID-19 vaccine</u> by the end of May in order to reduce potential waste...CVS and Walgreens <u>accounted for most of the nearly 180,000 COVID-19 vaccines</u> that had to gone to waste as of late March.

Pfizer/BioNTech <u>asked the FDA for full approval</u> of their COVID-19 vaccine... Moderna plans to <u>file for full approval</u> of its COVID-19 vaccine by the end of the month... A real-world study found that the Pfizer-BioNTech and Moderna COVID-19 vaccines <u>protected against two widespread COVID-19 variants</u>.

Moderna will supply 34 million doses of its COVID-19 vaccine to Covax in Q4 2021 for distribution to low-income countries, with the option of up to 500 million total through 2022... A booster shot to Moderna's vaccine has shown positive results against new virus variants in an early study.

Pfizer and BioNTech will <u>donate their COVID-19 vaccine for participants</u> in the Tokyo Olympics in July... A <u>federal judge ruled</u> that Pfizer and BioNTech must face a suit alleging development of <u>their COVID-19</u> <u>vaccine infringed</u> on a fluorescent protein patent... A <u>UK study found</u> that individuals who have not already been infected by COVID-19 are vulnerable to infection from variants after getting just one dose of Pfizer-BioNTech's vaccine... BioNTech increased its vaccine <u>manufacturing capacity to 3 billion doses</u> for 2021.

AstraZeneca <u>remains committed to receiving emergency use authorization</u> for its COVID-19 vaccine despite setbacks... Novavax has begun a clinical trial <u>testing its COVID-19 vaccine in adolescents ages 12 to 17</u>... The next generation of COVID-19 vaccines in development <u>could be in the form of a pill or nasal spray</u>, easing transport and storage.

Eli Lilly employees accused an executive of <u>altering government-required documents to downplay</u> <u>potential quality control issues</u> at a US facility manufacturing its monoclonal antibody treatment.