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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 proposed increasing 2022 payments for <u>inpatient rehabilitation</u> <u>facilities</u> by <u>1.8% (\$160M)</u>; <u>inpatient psychiatric facilities</u> by <u>2.3% (\$90M)</u>; <u>hospices</u> by 2.3% (\$530M); and <u>SNFs</u> by 1.3% (\$444M).

528,000 Americans <u>have signed up for ACA coverage</u> through the special enrollment period (SEP) to-date... DOL <u>affirmed that unemployed workers can enroll in ACA plans</u> through an SEP once American Rescue Plan fully-subsidized COBRA coverage ends (September).

CMMI paused 2022 Direct Contracting Model enrollment.

HHS is exploring regulations to <u>fix the "family glitch"</u>... CBO <u>concluded that a public insurance option</u> would likely help contain ACA market provider rates and lower administrative costs.

FDA approved <u>Supernus' pediatric ADHD</u> treatment and a Gilead <u>triple-negative breast cancer drug</u>... FDA released <u>generic drug development</u> <u>guidance</u> for the pandemic, including that facility inspection delays could threaten 180-day exclusivity for certain products.

Special Counsel urged FDA to <u>closely reexamine biologic plant inspection</u> compliance matters... Industry lawyers expect <u>more FDA dietary</u> <u>supplements oversight</u>.





Healthcare law and policy news

Senate Finance will <u>hold a confirmation hearing</u> April 15 for CMS Administrator-nominee Chiquita Brooks-LaSure.

Supreme Court <u>continued its hold</u> on Medicaid work requirement cases, while the Biden Administration revoked <u>Wisconsin</u> and <u>Michigan</u> Medicaid work requirements.

The Senate parliamentarian will allow <u>another reconciliation bill</u> this year, setting up a possible opportunity for Democratic-led drug-pricing reform and coverage expansion to avoid filibuster hurdles... A <u>multinational corporation tax plan</u>, released by Senate Democrats, could negatively impact pharmaœutical companies.

OIG <u>recommended</u> an HCA-owned hospital <u>repay \$23.6M in Medicare</u> overpayments.

LumiraDx will go public through a \$5B SPAC merger... Bright Health acquired Zipnosis... FierceHealthcare reported that COVID-19 has accelerated hospital acquisition of ambulatory surgical centers... Rock Health reported that digital health startups raised \$6.7B across 147 deals in Q1 2021, the most funded quarter to-date.

40 healthcare organizations <u>signed a value-based-care compact</u>, aiming to tie 70% of payments to capitation and alternative payment models by 2024.

Health Affairs studies found that Medicaid expansion increased receipt of opioid use disorder medications in the criminal justice system; not-for-profit hospitals spent less on charity care (2.3% of expenses) than for-profit (3.8%) and government-run hospitals (4.1%) in 2018; and medical device industry payments to physicians averaged \$904M/year 2014-2017, compared to \$821M/year for the pharmaceutical industry.





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

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COVID-19 by the Numbers

There are now over 31 million confirmed COVID-19 cases in the US, with a <u>death toll over 560,000</u>... The country averaged <u>roughly 65,000 new confirmed cases/day over the past week</u>, while daily case counts increased in 13 states... The COVID-19 strain originating in the UK (B.1.1.7) is <u>now the most common variant in the US.</u>

175 million COVID-19 <u>vaccine doses have been administered</u> in the US (3.04M/day over the last week)... 112 million Americans (43.2% of Americans 18 and older and 76.9% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 25.6% of Americans 18 and older are fully vaccinated... The US <u>administered 4 million vaccines</u> in a single day for the first time over last weekend.

Executive and Administrative Action

President Biden announced that all US adults <u>should be made eligible for a COVID-19 vaccine</u> by April 19... HHS expanded its COVID-19 <u>vaccine program to all (1,470) community health centers</u> across the country... The Administration announced three more federally-run mass vaccination sites in <u>Columbia, SC, Pueblo, CA</u>, and <u>St. Paul, MN</u>.

Press Secretary Jen Psaki said that the Biden Administration will not mandate use of vaccine "passports."

The US is launching a fundraising campaign on April 15 to <u>support purchase of COVID-19 vaccines for the world's poorest countries</u> through COVAX... Secretary of State Anthony Blinken <u>named Gayle Smith as Coordinator for Global COVID-19 Response</u> and Health Security.

CDC Director Rochelle Walensky <u>declared racism as "a serious public health threat"</u> and vowed to use pandemic funds to invest in communities of color and other disproportionately affected groups to address disparities.

HHS extended by six months its <u>contract with TeleTracking to provide technology</u> used for its database through which hospitals report COVID-19 capacity data.

Healthcare Regulatory News

CDC revised guidance to say that <u>regular cleaning of surfaces with soap and water is sufficient</u> to reduce COVID-19 spread and that use of special disinfecting chemicals are only needed where there is a suspected or confirmed case.

Healthcare Law, Business, and Policy News

Politico reported <u>on growing concerns among privacy experts</u> over how patient data collected by retail pharmacies during COVID-19 vaccine administration may be used.

Planned Parenthood launched a \$2 million COVID-19 vaccination education campaign and plans to distribute thousands of vaccines at sites across five states.

A Surgo Ventures <u>poll found that 59% of the US population</u> has already received a COVID-19 vaccine or plans to as soon as it becomes available to them and that vaccination rates will likely plateau in April before the country reaches herd immunity... An AP-NORC poll found that <u>75% of Americans are willing to receive the COVID-19 vaccine or have already received</u> at least one dose, up from 67% in late January; vaccine hesitancy varies across age group, political affiliation, ethnicity, and geography... A STAT-Harris poll found <u>that 21% of Gen Z Americans (ages 18-24) do not plan</u> to get vaccinated... Only 52% of US parents <u>responding to an Axios-Ipsos poll</u> plan to get their children vaccinated for COVID-19 as soon as possible.

A <u>JAMA Pediatrics</u> analysis estimated that 37,300 to 43,000 children have lost a parent due to COVID-19... Another <u>JAMA Pediatrics</u> study concluded that multisystem inflammatory syndrome in children (MIS-C) resulted from delayed immunological responses to COVID-19, peaking 2 to 5 weeks after COVID-19 peaks... A <u>Lancet</u> study found that <u>33% of COVID-19 patients had a neurological or psychiatric illness</u> within six months of COVID-19 diagnosis; 13% of COVID-19 patients received a neurological or psychiatric diagnosis for the first time.

Surveillance, Testing, and Treatment

The European Medicines Agency concluded that AstraZeneca's COVID-19 vaccine is <u>linked to dangerous</u> <u>blood clots in "very rare" cases</u>, but that overall benefits of the vaccine outweigh risks... The World Health Organization acknowledged <u>a "plausible" connection</u> between the vaccine and blood clots... As a result of blot clot concerns, University of Oxford <u>paused dosing in a clinical trial of children and teenagers</u> testing its COVID-19 vaccine with AstraZeneca.

Johnson & Johnson (J&J) <u>assumed full responsibility for manufacturing</u> its COVID-19 vaccine at a Baltimore plant where 15 million doses were ruined; while AstraZeneca is working with the federal government to <u>identify a new vaccine plant to support production</u> of its vaccine... J&J will <u>allocate 86% fewer doses of its vaccine</u> across the country next week, down to just 700,000... J&J is testing its COVID-19 vaccine in pregnant women and children ages 12 to 17.

CDC Director Rochelle Walensky said that <u>Pfizer-BioNTech's COVID-19</u> vaccine could be expanded to <u>children as young as 12 years old as soon as May</u> and that Moderna's could be available by summer.

NIH began a <u>clinical trial to study the risk of allergic reactions</u> to Moderna and Pfizer-BioNTech's COVID-19 vaccines.

Walgreens will <u>change its scheduling system for the Pfizer-BioNTech COVID-19 vaccine</u> after it was discovered that second doses were being scheduled four, rather than three, weeks apart.

Production of Moderna's COVID-19 vaccine will <u>nearly double after reaching an agreement with contract</u> <u>manufacturer Catalent</u> to increase output to roughly 400 vials per minute.

Politico reported on growing concerns among vaccine manufacturers about lack of capacity to produce vaccine boosters or revised vaccines alongside original versions.

The US Army <u>will begin testing of an Army-developed COVID-19 vaccine</u> potentially effective against emerging variants.

COVAX has delivered nearly 38.4 million COVID-19 vaccine doses to more than 100 countries.

An Eli Lilly-Incyte rheumatoid arthritis therapy <u>failed to keep hospitalized COVID-19 patients from progressing to mechanical ventilation</u>.

Merck and Ridgeback Biotherapeutics reported <u>that the antiviral molnupiravir "significantly reduced infectious virus</u> in subjects in a mid-stage study after five days of [COVID-19] treatment."