



Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



January 15, 2021 | Issue 155

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.



Special Supplements: COVID-19 News and Medicare Enforcement Issue Brief

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](#).

In addition, the Center for Healthcare Regulatory Insight published [an issue brief examining trends in Medicare Part C & D civil monetary penalties](#) during the Obama and Trump Administrations and what it could mean for enforcement activity in the upcoming Biden Administration.



Healthcare regulatory news

CMS [finalized](#) the [2022 ACA exchange rule](#), allowing off-exchange enrollment; advocates [sued to stop Georgia's 1332 waiver](#)... [8.286.871 enrolled in 2021 healthcare.gov plans](#), up 7% from 2020... An [IRS final rule clarifies employer](#) HRA responsibilities.

CMS [issued](#) its CY2022 [MA and Part D final rule](#)... CMS [finalized its rule](#) reducing provider/patient burden through prior authorization improvements and streamlined data exchange... [CMS finalized](#) a coverage pathway to [expedite beneficiary access](#) to breakthrough medical devices... CMS [approved Tennessee's Medicaid](#) 1115 waiver, including allowing a [closed Medicaid drug formulary](#)... CMS will [require 1115 demonstrations](#) to run at least nine months before termination... CMS [delayed by two months the filing deadline](#) for provider facility cost reports.

An [HHS final rule](#) prevents [civil enforcement actions based solely upon guidance](#)... HHS [practice guidelines](#) expand the [number of providers who can prescribe buprenorphine](#) for opioid use disorder.

FDA issued an “action plan” for [regulating AI/machine learning-based medical software](#)... HHS will require an FDA [annual report on drug approval timelines](#) and make permanent a waiver of [premarket review requirements](#) for certain medical devices.

A Commerce Department [proposed rule would bar federal](#) “march-in rights” to combat high drug prices... Trump Administration [acknowledged its \\$200 Medicare drug discount card](#) plan won't happen.

Janet Woodcock will [serve as Acting FDA Commissioner](#) to start the Biden Administration.



Healthcare law and policy news

Healthcare-related cases [accounted for \\$1.8B of the \\$2.2B](#) in FY2020 False Claims Act settlements/judgments.

PCMA [sued](#) to [block implementation](#) of the Part D “rebate rule”... AstraZeneca, Sanofi, and Eli Lilly [sued over HHS' advisory opinion](#) on providing 340B discounts to contract pharmacies.

CommonSpirit Health [will sell 14 hospitals to Essentia Health](#)... Aspirus Health [will purchase 7 hospitals and other facilities](#) from Ascension... Optum [signed an MOU to acquire](#) Atrius... Bluebird Bio [is spinning off its oncology unit](#)... Sanofi [will acquire Kymab \(\\$1.45B\)](#)... Steris will [acquire Cantel Medical](#) (\$3.6B)... BeiGene will [partner with Novartis on](#) an

oncology product... Talkspace [will go public through a SPAC merger](#)... FTC [ordered major insurers to share claims data](#) for an examination of consolidation impacts on prices.

More than [100 pharmaceutical companies](#) reportedly raised prices on 636 drugs (4.99% average) in 2021... 53.6% of [behavioral health patients used telehealth](#) mid-March-early May.



Questions or comments, please send to us-hcinsight@kpmg.com.



kpmg.com/socialmedia



[Privacy](#) | [Legal](#)

You have received this message from KPMG LLP. If you wish to unsubscribe from Around the world of U.S. healthcare in 360 words or less, please [click here](#). If you wish to unsubscribe from all KPMG communications, please [click here](#).

KPMG LLP, 3 Chestnut Ridge Road, Montvale, NJ 07645

© 2020 KPMG LLP, a Delaware limited liability partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved. NDP131714-1A

The KPMG name and logo are trademarks used under license by the independent member firms of the KPMG global organization.



COVID-19 News Supplement

Center for Healthcare Regulatory Insight



COVID-19 by the Numbers

There are now over 23.3 million confirmed COVID-19 cases in the US, with a [death toll over 385,000](#)... the country is now [averaging nearly 250,000 new cases](#) and [4,000 deaths/day](#)... COVID-19 deaths have [risen 10% or more since last week in 25 states](#)... CDC reported that [cases of COVID-19 in children, adolescents, and young adults](#) have increased since this summer... The pandemic is expected to [lower US life expectancy by 1.13 years](#) in 2020.

11.9 million COVID-19 [vaccine doses have been administered in the US](#), 39% of total doses distributed to states.

Executive and Administrative Action

HHS Secretary Alex Azar [renewed the COVID-19 public health emergency](#).

HHS Secretary Alex Azar [recommended states expand the categories of individuals prioritized](#) to receive COVID-19 vaccines to everyone 65 and older and those 16 and older with [one high-risk medical condition](#), putting up to 152 million Americans in the priority category and widen vaccine distribution to include pharmacies, clinics, and other venues; the federal government will also [release second doses of the vaccine](#) that it had been reserving for those who already received the first dose.

President-elect Biden outlined his plans for a [\\$1.9T COVID-19 relief package](#), including [\\$415 billion to directly combat the virus](#) through funding for vaccine distribution, testing, contact tracing, genomic sequencing, supplies and protective equipment, and other measures... Biden will lay out [his vaccine distribution plan this afternoon](#)... Biden named former FDA Commissioner [David Kessler to lead Operation Warp Speed](#).

President-elect Biden [received his second dose](#) of Pfizer's COVID-19 vaccine.

The Director of the Administration's Supply Chain Task Force [said that the US will need 2.2 billion N95 masks a year](#) after the pandemic... The federal government [purchased an additional 1.25 million doses](#) of Regeneron's COVID-19 antibody cocktail treatment.

The [Pandemic Recovery and Preparedness Plan report](#) concluded that FDA [needs to react faster](#) to pandemics and other health emergencies.

Beginning January 26, CDC will [require all international air passengers to the US](#) to show proof of a recent negative COVID-19 test before boarding their flight.

Healthcare Regulatory News

FDA granted [emergency use authorization for Quanterix's](#) COVID-19 antigen test.

Healthcare Law, Business, and Policy News

Senate Democrats [urged HHS to provide states with new resources and guidance](#) to correct “significant failures of the COVID-19 vaccine distribution”... Senator Elizabeth Warren urged the Biden Administration to [take a series of executive actions to address the pandemic](#), including those to improve transparency and oversight, address disparities, rectify supply chain issues, and de-politize the response.

An Axios-Ipsos survey found that [60% of Americans would likely receive a COVID-19 vaccine as soon as available](#) to them, up from 52% in mid-December... 47% of respondents to a Harris poll believe the COVID-19 [vaccine rollout is moving “too slowly.”](#)

Dollar General will [offer employees four hours of pay](#) if they get the COVID-19 vaccine.

The Rockefeller Foundation [contributed \\$30 million toward a stockpile of COVID-19 tests](#), from which states and territories participating in its testing alliance can purchase tests.

Surveillance, Testing, and Treatment

AstraZeneca [applied for emergency use authorization](#) in Europe for its COVID-19 vaccine developed with University of Oxford... A UK official involved in approval of the Oxford-AstraZeneca vaccine said [it can be 80% effective when there are three months](#) between doses.

Moderna said that its COVID-19 [vaccine would provide immunity for at least a year](#); it plans to deliver between 600 million and 1 billion doses of the vaccine in 2021... Moderna's CEO said the US [could reach herd immunity](#) by this summer if rollout of Moderna's and Pfizer-BioNTech's vaccine continues as expected.

Early [data show](#) that Johnson & Johnson's COVID-19 vaccine provided participants with at least some immunity after one dose, which the company [hoped would be as effective as existing two-dose vaccines](#); however [production of the vaccine has slowed](#), likely pushing back the timeline for meeting initial production projections.

Pfizer and BioNTech plan to [produce 2 billion doses of its COVID-19 vaccine](#) this year.

Now that it has fulfilled the federal government's order, Abbott Labs will make its [BinaxNOW COVID-19 rapid antigen test available](#) to schools, universities, pharmacies, and workplaces.

CDC [awarded LabCorp a contract](#) to study and provide genome sequencing of COVID-19 variants.

World Health Organization's (WHO) Chief Scientist [said herd immunity to COVID-19 is unlikely this year](#) despite millions of vaccinations... A team of WHO [researchers arrived in China](#) to study the virus' origins... A [Lancet study](#) of patients hospitalized with COVID-19 in China found that a [majority of patients had at least one symptom six months](#) after initial illness.