



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

Center for Healthcare
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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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Healthcare regulatory news

FDA [granted accelerated approval](#) to Sarepta Therapeutics' [Duchenne muscular dystrophy gene therapy](#) for children aged 4 through 5... FDA [announced a pilot program](#) to reduce risks associated with using [in vitro diagnostics to select appropriate oncology](#) drugs for patients... FDA [approved a new drug class](#) to treat pediatric type 2 diabetes alongside diet and exercise.

CMS [proposed](#) a [Transitional Coverage for Emerging Technologies](#) pathway for breakthrough devices... CMS [released additional details about patient registries for coverage](#) of FDA-approved amyloid-targeting Alzheimer's drugs.

A CDC advisory committee: (1) voted to [allow RSV vaccination](#) of patients aged 60-64 (13-0) and patients aged 65+ (9-5) based on shared decision-

making with their doctor; and, (2) discussed an [RSV vaccine \(administered to pregnant individuals\) and antibody](#) to protect infants.

SAMHSA [released an advisory](#) on identifying/managing long COVID [mental health symptoms/conditions](#).

FTC brought an [enforcement action](#) against 1health.io for exposing sensitive user genetic data and unfairly changing its privacy policy.

USPSTF [recommended all adults 64 or younger be screened for anxiety](#).

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Healthcare law and policy news

President [Biden will appoint Mandy Cohen as Director of the CDC](#).

PhRMA, National Infusion Center Association, and Global Colon Cancer Association [sued](#) to stop [implementation](#) of the Medicare Drug Price Negotiation Program... Bristol Myers Squibb filed a separate [suit](#).

HHS [asked a federal judge to overturn](#) a decision finding Gilead did not owe \$1B in royalties for patents held by CDC for HIV PrEP.

Eli Lilly [will acquire DICE Therapeutics](#) (\$2.4B)... Washington Health System [plans to integrate](#) into UPMC... Ochsner and MD Anderson [announced an oncology partnership](#).

Commonwealth Fund [reported](#) preventable/premature deaths reached historic levels from 2019-2021 due to COVID-19, treatable chronic diseases, and record-high drug overdoses and alcohol-induced deaths... KFF [estimated states received over \\$117B in increased Medicaid FMAP](#) during the pandemic's continuous coverage period, keeping state Medicaid spending below 2019 levels.

Humana and UnitedHealth are [considering Medicare Advantage \(MA\) benefit adjustments](#) due to changes in expense and reimbursement trends... A majority of [House members](#) and [Senators](#) urged CMS to finalize streamlined MA prior authorization policies.

The House passed [legislation \(220-209\) making it easier for employers to offer individual coverage health reimbursement arrangements](#), which [CBO estimated](#) could increase the deficit by \$348M over 10 years.

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