



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

Center for Healthcare Regulatory Insight



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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

An [HHS-Treasury-Labor final rule](#) amends the independent dispute resolution process for [out-of-network bills](#) under *No Surprises Act*.

CMS awarded [\\$25M to states/territories to expand home and community-based services](#) through Medicaid's Money Follows the Person... CMS issued an [informational bulletin](#) to states on [using Medicaid authorities](#) to improve nursing home resident outcomes and improve staffing.

CMS indefinitely [delayed the start](#) of the Radiation Oncology Model.

FDA released [draft guidance](#) on [charging for investigational new drugs](#) in clinical trials.

ASPE [estimated 17.4% of Medicaid/CHIP enrollees](#) (15M) could lose coverage with expiration of the COVID-19 PHE.

White House OSTP directed federal departments/agencies to [make federally-funded research freely available](#) to the public.



Healthcare law and policy news

A [federal judge reversed CMS' decision](#) rescinding [Georgia's Medicaid expansion work requirement](#).

An [appeals court ruled](#) FDA arbitrarily denied six e-cigarette manufacturers' applications and [failed to adequately consider](#) their marketing plans.

Centene [settled \(\\$33M\) allegations](#) that its PBM overcharged Washington's Medicaid program... DOJ [joined a Medicare Advantage False Claims Act suit](#) against Cigna.

Signify Health is [considering bids](#) from several companies... Alcon [will acquire Aerie Pharmaceuticals](#) (\$753M)... Amazon Care [will cease operations](#) at year-end... Novartis will [spin off its Sandoz generic drug unit](#).

JAMA studies found: (1) [naloxone out-of-pocket costs](#) have become an access barrier for uninsured patients with opioid use disorder; (2) [just 38.9% drugs granted accelerated approval](#) by FDA from 2007-2021 demonstrated high therapeutic value; and, (3) individuals with [more chronic conditions have higher likelihood](#) of financial hardship... A [simulation study found](#) primary care physicians would need 26.7 hours/day to follow national guidelines for preventive, chronic, and acute care on an average number of patients.

KFF reported [48% of Medicare beneficiaries \(28.4M\) are now enrolled in MA](#).

Altarm reported [Medicare prices fell 0.5% from January 2021-July 2022](#), while private insurer prices increased 5.4%... Business Group on Health reported employer [healthcare costs increased a median of 8.2% in 2021](#); cancer is the top driver of costs... Aon [projected employer health costs could increase 6.5% in 2023](#) to \$13,800/employee.

CDC reported [US life expectancy dropped in all states and DC from 2019 to 2020](#) (down 1.8 years nationwide to 77) and [non-fatal opioid overdoses increased 4% quarterly](#) from January 2018-March 2022.

Special Section: COVID-19 and Monkeypox News

As announced last week, we have discontinued our separate COVID-19 News supplement; however, we will continue to provide a short summary of COVID-19 and Monkeypox news (below).

FDA [expanded emergency use authorization](#) of Novavax's COVID-19 vaccine for children ages 12 to 17; CDC [recommended the vaccine](#) for that age group... [Pfizer-BioNTech](#) and [Moderna](#) asked FDA to authorize their respective COVID-19 bivalent booster vaccines targeted at Omicron BA.4/BA.5 variants, with doses ready for shipment in September, pending authorization... FDA could [authorize the vaccines without convening its vaccines advisory committee](#), while CDC is likely

to recommend the vaccines after its Advisory Committee on Immunization Practices (ACIP) [meeting on September 1 and 2](#)... the Biden Administration is [planning a fall COVID-19 booster vaccine campaign](#) to launch next month with distribution of 175 million updated vaccine doses... Moderna is [suing Pfizer and BioNTech for alleged patent infringement](#) on technology used to develop its COVID-19 vaccine.

Chinese researchers found the [incubation period for COVID-19 has shortened](#) with each subsequent variant.

A [NEJM study found](#) Pfizer's Paxlovid significantly [reduced hospitalization/death from COVID-19 in patients age 65+](#), but did not benefit younger adults... FDA [told Pfizer to test the effects of an additional course of Paxlovid](#) among individuals who experience COVID-19 rebound after initial treatment.

Monkeypox has [been identified in all 50 states and DC](#)... World Health Organization reported [monkeypox cases fell 21% globally](#) in the last week... An [NIAID official said NIH](#) will soon begin a trial to [evaluate use of monkeypox vaccine dose-sparing](#) to increase supply.



Questions or comments, please send to
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