



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](#).

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Healthcare regulatory news

CMS [announced](#) the [States Advancing All-Payer Health Equity Approaches and Development \(AHEAD\) Model](#), beginning July 2024 for up to 8 states to [test population health improvement approaches](#) through hospital global budgets and enhanced primary care payments.

OCR [proposed updating](#) regulations to prevent disability discrimination in federally funded programs.

FDA [issued three draft guidances](#) to modernize the medical device premarket notification 510(k) Program... FDA [could approve updated COVID-19 booster vaccines](#) today.

FTC [will consider](#) whether improper patent listings in FDA's Orange Book are anticompetitive.

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Healthcare law and policy news

Novartis [sued to stop](#) the Medicare Drug Price Negotiation Program; Astellas [withdrew its lawsuit](#) after [none of its drugs were selected](#) for the program's first year... Humana [sued HHS](#) over its Medicare Advantage risk adjustment data validation (RADV) final rule for [alleged "shifting justifications and erroneous legal reasoning."](#)

FTC [accepted a binding settlement](#) allowing Amgen's \$28B acquisition of Horizon Therapeutics to proceed... Thoma Bravo [will acquire NextGen Healthcare \(\\$1.8B\)](#)... Bicycle Health and Albertsons are [partnering to expand patient access](#) to buprenorphine injections.

Moody's [predicts financial impact of the Drug Price Negotiation Program](#) to the pharmaceutical industry will be "relatively modest in 2026," but grow over time.

A [JAMA study found](#) "vertical relationships" between primary care physicians and large health systems were associated with increases in total medical expenses per patient-year (6.3% or \$357), specialist visits (23%), and ED visits (14%), relative to the comparison group... *Health Affairs* studies found: (1) [41% \(19/46\) of drugs in 2017](#) were approved by FDA based upon only one clinical trial; (2) unobserved [favorable selection in Medicare Advantage \(MA\)](#) led to underpayments in counties with lower MA penetration and overpayments in counties with higher MA penetration; and, (3) the [share of Medicare beneficiaries switching](#) from traditional fee-for-service to MA increased from 61% to 80% between 2011-2022... A [JAHA study found](#) the US [rate of obesity-related heart disease tripled](#) between 1999 and 2020.

House Committees [released a legislative package](#), including provisions on [price transparency](#), [PBM oversight/requirements](#), site-neutral physician-administered drug payment, and health extenders, with hopes for a floor vote this month.

A Mercer survey found [employee health benefit costs could rise 5.4%](#) in 2024, up from 3-4%, on average, over the past decade.

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