



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

Center for Healthcare
Regulatory Insight



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Editor's note

Due to expiration of the COVID-19 public health emergency (PHE) on May 11th, our special section on “COVID-19 and Other Respiratory Illnesses” will be discontinued after today's edition.

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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Special Supplement: MA Risk Adjustment Data Validation (RADV) Final Rule

The Center for Healthcare Regulatory Insight is pleased to release [a Center Insight Brief on the Medicare Advantage Risk Adjustment Data Validation \(RADV\) Final Rule](#) published in February. The Insight Brief summarizes the history of the RADV program, policies in the Final Rule, and early industry reactions. The brief also prompts CMS to consider expanding its use of emerging standards for interoperable data exchange to streamline and address remaining limitations of the RADV process.



Healthcare regulatory news

An [FDA advisory committee narrowly recommended](#) (8-6) accelerated approval of Sarepta's gene therapy for Duchenne muscular dystrophy.

FDA released [draft guidance documents](#) to [support pediatric drug product approvals](#).

FTC [expanded its inquiry](#) into PBMs... an FTC [proposed rule would amend](#) the Health Breach Notification Rule to further clarify its scope and enforcement action/fines.

ARPA-H's [first program, NITRO](#), will target bone/joint self-repair to treat osteoarthritis.

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Healthcare law and policy news

President Biden [nominated National Cancer Institute Director Monica Bertagnolli](#) to be NIH Director.

Fifth Circuit Court of Appeals [issued a stay](#) while it [considers a lower court ruling vacating the ACA's preventive services requirement](#)... the Supreme Court (SCOTUS) unanimously [upheld a lower court ruling](#) that found [Amgen's broadly worded Repatha patents](#) were invalid... SCOTUS [declined to review](#) a Teva [case over "skinny labeling."](#)

FTC [sued to block Amgen's \\$28B acquisition](#) of Horizon Therapeutics... Envision Healthcare [filed for bankruptcy](#)... CVS is [shutting down its clinical trials division](#)... LRVHealth [launched a \\$200M digital health fund](#) with investments from 29 companies... Walgreens [will pay San Francisco \\$230M for its role](#) in the opioid epidemic... AstraZeneca [is leaving PhRMA](#), the third member to do so since December.

The VA [renegotiated its EHR contract with Oracle Cerner](#) to increase accountability for system performance.

House Energy & Commerce [advanced several bills](#), including those to [codify/enhance hospital and insurer price transparency](#) requirements, create [site neutral payment for drug administration](#), [ban "spread pricing"](#) in Medicaid, impose [new PBM reporting requirements](#), increase [340B transparency/oversight](#), and delay DSH cuts to FY2026... House Ways & Means Committee held hearings on [price transparency](#) and [competition/consolidation](#)... Senate HELP Chair Bernie Sanders [is developing a \\$200B healthcare package](#) to, among other things, provide community health center funding and expand the healthcare workforce.

A [JAMA study estimated that Medicare spending](#) for coverage of the Alzheimer's drug lecanemab could cost between \$2B-\$5.1B annually... A [JAMA study found](#) the US Black population [had 1.63M excess deaths](#), compared to the White population from 1999-2020... KFF estimated [insurers will pay consumers approximately \\$1.1B](#) this year in ACA medical

loss ratio rebates, comparable with last year (\$1B)... GAO reported [57% of healthcare and social assistance employers surveyed](#) require new employees to sign noncompete agreements.

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Special Section: COVID-19 News

The World Health Organization [called for updating the composition of COVID-19 vaccines](#) to reflect newer circulating variants, while still recommending individuals receive currently available vaccines if they have not already.

State and [KFF data](#) show at least 400,000 individuals have been disenrolled from Medicaid since redeterminations began, including nearly 250,000 in Florida.

A senior FDA official [urged manufacturers of COVID-19 tests and other devices to pursue full approval of their products](#) before emergency use authorizations are revoked.

FDA's vaccine advisory committee [recommended approval of Pfizer's RSV vaccine](#) for newborns, administered to pregnant mothers in their second or third trimester, although some committee members expressed concerns about the vaccine's safety.

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