

Around the world of US healthcare in 360 words or less



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Editor's note

<u>This series</u> is produced by KPMG Healthcare and is intended to be short and succinct, less than 360 words, to provide a weekly digestible bite of healthcare regulatory, policy, and industry news relevant to our clients. Links are provided to source material (proposed and final regulations, agency guidance and press releases, reports, research, etc.) when available. Please share this email with colleagues and other interested individuals, and encourage them to <u>subscribe to our mailing list here</u>.

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Healthcare regulatory news

HHS <u>announced</u> the termination of 22 mRNA vaccine development projects under the Biomedical Advanced Research and Development Authority (BARDA), totaling around \$500M. Some vaccine experts have <u>stated</u> that the decision may harm the nation's ability to respond

rapidly to future pandemics – mRNA technology was used to produce several vaccines for COVID-19 and has potential applications for other infectious diseases and cancer.

CMS <u>issued</u> the FY 2026 Inpatient Rehabilitation Facilities (IRF) Prospective Payment System Final Rule, finalizing a 2.6% overall increase to IRF payment rates which reflects a 3.3% market basket update offset by a 0.7% productivity adjustment. The rule also eliminates COVID-19 vaccination reporting requirements, updates case-mix weights, wage index, and outlier thresholds, and removes certain social determinants of health data elements.

FDA <u>announced</u> its new "FDA Pre-Check" program for new drug manufacturing facilities, which will allow manufacturers to communicate more frequently with FDA during facility design, construction, and pre-production, <u>according to the agency</u>. The FDA Pre-Check program is being launched in response to President Trump's executive order directing FDA to "eliminate unnecessary regulatory requirements" to domestic manufacturing.



Healthcare law and policy news

In a new <u>report</u>, the GAO determined that the Trump administration violated the Impoundment Control Act of 1974 by withholding and terminating over 1,800 congressionally approved grants and reducing new awards for the NIH, resulting in approximately \$8B less in obligated grant funding between February and June 2025.

HHS Secretary Robert F. Kennedy Jr. <u>requested</u> that governors share state Medicaid data to enable the department to monitor health outcomes associated with specific medications, including GLP-1 drugs and SSRI antidepressants. According to Kennedy, three governors have already agreed to provide this data, which will be de-identified before being made publicly available to researchers.

Continuing the trend of unsuccessful legal challenges against the Medicare Drug Price Negotiation Program, this week Federal judges dismissed arguments against the constitutionality of the in Ohio, Connecticut, and Texas. In Ohio and Connecticut, the 6th and 2nd District Courts of Appeals upheld decisions by lower courts to dismiss challenges to the program by the U.S. Chamber of Commerce and Boehringer Ingelheim, respectively. In Texas, U.S. District Judge David Alan Ezra dismissed a lawsuit brought by PhRMA with prejudice.



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