

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

The Trump administration finalized the <u>HTI-4 rule</u>, which includes several healthcare technology and interoperability provisions, including updated certification criteria for electronic

prior authorization, electronic prescribing, and real-time prescription benefit checks. The rule is <u>expected</u> to save \$19B in labor costs for clinicians and providers over 10 years and reduce administrative burdens.

A new Executive Order directs HHS to collaborate with the White House to develop a plan to stockpile a 6-month supply of active pharmaceutical ingredients (APIs) for 26 critical drugs as part of the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR). The order tasks HHS' Administration for Strategic Preparedness and Response, along with White House advisors, to identify the list of drugs and assess available funding to establish and operate the SAPIR repository.

NIH released <u>guidance</u> on the use of AI in research grant applications, stipulating that the agency may reject applications "substantially developed" by AI. The policy also limits principal investigators to submitting no more than 6 applications per calendar year, primarily to prevent undue strain on the NIH review process. The policy will become effective September 25, 2025.

The FDA is considering revoking the emergency use authorization for Pfizer's COVID-19 vaccine for healthy children under 5, which may limit vaccination options for young kids. The company is negotiating to retain the authorization, emphasizing the vaccine's continued safety and efficacy despite recent policy shifts in vaccination strategies.



Healthcare law and policy news

The MA market is <u>facing upheaval</u> as key players such as Humana and CVS pull back from less profitable areas and scale back benefits, while insurers like UnitedHealth continue to grow despite grappling with increasing medical expenses and other financial setbacks.

A group of House Democrats <u>raised concerns</u> to CMS Administrator Mehmet Oz about <u>WISeR</u>, a new Innovation Center pilot that will test AI-assisted prior authorization in the Medicare Fee-for-Service program starting in 2026. The group argued that the pilot will add administrative burdens and reduce access to necessary services for traditional Medicare

beneficiaries and urged CMS to provide clarity on implementation, noting that prior authorization can worsen patient outcomes.



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