



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

Center for Healthcare Regulatory Insight



October 6, 2023 | Issue 291

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 to this email with any comments or requests.

[> Subscribe here](#)



Healthcare regulatory news

HHS/Labor/Treasury are [seeking comments on requiring health plan coverage of over-the-counter preventive items/services](#) without cost-sharing or a prescription.

FDA [granted emergency use authorization](#) for Novavax's updated COVID-19 vaccine... FDA approved the [first biosimilar for Actemra](#)... FDA [issued draft guidance](#) aiming to [spur development of stimulant use disorder treatments](#)... Reagan-Udall Foundation [provided recommendations for FDA](#) to improve public communication and combat misinformation.

SAMHSA [awarded nearly \\$35M in grants](#) for behavioral health services and HIV prevention/care in underserved communities.

HHS [OIG estimated increased biosimilar use in 2021](#) could have decreased Medicare Part B and enrollee spending by \$179M (4%).

→



Healthcare law and policy news

The [continuing resolution](#) enacted last weekend [delays Medicaid DSH cuts and extends funding for several health programs](#), including community health centers, through November 17.

A federal court [denied Chamber of Commerce's request for injunctive relief](#), allowing [CMS to continue implementing](#) the Medicare Drug Price Negotiation Program... Manufacturers of [all 10 drugs selected for negotiation](#) agreed to participate in the process.

A [federal court struck down](#) an HHS rule allowing insurers [not to count drug manufacturer copay assistance toward patient out-of-pocket costs](#)... Cigna [will pay \\$172M to settle False Claims Act violation](#) allegations related to Medicare Advantage (MA).

US PTO's Patent Trial and Appeal Board [will review](#) one of Novo Nordisk's patents for Ozempic and Wegovy [following a challenge from Mylan](#); the Board [rejected two other Mylan challenges](#).

Sutter Health [finalized its acquisition of Sansum Clinic](#)... Lilly [plans to acquire Point Biopharma](#) (\$1.4B)... Sanofi is [exploring acquiring Mirati Therapeutics](#)... Sanofi and Teva will [collaborate \(up to \\$1.5B\) on development/commercialization](#) of an inflammatory bowel disease treatment... Viatrix [divested \\$3.6B in assets](#), including [its over-the-counter business](#) (\$2.17B)... Rock Health [reported digital health investment in Q3](#) (\$2.5B across 119 deals) was the second lowest quarter since Q4 2019.

Boehringer Ingelheim [launched an unbranded version of its Humira biosimilar](#), priced 81% cheaper than the original biologic... Alignment Health and Instacart plan to [launch co-branded MA plans](#) in 2024... Beginning next year, SCAN will [offer MA beneficiaries free or \\$11 monthly co-pays](#) for 13 name-brand drugs, including six subject to Medicare price negotiation.

Kaufman Hall [reported hospital monthly operating margins](#) were up 2.9% in August and 1.1% year-to-date.

→



Questions or comments, please send to us-hclspractice@kpmg.com.

kpmg.com/socialmedia



[Privacy](#) | [Legal](#)

You have received this message from KPMG LLP. If you wish to unsubscribe from Around the world of U.S. healthcare in 360 words or less, please [click here](#). If you wish to unsubscribe from all KPMG communications, please [click here](#).

KPMG LLP, 3 Chestnut Ridge Road, Montvale, NJ 07645

© 2023 KPMG LLP, a Delaware limited liability partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved. NDP295619-1E

The KPMG name and logo are trademarks used under license by the independent member firms of the KPMG global organization.