



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

Center for Healthcare Regulatory Insight



September 30, 2022 | Issue 240

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 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.

[› Subscribe here](#)

*\*\* Correction: In last week's edition of ATW 360 (September 23, 2022), we reported on "a bi-partisan Senate bill to [increase funding and training for mental health care providers](#) to address workforce shortages". The legislation is still being discussed; our note referenced the "proposed provisions for Senate Finance Committee (SFC) Bipartisan Mental Health Workforce discussion draft".*



## Healthcare regulatory news

A federal judge ruled [that HHS must restore full Medicare drug reimbursement to 340B hospitals](#) for the remainder of the year.

[CMS announced 2023 Medicare Part A and B premiums, deductibles, and coinsurance amounts](#) and Part D income-related monthly adjustment amounts.

[FDA approved Amylyx Pharmaceuticals' drug, Relyrio](#), to treat Lou Gehrig's disease.

[FDA proposed new rules](#) revising requirements for using “healthy” in food labeling... [FDA issued final guidance](#) clarifying its regulatory oversight on Clinical Decision Support (CDS) software functions... [FDA released a report](#) stating that aspects of its adaptive regulatory approach, the Software Precertification Pilot Program, are not practical to implement under current statutory or regulatory authorities.

The [Biden Administration announced: \(1\)](#) \$1.5B in funding to support states’, tribal lands’, and territories’ efforts to address the opioid crisis; (2) \$20.5M to increase access to community resources, (3) \$104M to expand access to substance use treatment; and, (4) [more than \\$8B from over 100 organizations to](#) address hunger and nutrition.

---



## Healthcare law and policy news

Senate and House leaders [agreed](#) to [reauthorize FDA user fee programs through 2027, with FDA policy riders deferred for consideration as part of the year-end appropriations package](#).

Stat News reported on CMS’ [plans](#) to [establish a new division](#) to implement the Medicare drug price negotiation and inflation rebate provisions of the Inflation Reduction Act... [AHA and AMA, and others requested](#) that HHS postpone implementation of electronic health information blocking rules.

[Biogen will pay \\$900M](#) to settle False Claims Act allegations that it provided kickbacks to physicians... [Centene will pay \\$14M](#) to Massachusetts to resolve claims it overcharged for Medicaid pharmacy services... [a federal judge allowed an anti-poaching class-action lawsuit against Surgical Care Affiliates, DaVita and Surgical Partners International](#) to proceed.

New studies found: (1) [telemedicine was associated with significantly better \(or no difference\) in 13 of 16 quality measures as compared to “in office” care](#); (2) [double bonuses in Medicare Advantage are not associated with improvements in clinical or administrative plan performance](#); (3) [43% of working-age adults were under-insured in 2022](#).

A [report from the American Association for Cancer Research](#) predicted increased incidence of late-stage cancer next year due to a decline in early detection during the COVID-19 pandemic.

---

## Special Section: COVID-19 and Monkeypox News

The [CDC updated guidance](#) on masking in hospitals and nursing homes; facilities in communities with low levels of COVID-19 transmission can choose not to require doctors, patients, and visitors to wear a mask.

The [FDA updated its policy on Emergency Use Authorization](#) (EUA) for COVID-19 tests, stating that they will only review a small subset of new EUA requests.

Pfizer and Moderna [asked the FDA](#) to authorize their omicron boosters for children aged 5 to 11.

The White House announced the [expansion of the National Monkeypox Vaccine Strategy](#) to include pre-exposure prophylaxis.

---

New [CDC data showed](#) that eligible individuals who did not receive the monkeypox vaccine were 14 times more likely to become infected.

---



Questions or comments, please send to  
[us-hcinsight@kpmg.com](mailto:us-hcinsight@kpmg.com).

---

[kpmg.com/socialmedia](https://kpmg.com/socialmedia)



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

This email was sent by KPMG LLP, 3 Chestnut Ridge Road, Montvale, NJ 07645

© 2022 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. NDP295619-1A

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