

## **September 8, 2025 | Issue 384**

### 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>.

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

The CMS Innovation Center <u>announced</u> changes to the Achieving Healthcare Efficiency through Accountable Design (AHEAD) Model, extending its end date to December 31, 2035, with new requirements for states beginning in January 2026 to implement policies promoting "choice and competition," and a population health accountability plan focused on preventive care and chronic disease prevention.

HHS <u>plans to</u> intensify enforcement against healthcare entities that engage in information blocking, a practice that restricts patient access to their electronic health information. The initiative comes amid ongoing implementation of the <u>21st Century Cures Act</u>, which mandates timely, electronic access to health information.

CMS provided additional information about the <u>Rural Health Transformation Program</u>, emphasizing strategic goals to enhance access, quality, and sustainability of care in rural communities. The agency shared a timeline, stating the Notice of Funding Opportunity will be released by mid-September, with state application deadlines set for early November.

FDA will now <u>release</u> Complete Response Letters (CRLs) in real time, publishing them promptly after issuance to drug developers and making all related letters for approved applications available publicly. As part of this effort, the agency has also posted a previously unpublished batch of 89 CRLs issued since 2024.



# Healthcare law and policy news

HHS Secretary Robert F. Kennedy Jr. <u>testified</u> before the Senate Finance Committee amid scrutiny over major changes at the CDC, including the departure of director Susan Monarez and proposed budget cuts. Senators questioned Kennedy on broader federal health system reforms, vaccine policy shifts, and funding reductions, which have raised concerns about the impact on public health programs and scientific research.

Florida Surgeon General Joseph Ladapo <u>announced</u> plans to eliminate all vaccine mandates in the state, including those for schoolchildren, making Florida the first state to seek complete repeal of immunization requirements. The repeal process will likely require legislative action and face <u>potential</u> legal challenges.

According to CMS, Medicare Shared Savings Program Accountable Care Organizations (ACOs) generated a record \$2.4B in net savings for Medicare in 2024, with 75% of participating ACOs earning performance payments for meeting financial and quality benchmarks.



Please send your questions or comments to <u>us-hclspractice@kpmg.com</u>.

### KPMG. Make the Difference.

Learn about us:



kpmg.com



Some or all of the services described herein may not be permissible for KPMG audit clients and their affiliates or related entities.

### Privacy | Legal

You have received this message from KPMG LLP. If you wish to unsubscribe from this publication or from other KPMG communications, please click <a href="https://example.com/here-to-visit-your-kPMG">here-to-visit-your-kPMG</a> Communication Preferences Center. To unsubscribe from all KPMG communications, click here.

© 2025 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.

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

USCS030123-1B