

June 9, 2025 | Issue 373

Editor's note

This note is produced by KPMG's Federal Healthcare Advisory Practice and is intended to be short and succinct, less than 360 words, to provide a digestible bite of news relevant to our clients and practices. Links are provided to source material (proposed and final regulations, agency guidance and press releases, reports, research, etc.) when available.



Healthcare regulatory news

HHS released its <u>proposed budget</u> totaling nearly \$95B for FY 2026, a 25% reduction compared to FY 2025. The proposal includes significant departmental reorganization, creating a new Administration for a Healthy America (AHA) by merging HRSA, SAMHSA, select CDC programs, and other agencies. Additionally, oversight of the 340B Drug Pricing Program would shift from HRSA to CMS.

FDA has <u>launched</u> Elsa, an agency-wide generative AI tool designed to help employees work more efficiently by streamlining complex review tasks and enhancing data analysis. Built within a high-security GovCloud environment, the tool aims to modernize FDA operations, accelerate scientific reviews, and improve overall agency efficiency.

CMS intends to introduce several new technology-focused initiatives, including the development of a national provider directory, a new identity verification processes for Medicare beneficiaries, digital insurance cards, and expanded access to patient data through APIs.

FDA has granted de novo authorization to Clairity for the <u>first Al tool</u> designed to predict five-year breast cancer risk using routine screening mammograms, rather than relying solely on traditional risk factors like age or family history. Clairity intends to launch the tool in health systems through 2025.





According to a report from the WSJ, Humana supports legislative reforms to limit MA billing practices that generate billions in extra payments, specifically targeting diagnoses added from home visits that are often not linked to medical encounters or direct treatment.

According to the latest CBO estimates, the One Big Beautiful Bill (H.R.1) that passed the House would result in nearly 11M people losing health insurance, with an additional 5.1M losing coverage due to expiring ACA subsidies and other program changes. The bill achieves federal savings primarily through mandatory nationwide Medicaid work requirements and enrollment policy changes, as well as restrictions on ACA Exchange eligibility.

Provider groups and ACOs have requested that Congress restore and extend the Medicare Advanced Alternative Payment Model (APM) incentive bonuses, emphasizing that the payments are critical for covering investments in care improvements and coordination. Bipartisan legislation in the House was introduced this year to reinstate the bonuses but has not made it through the committee process.





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