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#### 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

FDA <u>published</u> over 200 Complete Response Letters (CRLs) issued between 2020 and 2024, revealing detailed reasons why drug and biologic applications were initially rejected. According to the agency, the initiative aims to improve transparency; however, a former FDA associate commissioner <u>noted</u> the released documents were already available to the public as part of the standard approval process.

CMS proposed cutting Medicare payments to home health providers by 6.4% next year, which would decrease total spending by more than \$1.1B. The Medicare Payment Advisory Commission called for a 7% payment reduction this past March, noting home health agencies are getting payments that "are substantially in excess of costs."

CMS released its annual Risk Adjustment Summary Report, announcing it will redistribute \$10.4B in ACA marketplace risk-adjustment payments among insurers for the 2024 plan year. Notably, risk adjustment transfers declined as a percentage of premiums, to 8.9% from 10.3% in 2023.





# Healthcare law and policy news

Newly signed into law, <u>H.R. 1 (One Big Beautiful Bill Act)</u> enacts mandatory Medicaid work requirements, tightens Medicaid eligibility checks, and imposes new cost-sharing for expansion adults starting in 2028. The law also allocates \$50B to support rural health providers, imposes stricter Marketplace eligibility policies and prohibits subsidies for certain

immigrants, and increases the Medicare physician fee conversion factor by 2.5% for 2026.

According to <u>new data</u> from the CDC, nearly 1 in 3 adolescents aged 12 to 17 (approximately 8.4M teens or 32.7% of the adolescent population) had prediabetes in 2023, putting them at increased risk for type 2 diabetes, heart disease, and stroke.

Medical organizations, including the American Academy of Pediatrics and the American Public Health Association, <a href="https://have.sued">have.sued</a> HHS Secretary Robert F. Kennedy Jr. for changing COVID-19 vaccine recommendations by removing guidance without input from federal advisory groups. The <a href="https://lawsuit.auksuit.com/lawsuit">lawsuit</a> alleges these actions undermine established vaccine science and bypass required procedures.

The Supreme Court, in an <u>apparent 8-1 ruling</u>, lifted a lower court injunction blocking the Trump administration's directive for mass layoffs across several federal agencies. The ruling permits the executive branch to proceed with significant workforce reductions while not ruling on the legality of specific layoff plans.





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