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Editor's note

This series 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 subscribe to our mailing list here.

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🏛 **Healthcare regulatory news**

CMS released the annual proposed rule for the MA and Part D prescription drug programs, which included a proposal to cover anti-obesity medications (AOMs) for weight loss under both Medicare and Medicaid programs; The agency explained the policy as a reinterpretation of existing statute, which has traditionally prohibited Medicare from covering weight loss drugs... If finalized, CMS estimated federal spending on GLP-1 drugs would increase by $36B over a 10-year period.

New guidance issued by FDA requests that sponsors of digital technology, such as over-the-counter mobile medical apps, submit predetermined change control plans prior to incorporating AI capabilities.

CMS finalized the six-year Increase Organ Transplant Access Model... The final rule maximizes payment to hospitals and removes a health equity performance adjustment but does not provide guidance on dedicated navigators for donors and recipients, as requested by bipartisan Congressional members.

📄 Healthcare law and policy news

SAMHSA has released additional resources to help communities address gun violence and the resulting mental health and trauma implications. Gun violence has risen significantly since 2020, particularly in low-resource communities, and has been linked to the mental health crises exacerbated by the COVID-19 pandemic.

A bipartisan group of senators introduced the Rural Hospital Flexibility Act, which aims to permanently authorize the Medicare Rural Hospital Flexibility (FLEX) program, a program that provides states with funding to support critical access hospitals.

NIH researchers developed an AI based algorithm that assists clinicians in matching eligible patients to relevant clinical research trials listed in ClinicalTrials.gov; researchers hope this algorithm will identify and enroll patients in appropriate trials more quickly.

According to the CDC, less than 42% of individuals eligible for private health plans were enrolled in high deductible health plans (HDHPs)... Studies show that the high upfront cost of HDHPs have led individuals to forgo both necessary and optional care.

Since 2010, over 500 rural and urban hospitals have closed their labor and delivery departments, according to a JAMA study, which researchers attribute to the marginal profits generated by maternity wards. In areas with limited access to maternity care, pregnant people

[are more likely](#) to give birth in emergency rooms or outside of a hospital, increasing their risk for pregnancy-related complications.

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