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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>.

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Healthcare regulatory news

FDA is <u>removing</u> the "boxed warning" from certain hormone replacement therapy products used for menopause, noting the warnings were based on outdated studies and deemed misleading. This change affects low-dose estrogen products and is intended to provide more accurate information for women and doctors making treatment decisions.

Federal health officials have again <u>proposed</u> a temporary extension of the pandemic-era rules that allow for the remote prescription of controlled substances, including medications

for opioid use disorder and ADHD treatments. The <u>latest extension</u> pushes the deadline forward another year, giving agencies more time to finalize permanent regulations for telehealth prescribing.

In response to a landmark "n-of-1" gene-editing case, the FDA wants to develop a <u>more</u> <u>robust pathway</u> for developing similar individualized therapies. The outline aims to provide a clear regulatory pathway for researchers to scale these unique treatments efficiently for future patients.



Healthcare law and policy news

The recent federal government shutdown <u>concluded</u> following a temporary funding agreement for much of the government through January 30, 2026, which did not include a resolution on the expiring ACA premium tax credits. While the deal included the promise of a future vote on the ACA subsidies, there is still no consensus on the details of such an extension.

Publicly traded health insurers <u>continued to report</u> margin pressure in government programs in Q3 of 2025 due to a range of factors, including higher medical costs, regulatory changes, and risk pool deterioration. Companies have taken a variety of actions to turn profitability around, including paring back benefits and exiting certain markets.

Some state insurance regulators <u>are urging</u> Medicare Advantage insurers to restore compensation to brokers, which insurers had cut to control rising costs. Regulators in several states argue these cuts are unfair trade practices intended to limit enrollment and have issued warnings and cease-and-desist orders.

Michigan's Department of Health and Human Services is <u>offering</u> up to \$9.5M in grants that would expand mobile behavioral health crisis intervention services. Eligible entities include local public entities and health departments as well as federally recognized tribal governments.



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