



# Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



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Editor's note

**Due to the holidays, we are providing an early issue of ATW 360 this week and will not publish next Friday, December 30<sup>th</sup>. We'll be back with our next issue on January 7<sup>th</sup>. The KPMG Center for Healthcare Regulatory Insight team wishes you the best of the holiday season and a great New Year!**

*This note is produced every Friday by the [KPMG Center for Healthcare Regulatory Insight](#) and is intended to be short and succinct, no more than 360 words, to provide a digestible bite of healthcare and life sciences news from the past week. Please share this email with colleagues and other interested individuals, and encourage them to [subscribe to our mailing list here](#).*

We welcome your feedback. Let us know if KPMG can help. Please [reply here to me](#), **Larry Kocot**, principal and national leader, KPMG Center for Healthcare Regulatory Insight or simply reply to this email with any comments or requests.

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Healthcare regulatory news

CMS [proposed standards](#) for [electronic health care attachments transactions](#).

HHS [released ownership information](#) for all 7,000+ Medicare-certified hospitals... HHS will [award \\$130B+ in 988 Suicide & Crisis Lifeline](#) grants.

NIH [launched a research network](#) to test efficacy of harm-reduction services/tools.

FDA [approved the first gene therapy](#) for high-risk, non-muscle-invasive bladder cancer... FDA [declared](#) a [shortage of Lilly's diabetes drug](#) Mounjaro... FDA [lifted a partial clinical hold](#) on studies of Bluebird bio's sickle cell disease therapy... FDA [revised guidance](#) on [applicant timeframes for responding to complete response letters](#) to abbreviated new drug applications.

An [FDA-commissioned report](#) found the agency's Center for Tobacco Products [has not effectively regulated the industry](#), particularly vaping products.

A DEA investigation [found Truepill filled illegitimate prescriptions](#) (from unlicensed providers or surpassing 90-day supply limits) for ADHD treatments.

OIG reported [Medicare Part B spending on lab tests increased 17% last year to \\$9.3B](#), driven by COVID-19 tests and demand for genetic tests... OIG [recommended](#) CMS issue instructions/guidance to administrative contractors to [improve review of Medicare bad debt](#) reimbursement claims.



#### Healthcare law and policy news

Congress is expected to pass and President Biden to sign [an omnibus FY2023 appropriations bill](#) on funding. The package includes several [healthcare policy provisions](#) including: reducing Medicare physician payment cuts to 2% in 2023 and 3.5% in 2024; allowing states to begin Medicaid eligibility redeterminations in April, regardless of when the PHE ends; extending pandemic telehealth policies by two years; extending hospital at-home waivers for two years; [reforms](#) to the FDA Accelerated Approval pathway; and, extending Advanced APM bonus payments for an additional year at 3.5%.

Cooper University Health Care and Cape Regional Health System [plan to merge](#), creating a \$2.2B system... Kite [will acquire Tmunity Therapeutics](#)... Signify Health and Ardent Health Services [expanded their accountable care](#) partnership.

*Wall Street Journal* reported on (1) [shortcomings of online mental health](#) company offerings and (2) [340B Program spending accountability](#).

The Joint Commission will [make major revisions](#) to its quality and safety standards, including retiring 14% of its quality standards, effective January 1 and [announced a Health Care Equity certification](#) program.

KFF reported ACA [benchmark silver plan premiums are increasing](#) on average by 4.1% in 2023.

## Special Section: COVID-19, Respiratory Illnesses, and Monkeypox News

FDA's Vaccines and Related Biological Products Advisory Committee [will meet January 26<sup>th</sup> to consider](#) whether to update the primary series of COVID-19 vaccines to a bivalent version.

USAg and the National Council on Aging [will receive a combined \\$125M](#) from HHS to bolster efforts to vaccinate the most at-risk older Americans and people with disabilities for COVID-19 and the flu.

The Supreme Court [temporarily halted](#) the end of the Title 42 immigration policy, pending the court's decision on whether to hear a Republican-led states' challenge to keep the policy in place.

ICER [cut its suggested price range](#) for Pfizer's Paxlovid [by more than 80%](#) to reflect common thresholds of cost-effectiveness.

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Questions or comments, please send to  
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