



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

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Editor's note

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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Special Supplements

The Center for Healthcare Regulatory Insight is pleased to release two Center Insight Briefs for public distribution:

- 1) [A summary of Part D benefit-related provisions of the Inflation Reduction Act](#), along with insights on how these changes could affect financial incentives and market response of Part D plan sponsors and pharmaceutical manufacturers; and,
- 2) [A summary of three CMS Innovation Center model concepts](#) recently announced to reduce beneficiary prescription drug costs and ensure continued access to innovative products, along with details on anticipated timelines and next steps for implementation.



Healthcare regulatory news

HHS released a [cybersecurity implementation](#) guide... HHS OIG [recommended CMS begin requiring Medicare Advantage Organizations](#) to definitively indicate on encounter data records when payment for a service has been denied.

FDA [granted priority review for approval](#) of Biogen-Eisai's Alzheimer's treatment lecanemab... FDA Commissioner Robert Califf indicated he would like [agency advisory committees to move away from voting](#) on every product approval recommendation... FDA [proposed](#) new [tobacco product manufacturing requirements](#)... FDA [updated mammography](#) regulations.

ONC's [annual report to Congress](#) included recommendations to support access/exchange/use of electronic health information. FTC [extended to April 19](#) the comment period for its proposed rule banning noncompete clauses.

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Healthcare law and policy news

President Biden [released his FY2024 Budget](#), which would reduce the deficit by \$2.9T over a decade and [increase 2024 HHS discretionary spending by 11.5%](#) to \$144.3B. The budget includes: [a plan to extend Medicare solvency](#) by increasing taxes on individuals earning \$400,000+ and expanding IRA drug pricing reforms; \$2 cost-sharing for chronic condition generic drugs in Part D; permanent enhanced ACA subsidies; no cost-sharing for three mental/behavioral health visits annually; a [\\$35/month insulin cap](#) for all Americans; and a [national testing/treatment/prevention](#) program for hepatitis C.

Transarent plans to [acquire 98point6's AI-powered virtual care platform](#) and care business... WeightWatchers [acquired digital health company Sequence](#)... Atrium and Best Buy [will partner on a hospital-at-home](#) program.

A [federal circuit court upheld](#) a Patent Trial and Appeal Board decision that a University of Minnesota hepatitis C treatment patent was overly broad.

STAT reported [Eli Lilly will save roughly \\$150 in Medicaid rebates](#) per insulin vial by lowering the list price of its insulin.

A [study found 13%](#) of accelerated approval drug labels [failed to comply with 2019 labeling transparency guidance](#).

A [Health Affairs study found 54% of the public trusted doctors “a great deal,”](#) compared to just 37%, 26%, and 25% for the CDC and local and state public health departments, respectively... A [Medscape survey found](#) 24% of physicians report clinical depression and [9% had suicidal thoughts](#) in 2022.

House Energy and Commerce Health Subcommittee [advanced](#) legislation to [permanently classify fentanyl-related substances](#) as schedule I drugs and [prohibit use of quality-adjusted life years](#) (QALYs) in coverage/payment decisions for federal programs.

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Special Section: COVID-19, Other Respiratory Illnesses, and mpox News

A [district court ordered HHS](#) to stop enforcing a Trump Administration rule that [resulted in some Medicaid beneficiaries losing coverage](#) in violation of continuous coverage policy in place for the pandemic. FDA [granted marketing approval](#) of the [first COVID-19 antigen test](#) using the traditional premarket review process.

A [JAMA study found people](#) experiencing long COVID symptoms for one year had a higher risk of cardiovascular complications, such as stroke, and respiratory complications, including asthma... A [preprint study found COVID-19 bivalent booster dose protection](#) against death and hospitalization in elderly people began to wane as soon as two months after vaccination.

Several states, including progressive states such as [California, Oregon, and Washington](#), are formally ending mask requirements within the next month.

GlaxoSmithKline and Pfizer [hope to launch their respective RSV vaccines](#) in the US this year.

The US will [lift COVID-19 testing requirements on travelers](#) from China.

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Questions or comments, please send
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