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#### Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare</u> <u>Regulatory Insight</u> 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 <u>subscribe to our mailing list</u> <u>here</u>.

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## Healthcare regulatory news

FDA granted accelerated approval to Eisai-Biogen's Alzheimer's treatment Leqembi, priced at \$26,500/year (higher than ICER's value estimate: \$8,500-\$20,600)... FDA approved a first-of-its-kind combination adult asthma rescue inhaler... FDA advisory committees will meet February 15 to discuss Emergent BioSolutions' over-the-counter naloxone application.

*Wall Street Journal* reported FDA is <u>increasingly placing holds on clinical trials</u> of experimental treatments.

CMS <u>released a timeline</u> for the first year of the Medicare Drug Price Negotiation Program and <u>encouraged stakeholder feedback/insights...</u> CMS released <u>guidance for states</u> to prepare for termination of Medicaid

continuous enrollment on March 31 and <u>help beneficiaries maintain</u> continuity of coverage.

HHS <u>awarded \$245M to SAMHSA and HRSA</u> to support youth mental health and the mental health workforce.

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# Healthcare law and policy news

MedPAC <u>recommended increasing</u> 2024 Medicare physician (1.25%) and hospitals (1%) payments.

A record <u>15.9M individuals have selected</u> ACA plans... KFF estimated <u>5M uninsured individuals could enroll in coverage</u> with virtually no premiums.

A <u>district court remanded</u> the issue of \$1B+ in 340B underpayments back to <u>HHS to devise a remedy</u>.

California <u>sued insulin manufacturers and PBMs</u> for unlawfully increasing insulin price.

AstraZeneca will acquire CinCor Pharma (\$1.8B)... BioNTech acquired InstaDeep (\$682M)... CVS invested \$100M in Carbon Health to pilot primary/urgent care clinics in its retail stores and is exploring acquiring Oak Street Health (\$10B+)... Blues plans and affiliated companies launched Synergie, a medication contracting organization to improve physician-administered drug affordability/access... Mark Cuban Cost Plus Drugs will partner with RxPreferred Benefits to lower employer plan drug prices.

AAP <u>recommended for the first time</u> that physicians <u>offer weight-loss drugs to children with obesity.</u>

A <u>JAMA</u> study found tele-mental health use during the pandemic offset decreased in-person care and generated higher utilization for several mental health conditions, as compared to pre-pandemic... <u>Health Affairs</u> studies found 1) private equity-acquired physician practices <u>rely more heavily on advanced practice providers</u> (e.g., NPs and PAs); 2) hospitalization rates for birthing people within 60 days of birth <u>decreased 17% in states that extended postpartum</u> Medicaid coverage; and 3) Black medical trainees are <u>significantly more likely to carry heavier debt burden</u> than other racial/ethnic peer groups... US <u>cancer deaths have fallen 33%</u> since 1991.

AHCA reported 84% of nursing homes face moderate/high staffing shortages.



HHS <u>renewed the COVID-19 public health emergency (PHE)</u>; HHS is reportedly considering allowing the <u>PHE to expire as early as April.</u>

Moderna plans to charge between \$110 and \$130 per COVID-19 vaccine once government purchasing ends, similar to the pricing of Pfizer and BioNTech for their vaccine.

Department of Defense <u>removed its COVID-19 vaccine mandate</u> for service members and announced plans to <u>overhaul its approach to countering</u> biological and chemical threats.

FDA reported <u>AstraZeneca's COVID-19 preventive monoclonal antibody drug.</u> <u>Evusheld, is likely not effective</u> at neutralizing infection from the XBB.1.5 variant... Regeneron is developing a COVID-19 monoclonal antibody that <u>could be effective against all known variants, with</u> clinical trials planned to begin this year.





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