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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.

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Healthcare regulatory news

FTC and Department of Justice released draft Merger Guidelines updates... FTC also: (1) withdrew two "outdated" antitrust enforcement policy statements; (2) released a statement cautioning against reliance on previous statements/studies on PBMs that no longer reflect current market realities; (3) requested additional information on Pfizer's proposed acquisition of Seagen; and, (4) sued to block IQIVIA's acquisition of Propel Media... FTC and OCR warned 130 hospitals/telehealth providers that third-party tracking technologies may impermissibly disclose PHI.

CMS proposed removing its national coverage determination for amyloid plague detection PET scans and allow MACs to make coverage decisions, supporting increased access to new Alzheimer's drugs.

CMS <u>ordered a half-dozen states to pause procedural-based Medicaid terminations</u> to correct redetermination errors and reinstate wrongly-terminated individuals... CMS-Treasury-Labor <u>urged employers/plans to extend</u> special enrollment periods for those losing Medicaid coverage.

FDA <u>approved the first monoclonal antibody</u> to prevent RSV in infants/newborns.

OIG: (1) reported Medicaid managed care plans denied 12.5% of prior authorization requests in 2019 with insufficient oversight; and, (2) projected 19% of \$4.2B in COVID-19 Uninsured Program payments were improper between March 1-December 31, 2020.

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Healthcare law and policy news

Johnson & Johnson <u>sued</u> to stop <u>the Medicare Drug Price Negotiation</u> <u>Program</u>.

Novartis <u>acquired DTx Pharma</u>... TPG <u>will acquire Nextech</u> (\$1.4B)... Big Health <u>is acquiring Limbix</u>.

Eli Lilly reported its Alzheimer's drug donanemab significantly delayed Alzheimer's disease progression in a late-stage trial; an FDA approval decision is expected by year-end... Flagship and Pfizer are each investing \$50M to co-discover/develop 10 potential drugs... Teladoc and Microsoft expanded their partnership to integrate Al and ambient clinical documentation into the Solo virtual care platform.

KFF analyses found: (1) 29% of nursing homes would meet staffing requirements recommended in a CMS-commissioned report; and, (2) health-related spending accounted for 15% of Medicare households' 2021 total spending, compared to 7% for non-Medicare households... AMA reported the share of physicians in private practices fell from 60.1% to 46.7% between 2012 and 2022... A JAMA study concluded COVID-19 relief funding may have been "larger than necessary for many hospitals," as evidenced by all-time high operating margins for some hospitals.

House Energy and Commerce Committee <u>advanced</u> 15 <u>healthcare bills</u>, <u>many along party lines</u>... Senate HELP Committee <u>advanced PAHPA</u> <u>reauthorization legislation</u>.



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