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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 here</u>.

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





Healthcare regulatory news

CMS will cover FDA-approved amyloid-targeting Alzheimer's drugs <u>if the prescribing physician participates in a clinical registry.</u>

OMB is reviewing proposed rules for: (1) <u>potential remedies</u> for <u>unlawful</u> <u>340B hospital payment rate cuts</u> from 2018-2022; and, (2) long-term care facility <u>minimum staffing standards</u>.

FDA approved Pfizer's RSV vaccine for individuals age 60+... FDA proposed a new, standardized one-page Patient Medication Information document requirement for prescription drug labels... FDA issued warning letters to 30 retailers of unauthorized disposable e-cigarettes.

HHS <u>lifted COVID-19 vaccination/testing requirements</u> for healthcare workers, while <u>encouraging vaccination through quality reporting and value-based incentives</u>.

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Healthcare law and policy news

The House (314-117) and Senate (63-36) passed <u>legislation</u> to suspend the debt ceiling until January 2025. It would also <u>claw back approximately</u> \$28B in <u>unspent COVID-19 funds</u>, while retaining \$5B for Project NextGen; <u>cap discretionary spending</u> for FY2024 and FY2025; and <u>expand SNAP</u> <u>work requirements</u>. President Biden will sign the bill.

President Biden reportedly <u>plans to nominate Mandy Cohen</u> as CDC Director.

A federal <u>appeals court ruled</u> that the <u>Sackler family is shielded from current/future opioid epidemic-related civil claims</u> due to their contribution to Purdue Pharma's bankruptcy settlement... Eli Lilly will: (1) <u>pay \$13.5M to settle a class-action suit</u> alleging it systematically overpriced insulin, and (2) continue its \$35/month cap on out-of-pocket insulin costs for four years.

BJC and Saint Luke's plan to merge into a 28-hospital, \$10B system... Coherus BioSciences plans to sell a Humira biosimilar at a 85% discount (\$995/carton) and partner with Mark Cuban Cost Plus Drug Company to make it available for about \$579... OptumRx launched initiatives to support independent and rural pharmacies in addressing care gaps, including in maternal/fetal health... Oak Street Health will expand into four additional states (25 total).

Altarum reported healthcare prices increased 3.4% year-over-year in April, the fastest rate since December 2007... Definitive Healthcare reported utilization at retail clinics has increased 200% over the past five years... A JAMA study found the forthcoming Medicare Part D \$2,000 out-of-pocket cap could lower costs for 125,000+ beneficiaries using "ultra-expensive" drugs as they switch from commercial insurance to Part D coverage.

KFF Health News reported 600,000+ Medicaid beneficiaries have been disenrolled since April 1, a majority due to "procedural reasons."

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