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#### Editor's note

This note is produced every Friday by the <u>KPMG Center for Healthcare 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 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.

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# Healthcare regulatory news

FDA approved GlaxoSmithKline's Boostrix, a vaccine for mothers in the third trimester to prevent pertussis in infants... FDA approved scPharmaceuticals' Furoscix, to treat chronic heart failure... FDA's Center for Devices and Radiological Health launched its Total Product Life Cycle Advisory Program Pilot.

IRS finalized a rule fixing the "family glitch" in the Affordable Care Act by basing eligibility for premium tax credits on the employee's share of the cost of covering both self and family members.

CMS officials wrote that the agency is considering an expedited coverage pathway for novel medical devices.

USDA invested \$110M to help 208 rural health care organizations expand critical services.



<u>President Biden will sign an executive order</u> directing HHS to outline how it will use new payment/care models to cut drug costs.

NIH funded a research project to collect data and develop AI to diagnose patients based on their speech.

Walmart launched its Healthcare Research Institute (WHRI) to help diversify clinical trials... Cost Plus Drugs, Mark Cuban's lower-cost prescription drug company, is <u>partnering with Capital Blue Cross... Illumina is partnering with AstraZeneca</u> to expand Al drug discovery... Walgreens Boots Alliance will complete acquisition of CareCentrix for \$392M... Brave Health raised \$40M in series C funding to increase access to behavioral health for Medicaid populations... Bright Health is discontinuing all plans on ACA exchanges and cutting MA offerings.

Medical Group Management Association's (MGMA) annual regulatory burden report showed that prior authorization and good faith estimate requirements were a top source of frustration for medical practices... Kaufmann Hall reported merger and acquisition transactions between hospitals and health systems remained low in Q3.

New studies found: (1) the <u>number of liver cancer deaths could increase</u> by over 55% by 2040; (2) <u>inflation could increase health benefit costs by 10% in 2023</u>.

A Kaiser Health News investigation found that very few hospitals have specialists to treat addiction or related conditions... A New York Times review of federal lawsuits found that 8 of the 10 largest MA insurers faced federal lawsuits for overpayments.

The U.S. Preventative Services Task Force recommended <u>anxiety screenings for children 8 and older</u> and <u>depression screenings for children 12 and older</u>.

### Special Section: COVID-19 and Monkeypox News

Xavier Becerra, Secretary of HHS, extended the COVID-19 Public Health Emergency by 90 days.

An HHS report found that <u>COVID-19 vaccines prevented over 300,000 deaths in adult Medicare beneficiaries last year</u>, saving the program over \$16B in medical costs.

Dr. Ashish Jha, head of the White House COVID Task Force, <u>said that there are three or four subvariants that the Task Force is closely monitoring</u> due to the variants having more immune invasiveness or their ability to render treatments ineffective.

FDA authorized Moderna and Pfizer-BioNTech Bivalent COVID-19 vaccines for children aged 6 and older and 5 and older respectively.

Novavax announced the booster dose of its COVID vaccine produced antibodies against several Omicron variants.

The FDA granted Emergency Use Authorization to Abbott's Alinity m MPXV test for monkeypox.

Questions or comments, please send to

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