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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 <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 <u>guidance directed</u> No Surprises Act independent dispute resolution arbitrators to resume processing decisions and to more directly consider multiple factors when determining the payment amount.

The Medicare Advantage VBID Model will be extended through 2030.

ONC is <u>considering new EHR certification</u> requirements to facilitate electronic prior authorization.

ASPE reported <u>40M+ individuals are enrolled</u> in ACA-related Marketplace or Medicaid expansion coverage.

HRSA will <u>rebid its contract to manage</u> the country's organ procurement and transplantation network and launched <u>a dashboard with data</u> on donors, recipients, and waitlist outcomes.

Despite concerns about full approval, an FDA advisory committee recommended accelerated approval (i.e., conditional) for Biogen's ALS drug... A senior FDA official said the agency should start using the Accelerated Approval pathway for gene therapies.



Healthcare law and policy news

Senate Homeland Security and Governmental Affairs Committee reported on health and national security risks of drug shortages, which increased 30% from 2021 to 2022... The White House set a goal of producing at least 25% of all small-molecule drug active pharmaceutical ingredients in the US within five years.

In response to a Congressional inquiry, CBO reported that <u>mandatory</u> <u>healthcare spending from 2010-2020 was 9% lower than projected</u> due to lower government spending per beneficiary (totaling \$1.1T); 2019 net spending for Medicare Part D drugs, in particular, was overestimated.

Hospitals <u>sued HHS to recoup tens of millions</u> in delayed DSH payments owed due to a miscalculation.

DOJ and state attorneys general <u>dropped their appeal</u> of the UnitedHealth-Change Healthcare merger.

NIH <u>denied a petition to use march-in rights</u> to lower the price of Pfizer-Astella's prostate cancer drug, Xtandi; petitioners <u>appealed the decision</u>.

Microsoft and Nuance will <u>add OpenAl's GPT-4 to its latest clinical</u> <u>documentation application</u>... Cleveland Clinic and IBM <u>unveiled the first</u> <u>quantum computer dedicated to biomedical research...</u>

California <u>contracted with CivicaRx to produce state-labeled insulins</u> costing no more than \$30/vial.

North Carolina <u>passed</u>, <u>and the governor will sign</u>, legislation to expand Medicaid.

Senate Commerce Committee advanced a bipartisan PBM transparency bill... meanwhile, a bipartisan group of House members introduced legislation to ban the use of spread pricing by PBMs in Medicaid.

Novo Nordisk-funded research from NORC found $\underline{42\%}$ of US adults are living with obesity.

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Special Section: COVID-19 News

The White House will <u>disband its COVID-19 response team</u> after the public health emergency ends in May.

President Biden <u>signed legislation to declassify intelligence</u> on COVID-19 origins... Following findings that the <u>pandemic may have originated from infected racoon dogs</u>, WHO advisors <u>urged China to release all information on the origins</u> of COVID-19.

Moderna expects to price its COVID-19 vaccine at around \$130/dose in the US as purchases move to the private sector.

A COVID States Project's report concluded just 75% of US adults have received at least one COVID-19 vaccine, significantly lower than the 92.1% reported by the CDC... FDA is considering whether to recommend additional Omicron-specific COVID-19 booster doses for older adults and other vulnerable individuals.

A <u>Lancet study found</u> that COVID-19 "magnified the polarization and persistent social, economic, and racial inequities that already existed across US society," with significant variation in impacts across states based on their respective responses... A <u>JAMA study found</u> that the antiviral nirmatrelvir, one of the two pills in Paxlovid, could cut the risk of developing long COVID if given within five days of testing positive.

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