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Editor's note

Since we did not publish on July 7th, we've included a brief roundup of significant news from the week of July 3rd.

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</u> to our mailing list here.

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.





Healthcare regulatory news

CMS proposed decreasing the 2024 <u>physician payment conversion</u> <u>factor 3.34%</u>, increasing <u>hospital outpatient payments 2.8%</u>, and strengthening <u>hospital price transparency requirements/enforcement</u>.

CMS <u>proposed Medicare coverage of HIV PrEP without cost-sharing</u> for high-risk individuals... A <u>CMS review concluded</u> many Innovation Center models <u>lack sufficient data</u> to adequately assess health equity impacts.

FDA <u>approved the first</u> over-the-counter daily oral contraceptive.

OCR <u>proposed revising nondiscrimination requirements</u> for HHS grants.

CDC will provide free COVID-19 vaccines to uninsured/underinsured individuals.

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Healthcare law and policy news

The White House <u>released</u> a <u>plan</u> to address the emerging threat of fentanyl combined with xylazine in the illicit drug supply.

US Chamber of Commerce <u>filed a motion for preliminary injunction</u> to <u>block implementation</u> of the Medicare Drug Price Negotiation Program.

Aspirus Health and St. Luke's Duluth <u>plan to affiliate</u>... Eli Lilly <u>will acquire Versanis</u> (\$1.93B)... Following <u>launch of several Humira biosimilars</u>, Express Scripts and Optum will add <u>some to their formularies</u>... CVS Caremark will <u>offer members access to GoodRx prescription pricing on certain generic drugs next year.</u>

HCA <u>disclosed a data breach</u> impacting 11M patients; including this incident, HHS <u>data show</u> the total number of patients impacted by breaches year-to-date <u>already meets last year's total (52M)</u>.

KFF reported the 10 top-selling Part D drugs in 2021 <u>accounted for 22% (\$47.7B) of gross Medicare drug spending</u>, but just 0.3% of covered drugs... An EBRI <u>analysis found</u> allowed charges for innovator biologics were 121% <u>higher at hospital outpatient departments than physician offices</u> in 2020... A <u>JAMA study found 27.6% of children</u> had delayed/missed preventive care during the pandemic, with

disproportionate impact among Asian or Pacific Islander, Hispanic, and multiracial individuals.

An <u>Epic Research analysis</u> found most specialties have a greater rate of 90-day in-person follow-up visits after an in-person visit than after a telehealth visit... Another <u>study concluded</u> the benefits of telehealth are highest among diseases with "high virtualization potential" (e.g., mental health and skin conditions).

House Education and Workforce Committee <u>advanced hospital</u>, <u>health plan</u>, <u>and PBM price transparency</u> bills... House Energy and Commerce Committee <u>advanced healthcare bills</u>, including to <u>reauthorize</u> the <u>Pandemic and All-Hazards Preparedness Act</u> (PAHPA), <u>permanently allow employers to offer telehealth</u> as a separate tax-free benefit, and <u>reauthorize substance use disorder support</u> programs.

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Brief Roundup of News from the Week of July 3rd

- FDA granted <u>full, traditional approval</u> to Eisai-Biogen's <u>Alzheimer's</u> <u>drug, Leqembi</u>; CMS <u>made its facilitated registry</u> available, which a physician or clinical team members must participate in for Medicare to cover the drug.
- HHS <u>announced efforts</u> to protect consumers and reduce healthcare costs by: (1) <u>proposing</u> (along with Labor and Treasury) <u>rollback of short-term</u>, <u>limited-duration insurance</u> (STLDI) regulations that, among other things, expanded duration of plans; (2) releasing <u>an FAQ further clarifying</u> surprise billing and out-of-pocket cost protections, particularly with respect to facility fees and in-network status; and (3) issuing a <u>request for information</u> (along with Consumer Financial Protection Bureau and Treasury) on <u>use and impact of medical credit cards and loans</u> used to pay for healthcare.
- CMS proposed cutting 2024 home health agency payment 2.2%
 (\$375M); National Association for Home Care and Hospice sued to
 vacate 2023 home health payment cuts and withhold the 2024
 proposed rule.

CMS proposed paying 1,600 340B hospitals \$9B in lump-sum payments to make up for 2018-2022 cuts deemed unlawful by the Supreme Court and a 0.5% cut to non-drug aspects of the hospital outpatient system over 16 years, beginning in 2025, to ensure budget neutrality.

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