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HK Health Dose: March 25, 2025

A weekly dose of healthcare policy news

Looking Ahead: Congressional Leaders Prepare for Key Healthcare Confirmations and Budget Negotiations

Dr. Jayanta Bhattacharya, has been confirmed as director of the National Institutes of Health (NIH).

This week, both chambers of the U.S. Congress are back in session. U.S. Senate Majority Leader John Thune (R-S.D.) filed a procedural motion to tee up nominees to lead the NIH and the U.S. Food and Drug Administration (FDA) for confirmation votes on the floor as soon as this week. In addition, Congressional Republican leadership, including the chairs of key healthcare committees, are expected to meet this week to discuss what a compromise budget resolution could look like to bridge the gaps between the U.S. House of Representatives and Senate passed versions and solidify timing for potentially passing the compromise resolution.

The Senate Committee on Finance voted to advance Dr. Mehmet Oz's nomination to the full Senate for consideration in a 14-13 vote on March 25, 205. Additionally, a vote will be held on March 25, 2025, to confirm Dr. Martin Makary to be commissioner of the FDA.

Hearings This Week: Congressional Committees Address Veterans' Healthcare and CMS Leadership

The House Committee on Veterans' Affairs Subcommittee on Health Oversight will hold a hearing on March 25, 2025, at 2:30 p.m. entitled, "Breaking Down Barriers: Getting Veterans ACCESS to Lifesaving Care."

The Senate Committee on Finance will hold an executive session on March 25, 2025, to vote on advancing Dr. Mehmet Oz's nomination to be administrator of the Centers for Medicare & Medicaid Services (CMS). He is expected to receive a favorable vote.

Week in Review: Legislators Engage with Constituents During District Work Periods

Members of the House and Senate were in their districts last week during district work periods.

ADMINISTRATIVE UPDATES

Executive Order Updates

The Trump Administration has continued to release wide-ranging Executive Orders (EOs). For real time updates, see our "Trump's 2025 Executive Orders: Updates and Summaries" landing page online.

Recently released EOs with potential healthcare policy implications include:

March 20, 2025, EO entitled, "Eliminating Waste and Saving Taxpayer Dollars by Consolidating Procurement." The EO aims to centralize domestic federal procurement within the General Services Administration (GSA). Notably, it impacts federal procurement across a wide range of product categories, including medical supplies, information technology and more. According to media reports, a second EO related to procurement may be expected in the coming days, which will focus on revisions to Federal Acquisition Regulation (FAR).

Personnel Updates

Calley Means will become a "special government employee" at The White House, which is the same classification as Elon Musk and allows employees to join an administration on a temporary basis and does not require the normal

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lengthy hiring process for certain federal employees. Means is an ally of U.S. Department of Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. and will focus on food policy and the impact of large corporations on the food industry. He will also support the Make America Healthy Again (MAHA) Commission. He has previously worked with a coalition of stakeholders to advocate for changes to federal and state policies regarding the foods that may be bought with financial assistance program benefits.

Following The White House's decision to withdraw the nomination of Dave Weldon to be director of the Centers for Disease Control and Prevention (CDC), Dr. Susan Monarez, Ph.D., has been nominated for the role. Prior to her current role as acting director of the CDC, Monarez was deputy director of the Advanced Research Projects Agency for Health (ARPA-H).

LEGISLATIVE UPDATES

Congress Considers CDC Reorganization

Legislative text has been circulating crafted by Sens. Mike Lee (R-Utah) and Eric Schmitt (R-Mo.), which aims to move several CDC functions to the NIH. The bill would limit CDC's scope to infectious diseases only and shift eight CDC offices that deal with a range of issues from chronic disease and non-communicable illnesses or injuries to HIV and Tuberculosis prevention. Additionally, the bill would impose 12-year term limits on both the CDC and NIH directors.

REGULATORY UPDATES

HHS, FDA Announce "Operation Stork Speed" to Improve Infant Formula

Secretary Kennedy announced the initiation of Operation Stork Speed on March 18, 2025, to improve the quality, safety, nutrition and strength of the U.S. infant formula supply. As part of the effort, the FDA will begin a review of nutrients in formula and increase the testing of infant formula "and other foods children consume" for heavy metals and other contaminants. The FDA previously released new guidance in January 2025 for industry to reduce the presence of lead in processed foods for pediatric populations, however, this new initiative may lead to additional rulemaking activities. Operation Stork Speed will also include the initiation of a comprehensive update and review of infant formula nutrients for the first time since 1998. The HHS' announcement follows an earlier meeting convened by the HHS secretary with infant formula company leaders and mirrors recent efforts to increase regulatory oversight by the FDA of the ingredients used in food products.

FDA Further Delays Effective Date for Additional Condition for Nonprescription Use (ACNU) Final Rule

The FDA has again delayed the effective date for the ACNU final rule. The rule aims to expand access to certain over-the-counter (OTC) drugs and establishes new requirements for nonprescription drug products with an ACNU. The final rule was initially published on December 26, 2024, with an effective date of January 27, 2025. However, the effective date was delayed until March 21, 2025 following the regulatory freeze implemented by President Donald Trump on January 20, 2025. The final rule has now been delayed again, this time until May 27, 2025, which allows additional time for public comments. The FDA may use the 60-day delay to make additional changes to the final rule, such as to address issues raised by stakeholders regarding the meaningful clinical difference between prescription and nonprescription drugs. Secretary Kennedy has previously shared his support for making OTC products more widely available to consumers, raising the possibility that the HHS may seek to incorporate additional priorities from the secretary.

HHS Consider Rulemaking Related to the Definition of "Sex"

In a document filed in relation to two cases challenging a rule extending protections under Section 1557 of the Affordable Care Act (ACA) to cover sexual orientation and gender identity issued by the previous administration, the HHS signaled they are in the process of pursuing potential rulemaking related to the definition of "sex." The rulemaking follows directives given to agencies as part of President Trump's EO entitled "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government."

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Drug Enforcement Administration (DEA) Postpones Two Telehealth Prescribing Rules

The DEA pushed back the effective date of two telehealth prescribing rules on March 21, 2025. The first would have permanently allowed the prescription of a six-month supply of buprenorphine to new patients via telehealth. The second applies to the U.S. Department of Veterans Affairs (VA) and would permanently allow veterans to receive certain controlled substances through a telehealth visit if the individual had previously seen a VA provider in person. This delay is intended to align these flexibilities with the broader telehealth prescribing deadline of Dec. 31, 2025.

CDC Reschedules Meeting of Advisory Committee on Immunization Practices (ACIP)

The CDC announced on March 24, 2025, that its ACIP will meet April 15-16, 2025, to discuss recommendations for an array of vaccines for adult and pediatric populations, the current measles outbreak and whether to recommend certain vaccines for inclusion in the Vaccines for Children (VFC) program. There have been significant stakeholder concerns regarding the ACIP following a postponement of its planned meeting in February 2025. While the rescheduling of the ACIP meeting is a positive sign that the HHS does not intend to limit or interfere with its operations in the short-term, the tenor of the conversations will be more instructive to stakeholders moving forward.