



## HK Health Dose: February 5, 2025

A weekly dose of healthcare policy news

### LEGISLATIVE UPDATES

Robert F. Kennedy Jr.'s nomination to be the secretary of the U.S. Department of Health and Human Services (HHS) was advanced by the U.S. Senate Committee on Finance in a party-line 14-13 vote, with Senate Committee on Health, Education, Labor and Pensions (HELP) Chair and Senate Finance Committee member Sen. Cassidy (R-La.) ultimately voting in favor of his nomination despite previously sharing he had been "struggling" with Mr. Kennedy's nomination. The full Senate vote on his confirmation is anticipated as soon as next week, and the final vote is expected to be close. Additionally, Dr. Marty Makary's nomination hearing to be the U.S. Food and Drug Administration (FDA) commissioner is expected to be announced shortly.

### **This Week: Senate Hearings for HHS Nomination, and House and Senate Tackle Fentanyl Crisis Amid MAHA Agenda**

Mr. Kennedy had his nomination hearings before the Senate Finance and Senate HELP Committees to be Secretary of the HHS. Mr. Kennedy sat for several hours of questions over the course of two days, answering questions from members on vaccines and how he would implement plans to Make America Healthy Again (MAHA), as well as addressing questions about his historical anti-vaccine positions.

The U.S. House of Representatives Committee on Energy and Commerce's Subcommittee on Health will hold a hearing on Feb. 6, 2025, "Combatting Existing and Emerging Illicit Drug Threats." The hearing is expected to feature a panel of witnesses who will discuss the dangers of opioids, fentanyl and trends in illicit drug usage in the U.S.

The Senate Committee on the Judiciary will also hold a hearing regarding fentanyl titled "[The Poisoning of America: Fentanyl, its Analogues, and the Need for Permanent Class Scheduling.](#)"

Both hearings are timely, as the House is expected to vote this week on passage of the HALT Fentanyl Act (H.R. 27). The legislation would permanently place fentanyl-related substances under Schedule I of the Controlled Substances Act, the most strictly controlled category of substances with no accepted medical value. Last Congress, the legislation passed the House 289-133 but stalled in the Senate. The legislation is expected to pass the House.

The House Committee on Ways and Means is expected to hold a hearing regarding initiatives to be pursued as part of the Trump Administration's MAHA agenda. A date has not yet been announced.

### ADMINISTRATIVE UPDATES

#### Executive Order Update

The Trump Administration has continued to release wide-ranging executive orders (EOs). For real time updates, see Holland & Knight's "[Trump's 2025 Executive Orders: Updates and Summaries](#)" [landing page](#).

#### 10-1 Regulations – Overview

President Donald Trump signed an EO to implement his promise to reduce the number of federal regulations. The EO directs federal agencies to identify at least 10 existing rules, regulations or guidance documents to be repealed when a new rule or regulatory document is issued. The order closely resembles but is not identical to a Jan. 30, 2017, EO issued by President Trump, which primarily focused on notice-and-comment rulemaking. The previous EO mandated that the costs of significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs



associated with at least two prior regulations." As a result, agencies were required to include a section in each new regulation detailing how it complied with the EO. The [corresponding fact sheet](#) is available online.

The new EO expands on this approach beyond increasing the number of rules agencies should identify for elimination from two to 10 and states that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." Additionally, the new EO broadens the definition of "rules" or "regulations" to encompass a wide range of agency actions beyond formal rulemaking.

While the implementation of this EO falls largely under the discretion of the Office of Management and Budget (OMB) director, who may exempt specific regulations or categories of regulations, the inclusion of guidance documents and policy statements suggests that even informal actions by the Centers for Medicare & Medicaid Services (CMS) or the FDA could be subject to its repeal and cost-offset requirements. Once confirmed, the HHS secretary may promptly begin identifying agency actions to target for elimination. A number of healthcare rules are anticipated to be pulled back, including but not limited to the minimum staffing rule for nursing homes. Some rules proposed by the previous Biden Administration, including rules to limit access to menthol-flavored products, have already been withdrawn by the Office of Information and Regulatory Affairs (OIRA) following the Trump Administration's regulatory freeze.

## Tariff Update

President Trump announced a 30-day pause on the imposition of 25 percent tariffs after he struck agreements with the leaders of Canada and Mexico to address the flow of illegal immigration and illicit drugs. Mexico President Claudia Sheinbaum agreed to deploy 10,000 Mexican national guard troops to the U.S.-Mexico border to address illegal immigration, while Canada's Prime Minister Justin Trudeau agreed to appoint a new Canadian fentanyl czar to lead opioid reduction efforts in exchange for a 30-day reprieve of tariffs. Talks among the three nations will continue over the next 30 days to potentially find a longer-term solution.

President Trump's plans to impose new tariffs on other nations does not include exceptions for the healthcare and pharmaceutical industries.

Tariffs on Chinese goods were not delayed, with 10 percent across-the-board tariffs on Chinese goods taking effect as of Feb. 4, 2025. China imposed retaliatory 15 percent tariffs on U.S. liquefied natural gas (LNG) and coal products. Additional tariffs are expected to be proposed in the coming weeks, with potential risk to companies that source active pharmaceutical ingredients (APIs) and other pharmaceutical products from China. Medical device and pharmaceutical entities are in the interim planning to seek specific exemptions for their products.

## Department of Government Efficiency (DOGE)

In a recent interview, Elon Musk signaled intent to "shut down" the U.S. Agency for International Development (USAID), the agency primarily responsible for distributing civilian foreign aid and deployment assistance. Musk argued that the agency is "beyond repair" and suggested he had the support of President Trump in his efforts.

## Personnel

Troy Tabaz, FDA's top digital health official, has stepped down as director of the Digital Health Center of Excellence (DHCoE). The FDA has not announced a new acting director for DHCoE.

Shana Weir, a strong ally of President Trump who alleged widespread Nevada voter fraud before the Nevada Supreme Court, has joined the HHS as the principal deputy assistant secretary for the Trump Administration. Additionally, she will serve as a senior adviser to new HHS Chief of Staff Heather Flick.

## The View from Miami – GOP Policy Retreat Summary and Reconciliation Updates

House Republicans held their annual policy retreat in Miami the week of Jan. 27, 2025. The goal of the retreat was to find consensus about the content and scope of the reconciliation package, including potential changes to the Medicaid



program. However, an agreement has yet to be reached, with the House Committee on the Budget postponing plans to mark up the fiscal year (FY) 2025 budget resolution.

Republicans continue discussions regarding the size of funding cuts to include in reconciliation as an offset for tax extensions. Funding reductions of up to \$2 trillion have been discussed, but it is likely the reductions come in far below that number due to President Trump's insistence that no cuts to Medicare or Social Security be included. Taking those two programs off the table makes finding offsets of up to \$2 trillion within healthcare policies and programs significantly more difficult.

The mark-up delay makes it more difficult but not impossible for House Republicans to meet Speaker Mike Johnson's (R-La.) ambitious reconciliation schedule, which seeks to complete consideration of the budget resolution on the House floor by the end of February 2025. Further delays may entice the Senate to begin its own work on a reconciliation package, which is expected to focus less on healthcare and more on energy, defense and immigration.

Republican senators have been invited to Mar-a-Lago on Feb. 7, 2025, for a private dinner with President Trump. The invitation coincides with the National Republican Senatorial Committee's winter meeting in Palm Beach, Florida. The event signifies continuing close conversations between the Trump Administration and Republican senators as work to install President Trump's nominee and prepare to begin reconciliation, as well as push President Trump to support a plan to move forward on two reconciliation bills, instead of one.

## JUDICIARY UPDATES

### Latest Developments – Federal Funding Freeze

A federal district court judge in Rhode Island became the second court on Feb. 3, 2025, to freeze the Trump Administration's order halting the distribution of all federal financial assistance. There were 22 states and the District of Columbia that sued the Trump Administration to prevent the funding freeze from taking effect, arguing the implementation of the policy to withhold federal funding for states was unconstitutional and contravened laws regarding federal funding. Unlike a ruling issued by a district court judge in Washington, D.C., which set a temporary reprieve from the order until Feb. 3, 2025, the most recent court order did not set an expiration date for the injunction.

With this latest ruling, the initial federal funding freeze appears to be rescinded, but recent developments in district courts around the country suggest uncertainty remains ongoing. It is likely cases challenging the freeze will end up before the U.S. Supreme Court.