Holland & Knight

H&K Health Dose: January 21, 2025

A weekly dose of healthcare policy news

President Donald J. Trump was inaugurated as the 47th president of the United States on Jan. 20, 2025. After delivering his Inaugural Address and addressing supporters in a subsequent speech, President Trump signed five executive orders (EOs) from the Oval Office, which included 22 cabinet appointments, 47 sub-cabinet appointments, 31 acting designations to "take control of the government," 15 commission chair appointments and an order mandating that flags to be flown at full mast on this Inauguration Day and all future inauguration days. Following the Inaugural lunch, President Trump signed eight additional EOs at his post-inaugural rally. A record 46 EOs were signed into law on President Trump's first day, with former President Joe Biden setting the previous one-day record at nine. One of these executive orders rescinded 78 Biden Administration EOs, including at least 13 impacting the healthcare industry on subjects ranging from COVID-19 to drug pricing. This Holland & Knight Health Dose, identifies which EO (and EO roll-backs) to pay attention to, updates on agency confirmation hearings and other highlights from this last week in Washington.

Hearings

The first member of President Trump's cabinet was confirmed on Jan. 20, 2025, with Sen. Marco Rubio confirmed 99-0 to be Secretary of State. Additional nomination hearings will take place this week. Additional nominees are expected to be considered on the U.S. Senate floor throughout the week.

The timeline for consideration of Robert F. Kennedy Jr.'s nomination to be Secretary of the U.S. Department of Health and Human Services (HHS) remains in flux, with his financial disclosure and other paperwork remaining pending. He continues meeting with senators and staff from both parties.

President Trump formalized the nominations of several individuals on Jan. 20, 2025, to lead cabinet and sub-cabinet positions with jurisdiction over healthcare. These nominations had been previously announced and include:

- Dr. Mehmet Oz, Administrator, Centers for Medicare & Medicaid Services (CMS)
- Dr. Jayanta Bhattacharya, Director, National Institutes of Health (NIH)
- Dr. Martin Makary, Commissioner, U.S. Food and Drug Administration (FDA)
- Dr. David Weldon, Director, Centers for Disease Control and Prevention (CDC)
- Mr. Jim O'Neill, Deputy Secretary, HHS

Additional administrative personnel announcements are expected in the coming days, including formalized nominations of the following:

- Mr. John Brooks to be chief operating officer at CMS
- Mr. Drew Snyder to lead the Center for Medicaid & CHIP Services
- Mr. Abe Sutton to lead the CMS Center for Medicare and Medicaid Innovation (CMMI)
- Mr. Chris Klomp to lead the CMS Center for Medicare

LEGISLATIVE UPDATES

Senate Report Releases Private Equity Investment in Healthcare

Earlier this month, Senate Committee on the Budget Chair Chuck Grassley (R-Iowa) and Ranking Member Sheldon Whitehouse (D-R.I.) released a bipartisan staff report detailing the impact of private equity investment into healthcare for patients and healthcare providers. The report studied investments made into hospitals and hospital operating companies across the country. The report links ownership of healthcare facilities by private equity investors to declines in quality of care, lower staffing levels and higher rates of financial distress.

The report includes a "call to action for greater oversight, transparency, and reforms" regarding private equity investment in healthcare. Bipartisan interest in private equity investments in healthcare is expected to be a priority for the 119th Congress and additional developments for stakeholders will be tracked in future editions of Health Dose.

MedPAC Recommends Congress Increase Physician Payment, Cut Nursing Home Payments

On Jan. 16, 2025, the Medicare Payment Advisory Commission (MedPAC) held its monthly public meeting and endorsed several recommendations on Medicare payment reform. While many of the recommendations adopted by the commission are in line with previous MedPAC recommendations, tying payment increases to the Medicare Economic Index (MEI) hasn't been unanimously supported by all physician groups. In the draft recommendation, MedPAC suggests that Congress adopt an updated approach to MedPAC's March 2023 MEI-based recommendation, which specified an increase to the Medicare base payment rate for physician and other health professional services by 50 percent of the projected increase in the MEI. In the new draft and correlated vote, MedPAC commissioners voted to increase the payment rate for physicians and other health professional services by 1.3 percent, which represents a 2.3 percent projected increase based on a Medicare inflation rate. Notably, home health agencies and inpatient rehabilitation facilities would both see a 7 percent cut in Medicare payments in 2026 under the panel's recommendation. Final recommendations for 2026 will be included in the MedPAC's March 2025 report.

FTC Releases Second Report on PBM Practices

The Federal Trade Commission (FTC) released an interim report last week shedding light on how the nation's leading pharmacy benefit managers (PBMs) set prices for specialty generic medications. Additionally, the report reveals that specialty pharmacies owned by three PBMs account for nearly 70 percent of all U.S. specialty drug revenue. This interim report marks the FTC's second investigation into PBM contracting practices. The agency noted that the reports remain incomplete due to the PBMs' failure to provide requested information regarding their business operations. The FTC is now preparing legal action against three companies for their refusal to comply with agency subpoenas.

REGULATORY UPDATES

Several federal agencies issued new rules and guidance documents in the waning weeks of President Biden's term. Many of these rules and guidance documents are now in limbo following the "regulatory freeze" announced on Jan. 20, 2025, by President Trump. The freeze allows the Trump Administration to review and determine whether to revise, rescind or continue pursuing pending regulations.

Notably, HHS, in conjunction with the U.S. Department of Labor (DOL) and U.S. Department of the Treasury, withdrew a proposed rule that would have required most health insurance plans to cover over-the-counter (OTC) contraception for patients without cost-sharing or a prescription.

DEA Telemedicine Prescribing Rules

HHS and the U.S. Drug Enforcement Administration (DEA) issued rules on Jan. 15, 2025, related to telemedicine prescribing of controlled substances, including a special registration proposed rule and a final rule on telemedicine prescribing of buprenorphine. The proposed rule for special registration outlines three types of registration to waive in-person visit requirements prior to virtual prescribing of controlled substances and a state registration for every state in which a patient is treated by the special registrant. Providers would need to apply for the special registrations. The DEA also proposes that providers be required to review nationwide prescription drug monitoring programs after three years. Comments on the special registration proposed rule are due March 15, 2025.

In the final rule on prescribing buprenorphine, the DEA finalized a provision allowing prescribers to continue issuing six-month prescriptions for buprenorphine without requiring an in-person visit. Following the initial six-month period, patients could renew their prescriptions either through an in-person visit or, if the DEA's broader telehealth proposal is approved, via remote consultation with a prescriber specially registered under the new system. Under this framework, pharmacists would be responsible for verifying patients' identification at the time of prescription pickup. This rule will take effect in mid-February 2025.

2026 Medicare Advantage and Part D Advance Notice

CMS released the Calendar Year (CY) 2026 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies on Jan. 10, 2025, which makes proposals to update program policies for Medicare Advantage (MA) and Part D beginning in 2026. CMS also issued its Draft CY 2026 Part D Redesign Program Instructions, which center on implementing provisions of the Inflation Reduction Act of 2022 (IRA) related to the Part D benefit for 2026. If these proposals are finalized, CMS anticipates a 4.33 percent, or more than $21 billion, increase in MA plan payments from 2025 to 2026. Comments on the Advance Notice and Draft Part D Redesign Program Instructions are due by Feb. 10, 2025. The CY 2026 Rate Announcement and the CY 2026 Part D Redesign Program Instructions will be published no later than April 7, 2025.

Notice of Benefit and Payment Parameters for 2026

On Jan. 13, 2025, HHS and CMS issued the final Notice of Benefit and Payment Parameters for 2026 (CMS-9888-F), which goes into effect Jan. 15, 2025. The rule includes updates to premium payment thresholds, allowing fixed or percentage-based options, introduces flexibility for qualified plans to calculate the medical loss ratio (MLR) to better support those serving underserved communities and enhances reviews of Qualified Health Plans (QHPs) in Federally Facilitated Marketplaces (FFMs) to ensure adequate provider networks in states managing plan functions. This rule does not address the copay accumulator policy established in the 2020 Notice of Benefit and Payment Parameters (NBPP) rule. This policy permits plans to exclude manufacturer assistance from counting toward patients' out-of-pocket limit for only specific prescription brand drugs that have an available and medically appropriate generic equivalent. However, in the October 2024 proposed NBPP rule, CMS indicated plans for future rulemaking on this issue. HHS, along with the DOL and Treasury, will issue a proposed rule to clarify how manufacturer support applies to annual cost-sharing limits, though no timeline has been announced.

FDA

The FDA issued several healthcare policy announcements in the final weeks of President Biden's administration. While certain policies may find support among members of President Trump's incoming administration, the future of other recently proposed rules will be decided by agency leaders. Recently proposed and final rules, as well as draft guidance documents, that may be of interest to the Trump Administration include, but are not limited to:

- Final order revoking the authorized uses of Red Dye No. 3 under the Federal Food, Drug and Cosmetic Act (FD&C Act). Objections and requests for a hearing must be submitted by Feb. 18, 2025.
  - Red Dye No. 3 is a synthetic dye used to give some food, drinks and drugs a cherry-red hue.
  - This order directs manufacturers who use Red Dye No. 3 in their food and drug products to reformulate their products by Jan. 15, 2027, and Jan. 18, 2028, respectively.
  - The order follows a 2022 petition to revoke authorization of Red Dye No. 3 following studies showing cancer in male laboratory rats. Studies involving cancer among humans have not shown this effect.
- Proposed rule to set maximum levels of nicotine in cigarettes and certain combustible tobacco products. Public comments must be submitted by Sept. 15, 2025.
  - Limits maximum nicotine content to 0.70 milligrams (mg) of nicotine per gram of total tobacco for cigarettes, cigars (excluding premium cigars) and certain combusted tobacco products. Electronic nicotine delivery systems (ENDS), including e-cigarettes, smokeless tobacco and pouch products are not included.
- Final rule to update the definition of "healthy" when used in food labelling, which takes effect Feb. 25, 2028.
  - Requires food products claiming to be "healthy" to contain a certain amount of fruits, vegetables, protein, dairy and grains and sets limits on saturated fat, sodium and added sugars in "healthy" products.
- Proposed rule to require nutrition information boxes to be included on the front of food product packaging. Comments are due by May 16, 2025.
- Two draft guidance documents outlining the FDA's current thinking about artificial intelligence (AI), including:
  - Draft guidance for the use of AI for drug development provides a framework to support decision making about a drug or biological product's safety, effectiveness or quality using AI. Comments are due **within 90 days.**

- Draft guidance to support the development and marketing of safe, effective AI-enabled medical devices throughout its entire life cycle. Comments are due by **April 7, 2025.** The FDA will also hold a webinar on **Feb. 18, 2025,** to discuss the guidance.

CMS

Last week, CMS announced an additional 15 drugs covered under Medicare Part D for price negotiation, including three medications known commonly used to manage diabetes or address obesity. Notably, the Initial Price Applicability Year (IPAY) 2027 list is composed entirely of small-molecule drugs. Per CMS guidance, the agency is grouping drugs with the same active ingredient together for negotiation, regardless of dosage forms or indications. This is evident in the inclusion of Ozempic, Rybelsus and Wegovy. These products highlight an area of uncertainty, particularly concerning how the Trump Administration will approach these negotiations, along with the MA/Part D Technical Rule, which proposes expanding Medicare and Medicaid coverage for anti-obesity medications. Also, note Rybelsus falls into the "pill penalty" included in the IRA, which lets the government set the price of medicines that often come in pill form.

Drug manufacturers have until Feb. 28, 2025, to decide whether to participate in the negotiation process or face a significant excise tax on the sales of that drug.

- Ozempic, Rybelsus or Wegovy
- Trelegy Ellipta
- Xtandi
- Pomalyst
- Ibrance
- Ofev
- Linzess
- Calquence
- Austedo or Austedo XR
- Breo Ellipta
- Tradjenta
- Xifaxan
- Vraylar
- Janumet or Janumet XR
- Otezla

First Day EOs

On Day 1, President Trump issued an executive order rescinding 78 Biden Administration EOs including, but not limited to:

- EO 13985 of Jan. 20, 2021 (Advancing Racial Equity and Support for Underserved Communities through the Federal Government)
- EO 13987 of Jan. 20, 2021 (Organizing and Mobilizing the United States Government to Provide a Unified and Effective Response to Combat COVID-19 and to Provide United States Leadership on Global Health and Security)
- EO 13990 of Jan. 20, 2021 (Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis)
- EO 13996 of Jan. 21, 2021 (Establishing the COVID-19 Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID-19 and Other Biological Threats)
- EO 13997 of Jan. 21, 2021 (Improving and Expanding Access to Care and Treatments for COVID-19)
- EO 13999 of Jan. 21, 2021 (Protecting Worker Health and Safety)
- EO 14002 of Jan. 22, 2021 (Economic Relief Related to the COVID-19 Pandemic)

- EO 14009 of Jan. 28, 2021 (Strengthening Medicaid and the Affordable Care Act)
- EO 14007 of Jan. 27, 2021 (President's Council of Advisors on Science and Technology)
- The Presidential Memorandum of Jan. 3, 2025 (Designation of Officials of the Office of Science and Technology Policy to Act as Director)
- EO 14070 of April 5, 2022 (Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage)
- EO 14087 of Oct. 14, 2022 (Lowering Prescription Drug Costs for Americans)
- EO 14110 of Oct. 30, 2023 (Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence)

Additionally, Trump released several health-related EOs including:

- Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government
- Ending Radical and Wasteful Government DEI Programs and Preferencing
- Withdrawing the United States from the World Health Organization

Several additional EOs are expected to be released in the coming days and weeks. The breadth of this is yet to be seen but will likely address chronic disease and AI.

JUDICIARY UPDATES

U.S. Supreme Court to Hear Arguments that Challenge ACA Constitutionality

The U.S. Supreme Court announced on Jan. 10, 2025, it would hear arguments in a case that challenges the constitutionality of two elements of the Affordable Care Act (ACA): first, the makeup of the U.S. Preventive Services Task Force and second, the requirement that private health insurers cover recommendations made by the Task Force at no cost. Specifically, several businesses and individuals challenged the requirement on the basis that it requires employers to provide coverage for services and drug products that go against their religious beliefs. Arguments are expected to be heard in the spring, with a decision expected before the court's term ends in June 2025.