



H&K Health Dose: December 3, 2024

A weekly dose of healthcare policy news

The end of the 118th U.S. Congress is near, with just 17 days until government funding expires and 31 days until the new Congress is sworn in. U.S. House of Representatives and U.S. Senate Democrat and Republican leadership elections have concluded, which allows for greater focus on an agreement to keep the government funded.

House Leadership

Republicans

- **Speaker:** Mike Johnson
- **Majority Leader:** Steve Scalise
- **Majority Whip:** Tom Emmer
- **National Republican Congressional Committee (NRCC) Chair:** Richard Hudson
- **Conference Chair:** Lisa McClain
- **Conference Vice Chair:** Blake Moore
- **Republican Policy Chair:** Kevin Hearn
- **Conference Secretary:** Erin Houchin
- **Republican Study Chair:** August Pfluger
- **Freshman Class President:** Brandon Gill
- **Freshman Steering Representative:** Brian Jack

Democrats

- **Leader:** Hakeem Jeffries
- **Minority Whip:** Katherine Clark
- **Caucus Chair:** Pete Aguilar
- **Vice Chair:** Ted Lieu
- **Assistant Democratic Leader:** Joe Neguse
- **Democratic Policy and Communications Committee (DPCC) Chair:** Debbie Dingel
- **DPCC Co-Chairs:** Maxwell Frost, Lauren Underwood, Lori Trahan
- **Battleground Leadership Representative:** Susie Lee
- **Caucus Leadership Representative:** Robert Garcia
- **Freshman Class Representative:** Luz Rivas
- **Freshman Class President:** Yassamin Ansari
- **Freshman Steering Representative:** Johnny Olszewski

Senate Leadership

Republicans

- **Majority Leader:** John Thune
- **Assistant Majority Leader:** John Barrasso
- **Republican Conference Chair:** Tom Cotton
- **Republican Conference Vice Chair:** James Lankford
- **Republican Policy Committee Chair:** Shelly Moore Capito
- **National Republican Senatorial Committee Chair:** Tim Scott

Democrats

- **Minority Leader:** Chuck Schumer
- **Minority Whip:** Dick Durbin
- **Steering and Policy Chair:** Amy Klobuchar
- **Strategic Communications Committee Chair:** Cory Booker
- **Vice Chairs of Conference:** Elizabeth Warren, Mark Warner
- **Chair of Outreach:** Bernie Sanders
- **Vice Chair of Outreach:** Catherine Cortez Masto
- **Conference Secretary:** Tammy Baldwin
- **Deputy Conference Secretaries:** Brian Schatz, Chris Murphy



LEGISLATIVE UPDATES

Lame-Duck and Year-End Considerations

The government is funded through Dec. 20, 2024, but no agreement has been reached on a continuing resolution (CR) that includes health extenders. While Democrats and Republicans have differing motivations, both sides are keen to avoid a shutdown. The timeline for the CR remains uncertain; although many anticipate a March 2025 deadline, action in January or February is still possible. Health extenders are likely to be extended only through the CR's end date, with other healthcare priorities deferred to 2025 when Congress plans to pursue a reconciliation package. Reconciliation, however, will be a lengthy process, with many provisions unlikely to pass under the Byrd Rule. Key focus areas will include Medicaid and the Inflation Reduction Act (IRA).

Senate Health Hearings

This week, the U.S. Senate Committee on Health, Education, Labor and Pensions will hold a hearing on the U.S. Food and Drug Administration (FDA) and its role in reducing diabetes and obesity. The U.S. Senate Committee on Energy and Natural Resources will look at the public health impacts of per- and polyfluoroalkyl substances (PFAS).

ADMINISTRATIVE UPDATES

Trump Transition Team

On Nov. 26, 2024, the Trump-Vance transition team and the Biden Administration signed a memorandum of understanding (MOU), officially initiating the process of transferring executive power. However, the Trump team has chosen not to utilize certain government-provided resources, including technology and information security services offered by the U.S. General Services Administration (GSA). According to a press release from the Trump transition team, the organization will operate as a "self-sufficient entity," relying on private funding and its existing security and information protection systems.

Each transition team is assembling a landing team to join the Biden Administration in its early days, with joint meetings already underway. These teams will include individuals with extensive agency experience, although the Trump campaign's promises of roles to many supporters on the campaign trail necessitate considering names provided by the campaign. The Trump transition team has been advised to begin stakeholder engagement after Thanksgiving. This process, starting with trade associations, will focus on gathering feedback on industry priorities and requesting letters of support for nominees, rather than facilitating two-way dialogue. Additionally, the Trump transition team is establishing a sherpa program to assign guides who will assist nominees through the confirmation process.

Nominations Updates

Last week, President-Elect Donald Trump announced two new health nominees: Jay Bhattacharya, a Stanford University-trained physician, to lead the National Institutes of Health (NIH); and Jim O'Neill, a Silicon Valley investor and former federal health official, to be U.S. Department of Health and Human Services (HHS) deputy secretary. Below is a brief overview of the health nominees who were recently announced. Note that all five need to be confirmed by the Senate, as does Trump's previous pick of Robert F. Kennedy Jr. for HHS secretary.

Dave Weldon – Director of the U.S. Centers for Disease Control and Prevention (CDC) Nominee

For the first time in its 78-year history, the nominee for CDC director will require Senate confirmation. Weldon,



a Republican who represented a Florida district in the House for 14 years until 2009, is a medical doctor (internal medicine) and Army veteran known for his vocal concerns about vaccine risks.

Weldon's vaccine skepticism includes citing a discredited 1998 study by Andrew Wakefield that falsely linked the measles, mumps and rubella (MMR) vaccine to autism – a claim thoroughly debunked by subsequent research.

In 2007, Weldon introduced the Vaccine Safety and Public Confidence Assurance Act, which proposed removing vaccine safety research from the CDC and placing it within an independent agency under the HHS. The bill, however, never advanced beyond committee review. Weldon also opposed the removal of the feeding tube for Terri Schiavo and introduced legislation to require federal court review of cases like Schiavo's. Weldon did successfully pass what has now been dubbed the "Weldon Amendment" on "rights of conscience" regarding abortion policy. The amendment, which Congress has reapproved each budget cycle, stipulates that HHS cannot discriminate in funding decisions against programs or agencies that do not provide abortions.

During his seven terms in the House, Weldon served on several key committees, including Appropriations, Health and Human Services, Education and the Workforce, and Science, Space, and Technology. After leaving office in 2009, Weldon returned to practicing medicine and working as a consultant. He ran unsuccessfully for the U.S. Senate in Florida in 2012, losing in the Republican primary to Rep. Connie Mack IV.

Marty Makary – Food and Drug Administration (FDA) Commissioner Nominee

The nomination of Dr. Marty Makary, a Johns Hopkins University School of Medicine surgeon, for FDA Commissioner has been met with cautious optimism. While Makary has expressed concerns about the U.S. COVID-19 pandemic response, his vaccine-related critiques have been more nuanced. He questioned the data requirements for COVID-19 vaccine boosters and their broad rollout, advocating instead for prioritizing high-risk populations. Over his career, Makary has built a reputation as a health researcher and writer, focusing on hospital safety, quality and healthcare costs. Clinically, Dr. Makary is the chief of islet transplant surgery at Johns Hopkins. He is a recipient of the Nobility in Science Award from the National Pancreas Foundation and has been a visiting professor at more than 25 medical schools. He has published more than 250 peer-reviewed scientific articles and has served on several editorial boards. Makary was involved in the original research at Johns Hopkins on the surgical checklists that Dr. Atul Gawande popularized in his book, "The Checklist Manifesto," as a tool to improve patient safety and that are now standard in operating theaters. Makary has criticized in books and articles the overprescribing of drugs, use of pesticides on foods and undue influence of pharmaceutical and insurance companies over doctors and government regulators. Further, he has focused heavily on [transparency and surprise billing issues](#).

Janette Nesheiwat – U.S. Surgeon General Nominee

Dr. Janette Nesheiwat is a board-certified physician specializing in emergency and family medicine. She is a Fox News medical contributor and serves as the medical director at CityMD, a network of urgent care centers in New York and New Jersey. Nesheiwat has publicly supported vaccines, including those that Kennedy has questioned. However, she has at times criticized the CDC's guidance on COVID-19 vaccines, stating earlier this year that for many Americans – particularly young people – the vaccine's risks might outweigh the benefits, though she acknowledged that the risk is small for most patients. Nesheiwat has also been critical of government mandates during the COVID-19 pandemic.

Beyond issues related to COVID-19, Nesheiwat has questioned the American Academy of Pediatrics' standards of care for youth with gender dysphoria. She regularly contributes to media outlets, promotes dietary supplements she formulates and is the author of the forthcoming book, "Beyond the Stethoscope: Miracles in Medicine," which highlights inspirational stories of healing and the transformative power of prayer.



Nesheiwat completed her medical degree and residency at the University of Arkansas for Medical Sciences and an emergency room rotation at Johns Hopkins Hospital in Baltimore.

Jay Bhattacharya – NIH Director Nominee

Bhattacharya has spent almost his entire career at Stanford University, where he is currently listed as a professor of health policy. He received four degrees, including a medical degree and Ph.D. in economics, from Stanford.

In a statement last week, President-Elect Trump announced that Bhattacharya "will work in cooperation with [HHS Secretary nominee] Robert F. Kennedy Jr. to direct the Nation's Medical Research and to make important discoveries that will improve health and save lives."

Bhattacharya is a physician, former research fellow at the Hoover Institution and economist at RAND Corp. He gained significant attention during the COVID-19 pandemic as a vocal critic of the federal government's response. Bhattacharya was also a co-author of the Great Barrington Declaration, an open letter from October 2020 that advocated for rolling back coronavirus-related shutdowns while implementing "focused protections" for vulnerable populations such as the elderly.

Some of Bhattacharya's proposed reforms include increasing the number of studies that replicate others to strengthen confidence in science, promoting academic freedom among NIH scientists and introducing term limits for NIH leadership.

Jim O'Neill – HHS Deputy Secretary Nominee

Jim O'Neill first joined the HHS in 2002 under President George W. Bush. Over the years, he has held several key roles within the agency, including serving as a senior aide to the deputy HHS secretary. He also worked on pandemic preparedness, FDA reform and public health initiatives. After his time at HHS, O'Neill moved to Silicon Valley, where he worked closely with investor Peter Thiel, who was an advisor to Trump during his first term. O'Neill served as acting CEO of the Thiel Foundation and managing director at Thiel's investment firm, Mithril Capital Management, which also employed JD Vance.

O'Neill has shared many views aligned with those of Kennedy on platforms like X, including criticism of vaccine mandates and concerns about fluoride in drinking water and the food industry's influence on dietary guidelines. In a 2014 speech, O'Neill also argued that the FDA should focus solely on the safety of drugs when making approval decisions, rather than considering their efficacy.

REGULATORY UPDATES

CMS Finalizes Mandatory IOTA Model

On Nov. 26, 2024, the Centers for Medicare & Medicaid Services (CMS) [finalized a rule](#) establishing the six-year Increasing Organ Transplant Access (IOTA) Model with several changes from the draft version. The IOTA Model is mandatory and set to run from July 1, 2025, to June 30, 2031, encompassing a six-year performance period divided into six individual performance years (PYs). This model aims to evaluate whether performance-based incentives provided to or required from participating kidney transplant hospitals can improve access to kidney transplants for patients with end-stage renal disease (ESRD), while maintaining or enhancing care quality and reducing Medicare costs. As a mandatory model, selected kidney transplant hospitals will be required to participate, with their performance assessed annually throughout the program. CMS posted a [list of the 103 hospitals required to participate](#) on their website.

Changes from the proposal include increased maximum pay for participating hospitals and the removal of a proposed health equity performance adjustment. Notably, the final rule could fall under potential disapproval



based on the Congressional Review Act's (CRA) "lookback period." The CRA's lookback provision gives Congress an additional chance to review rules issued in the period starting 60 working days before the end of a session of Congress through the beginning of the subsequent session of Congress.

For more information, please review the IOTA Model [participant list](#), [fact sheet](#), [FAQs](#) and [press release](#).

CMS Releases CY 2026 Medicare Advantage and Part D Proposed Rule

On Nov. 26, 2024, CMS released the Contract Year (CY) 2026 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program (Part D), Medicare Cost Plan Program and Programs of All-Inclusive Care for the Elderly (PACE) [proposed rule](#) and [fact sheet](#). This is part of an annual rulemaking process that includes substantive and technical changes to the MA, Part D and PACE programs.

This year, the rule proposes new policies related to the coverage of anti-obesity medications in Part D and Medicaid, and requires MA plans to make provider directory information more widely available through the Medicare Plan Finder tool. It also includes medical loss ratio and utilization management requirements, use of artificial intelligence (AI) tools and more.

The proposed rule follows a letter sent last month to the Biden Administration by Senate Finance Committee Chair Ron Wyden (D-Ore.), House Ways & Means Committee Ranking Member Richard Neal (D-Mass.) and House Energy & Commerce Committee Ranking Member Frank Pallone (D-N.J.). In the letter, they urged CMS to "utilize every regulatory, oversight, and enforcement tool at the agency's disposal" to address challenges within the Medicare Advantage program.

Comments are due by Jan. 27, 2025, shortly after President-Elect Trump's inauguration, introducing uncertainty about whether the incoming administration will finalize the rule.