

# Impact Health Policy Weekly

# Framing the Week

The House returns from a week of recess today and is <u>scheduled</u> to vote on over a dozen bills on suspension, most of which relate to technology and veterans affairs. Still outstanding, with the ability to derail the House agenda, is the motion to vacate that Rep. Marjorie Taylor Greene (R-GA) filed prior to the recess. Whether or not she takes the steps necessary to trigger the motion this week is to be determined. The Senate will come into session on Tuesday and is <u>scheduled</u> to vote on a nomination before turning to the Federal Aviation Administration reauthorization bill. This is likely to be the last big piece of "must pass" legislation to be considered prior to the November elections.

With all fiscal year (FY) 2024 funding completed, including the foreign aid emergency supplemental, the House Appropriations Committee is wasting no time in moving on to FY 2025. Last week newly minted House Appropriations Committee Chairman Tom Cole (R-OK) announced the deadlines for member requests would be Wednesday, May 1 for programmatic requests and Friday, May 3 for community project funding requests. With a compressed schedule, markups could begin as early as May, though resolution on FY 2025 bills won't occur before the election. The Senate has not yet announced deadlines.

#### <u>Hearings</u>

House Energy & Commerce Committee: On Tuesday, the Energy & Commerce Subcommittee on Health will hold a <u>legislative hearing</u> on legislation to increase Medicaid access and improve program integrity. Included in the list of legislative bills to be discussed is <u>H.R. 7513</u>, *Protecting America's Seniors Access to Care Act* which would prohibit the Secretary of Health and Human Services from finalizing a proposed rule regarding minimum staffing for nursing facilities, and to establish an advisory panel on the skilled nursing facility workforce.

On Wednesday the House Energy & Commerce Subcommittee on Oversight and Investigations will hold a <u>hearing</u> titled "Examining the Change Healthcare Cyberattack."

<u>Senate Finance Committee:</u> On Tuesday the Senate Finance Committee will hold a <u>hearing</u> titled "Hacking America's Health Care: Assessing the Change Healthcare Cyber Attack and What's Next"

<u>Senate HELP Committee</u>: On Thursday the Senate <u>HELP Committee</u> will hold a <u>hearing</u> titled "What Can Congress Do to Address the Severe Shortage of Minority Health Care Professionals and the Maternal Health Crisis?"

# Regulatory Update

The Office of Management and Budget (OMB) completed reviewing several FDA final rules, including a <u>final rule</u> to make explicit that laboratory developed tests (LDTs) are subject to the FDA's device

regulations, which was released this morning. Additionally, OMB cleared a <u>proposed rule</u> on the removal of outdated regulations. OMB is also reviewing the following rules:

#### Medicare

- Calendar Year (CY) Payment Updates: The CY 2025 revisions to the Medicare Physician Fee
  Schedule proposed rule, the CY 2025 Hospital Outpatient PPS Policy Changes and Payment
  Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates
  proposed rule, the CY 2025 Changes to the End-Stage Renal Disease (ESRD) Prospective
  Payment System and Quality Incentive Program proposed rule (June 2024), and the CY 2025
  Home Health PPS Rate Update proposed rule (June 2024).
- Alternative Payment Models The <u>proposed rule</u> would implement a new Medicare payment model titled, Increasing Organ Transplant Access (IOTA) Model (was set for December 2023).

#### Medicaid

- Disproportionate Share Hospital Program The final rule would implement requirements under section 203 of the Consolidated Appropriations Act, 2021 (CAA), which relate to Medicaid shortfall and third-party payments (February 2024).
- Drug Rebate Program The <u>final rule</u> would establishes requirements related to manufacturers' misclassification of covered outpatient drug products under the Medicaid Drug Rebate Program (MDRP). In addition, it finalizes beneficiary protections, as well as MDRP program integrity and administration changes (June 2024).

#### **Commercial Insurance**

- Qualified Health Plans The <u>final rule</u> would make changes to definitions used to determine when consumers are eligible to enroll in a QHP (was set for November 2023).
- Association Health Plans The <u>final rule</u> would make changes the definition of employer under ERISA-Association Health Plans (April 2024)

# Other Topics:

- Healthcare System Resiliency and Modernization The proposed rule would revise and
  update national emergency preparedness requirements for Medicare- and Medicaidparticipating providers and suppliers (was set for December 2023).
- **Health IT** The <u>proposed rule</u> would advance interoperability through proposals for: standards adoption; public health IT certification; expanded uses of certified application programming interfaces (APIs), such as for electronic prior authorization, patient engagement, care

management, and care coordination; and information sharing under the information blocking regulations (was set for November 2023).

# This Week in Health Policy

## Mon. (4/29)

• 1:00pm – FDA Meeting: Medical Device Sterilization – The Food and Drug Administration (FDA) holds a medical device sterilization town hall to discuss suggestions the FDA received on potential topics for the sterilization town hall series, and how the FDA will pivot the format of the series to support more engaging discussions on topics of interest. Details.

# Tue. (4/30)

- 10:00am Hearing: OMB Oversight The House Oversight and Accountability holds a hearing to examine steps the Office of Management and Budget (OMB) is taking to improve operations, including increasing transparency regarding the effectiveness of policy proposals in included in President Biden's budget proposal for Fiscal Year 2025. <u>Details</u>.
- 10:00am Hearing: Medicaid Access The House Energy and Commerce Health
   Subcommittee holds a hearing to examine legislative proposals to increase Medicaid access and
   program integrity. Included in the list of legislative bills to be discussed is H.R. 7513, Protecting
   America's Seniors Access to Care Act which would prohibit the Secretary of Health and Human
   Services from finalizing a proposed rule regarding minimum staffing for nursing facilities, and to
   establish an advisory panel on the skilled nursing facility workforce. Details.
- 1:00pm BPC Discussion: Child Care Workforce The Bipartisan Policy Center (BPC) holds a
  discussion on state workforce registries and their use to support early childhood education,
  including how to expand the reach of registries, and how they can be used to support improving
  policies regarding the child care workforce. Details.
- 2:00pm Hearing: CISA Budget Request for FY 2025 The House Appropriations
   Subcommittee on Homeland Security holds a hearing to examine the President's proposed
   budget request for fiscal year (FY) 2025 for the Cybersecurity and Infrastructure Security
   Agency (CISA) with CISA Director Jen Easterly. <u>Details</u>.

# Wed. (5/1)

- 9:00am Hearing: Change Healthcare Cyberattack The Senate Finance Committee holds a hearing to examine the Change Healthcare cyberattack and how it impacts patients and providers with UnitedHealth Group, Inc., CEO Andrew Witty. <u>Details</u>.
- 10:00am Markup: Artificial Intelligence Research and Innovation The Senate Commerce, Science, and Transportation Committee holds an executive session to consider a package of bill that includes the CREATE AI Act and the Future of AI Innovation Act, both of which would codify efforts already underway in the Biden Administration. Details.
- 10:00am Hearing: COVID-19 Origins The House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic holds a hearing to examine discrepancies in Dr. Peter Daszak, EcoHealth Alliance President, testimony regarding EcoHealth's relationship with the Wuhan Institute of Virology (WIV). Details.

- 2:00pm Hearing: Change Healthcare Cyberattack The House Energy and Commerce
  Subcommittee on Oversight and Investigations holds a hearing to examine the Change
  Healthcare cyberattack and how it impacts patients and providers with UnitedHealth Group, Inc.,
  CEO Andrew Witty. <u>Details</u>.
- 2:00pm Hearing: Cyber Incident Reporting/Critical Infrastructure Act The House
  Homeland Security Cybersecurity and Infrastructure Protection Subcommittee holds a hearing
  on "Surveying CIRCIA (Cyber Incident Reporting for Critical Infrastructure Act): Sector
  Perspectives on the Notice of Proposed Rulemaking.". Details.

## Thurs. (5/2)

 10:00am – Hearing: Minority Health Care Workforce Shortage/Maternal Health Crisis – The Senate Health, Education, Labor, and Pensions Committee holds a hearing to examine what Congress can do to address the severe shortage of minority health care professionals and the maternal health crisis. <u>Details</u>.

#### Additional Multi-Day Events

Apr. 29-Apr. 30 – ASPE Meeting: ADRD Care Navigation and Challenges – The Assistant Secretary for Planning and Evaluation (ASPE) holds a meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council) to discuss Alzheimer's disease and related dementias (ADRD) care and navigation across health care settings from post-diagnosis through advanced disease, and challenges with long-term services and supports for people with young-onset dementia and their care partners/families, as well as challenges with dementia among aging populations experiencing homelessness or incarceration. Details

#### Featured Analysis

- Impact Roundup of January Behavioral Health Actions In the Policy Hub Insight Bank here.
- Impact Chart of Key Provisions of Legislative Proposals on Health Care Price Transparency Requirements In the Policy Hub Insight Bank here.
- Impact Regulatory Outlook: Fall 2023 Unified Agenda In the Policy Hub Insight Bank here.
- Impact Mental Health Legislative Update In the Policy Hub Insight Bank here.
- Impact Artificial Intelligence Policy Round Up In the Policy Hub Insight Bank here.

# Regulatory Lookback

#### Fri. (4/26)

• HHS released the <u>final rule</u> implementing Section 1557 of the ACA that prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in certain health programs and activities. <u>Details</u>.

• **HHS** announced the <u>selection of 20 states</u> to participate in two separate technical assistance programs that aim to enhance the recruitment, training, and retention of direct care workers. <u>Details</u>.

# Thurs. (4/25)

• **CMS** shared a <u>progress update</u> on its work with the Departments and OPM on rulemaking for the good faith estimate (GFE) and advanced explanation of benefits (AEOB) requirements of the No Surprises Act (NSA). <u>Details</u>.

## Weds. (4/24)

- The Biden Administration released the 2024 National Strategy for Suicide Prevention (National Strategy) along with a Federal Action Plan to create a coordinated and comprehensive national approach to suicide prevention. Details.
- The FTC issued a <u>final rule</u> prohibiting employers from imposing or enforcing non-compete clauses on workers. <u>Details</u>.
- The CDC <u>announced</u> the 2024 Racial and Ethnic Approaches to Community Health (REACH) Lark Galloway-Gilliam for Advancing Health Equity Award Challenge. Applications are due June 21.
   Details.
- The FNS released a <u>final rule</u> to align child nutrition program meal pattern requirements with the 2020 Dietary Guidelines for American. Details.

#### Tues. (4/23)

- ICER released a <u>white paper</u> entitled "Managing the Challenges of Paying for Gene Therapy: Strategies for Market Action and Policy Reform." <u>Details</u>.
- FNS announced two new grant opportunities to strengthen SNAP, the <u>SNAP Process and Technology Improvement Grants (PTIG) Program</u>, in which applications are due June 18, and the <u>SNAP Fraud Framework Implementation Grant (FFIG)</u>, in which applications are due June 24. <u>Details</u>.

# Mon. (4/22)

- CMS released a Minimum Staffing Standards for Long-Term Care (LTC) Facilities and Medicaid Institutional Payment Transparency Reporting <u>final rule</u>. <u>Details</u>.
- CMS released a <u>final rule</u> to improve access to and quality of care provided to Medicaid and CHIP managed care enrollees. Details.
- CMS released the <u>Ensuring Access to Medicaid Services Final Rule</u>. <u>Details</u>.
- HHS OCR released a <u>final rule</u> to modify the HIPAA Privacy Rule to better protect sensitive information related to reproductive health care. <u>Details</u>.
- HHS ONC and The Sequoia Project <u>announced</u> the Common Agreement Version 2.0 (CA v.2.0).
   <u>Details</u>.

# Comment & Application Deadlines

- April 29: CMS issued <u>final part one guidance</u> on a select set of topics for the Medicare Prescription Payment Plan and an <u>ICR</u> for model materials. <u>Details</u>.
- May 1: CMMI released the manufacturer <u>request for applications (RFA)</u> for the <u>Cell and Gene Therapy Access Model</u>. Applications are due May 1. <u>Details</u>.
- May 3: The NAM unveiled a draft framework aimed at ensuring the responsible adoption of artificial intelligence (AI) technologies in health care and biomedical sciences. Details.
- May 6: The FTC, DOJ, and HHS jointly issued a <u>request for information (RFI)</u> to inform the
  agencies' identification of enforcement priorities and future actions, including new regulations,
  aimed at promoting competition in health care markets and ensuring appropriate access to quality,
  affordable health care items and services. <u>Details</u>.
- May 20: HHS OMH issued an RFI to solicit input for the development of a universal symbol informing people about the availability of language assistance services in health settings. Details.
- May 27: CMS released the FY 2025 IRF PPS proposed rule. Details.
- May 28: CMS released the FY 2025 SNF PPS proposed rule. Details.
- May 28: CMS released the FY 2025 Hospice payment rate update proposed rule. <u>Details</u>.
- May 28: CMS released the FY 2025 IPF PPS proposed rule. Details.
- May 28: ONC published the draft 2024-2030 Federal Health IT Strategic Plan. Details.
- May 29: HRSA <u>announced</u> the opportunity to apply for <u>base and matching funds under the</u>
   Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program. <u>Details</u>.
- **June 3:** CISA issued an <u>NPRM</u> outlining regulations concerning cyber incident reporting and ransom payment reporting, aiming to bolster the <u>nation</u>'s cybersecurity posture. <u>Details</u>.
- June 10: CMS released the FY 2025 IPPS and LTCH PPS proposed rule. Details.
- June 10: HUD released a <u>proposed rule</u> entitled, "Reducing Barriers to HUD-Assisted Housing."
   <u>Details</u>.
- June 10: HHS ONC <u>released</u> its Health Equity By Design (HEBD) white paper discussion draft for public comment. <u>Details</u>.
- June 15: HRSA <u>announced</u> the availability of funding under the Maternal and Child Health Services Block Grant program. <u>Details</u>.
- June 17: CMMI <u>announced (model website)</u> a new voluntary model to test how prospective payments and increased funding for primary care in accountable care organizations (ACOs) impact health outcomes, quality, and costs of care. <u>Details</u>.
- **June 18:** FNS announced the <u>SNAP Process and Technology Improvement Grants (PTIG) Program</u>. <u>Details</u>.



- June 21: The CDC <u>announced</u> the 2024 Racial and Ethnic Approaches to Community Health (REACH) Lark Galloway-Gilliam for Advancing Health Equity Award Challenge. Applications are due June 21. <u>Details</u>.
- June 24: FNS announced the **SNAP Fraud Framework Implementation Grant (FFIG)**. Details.
- **September 30:** The CDC is <u>seeking nominations</u> for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). <u>Details</u>.