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# Impact Health Policy Weekly

# Framing the Week

The Senate is in session today and the House returns tomorrow for a few days of legislative business before recessing for the Memorial Day Holiday. The Senate is expected to take up the bipartisan immigration bill from earlier in the year for another vote this week. The bill is not expected to pass and is generally considered to be a political move to help incumbent Democrats in their reelections. This week is a busy one on a committee level as the House Agriculture Committee marks up the Farm Bill on Thursday (IHPP summary of House Majority bill), the House Armed Services Committee marks up the fiscal year (FY) 2025 National Defense Authorization bill, and the House Appropriations Committee starts to markup FY 2025 bills with the Military Construction-Veterans Affairs and Legislative Branch bills. Late last week House Appropriations Committee Chairman Tom Cole (R-OK) released a very aggressive markup schedule that plans to move all 12 spending bills through the Committee by mid-July. Chairman Cole also released the "interim" Subcommittee allocations. The allocations adhere to last year's Fiscal Responsibility Act, without the adjustments (or "side deals") that provided higher non-defense funding in both 2024 and 2025. As a result, House nondefense allocations are cut by 6%, with the Labor-HHS Appropriations Subcommittee receiving an 11% cut. House Appropriations Committee Ranking Member Rep. Rosa DeLauro (D-CT) channeled her inner Taylor Swift with a <u>one-page document</u> outlining the "tortured top-line department" and insisting on a true 1% increase for both defense and non-defense spending.

# Hearings and Markups:

**Senate Judiciary Committee:** on Tuesday the Senate Judiciary Committee will hold a <u>hearing</u> to examine competition in the prescription drug market, focusing on ensuring affordable and accessible medications.

# Senate Health, Education, Labor, and Pensions Committee:

- On Tuesday the Senate HELP Subcommittee on Primary Health and Retirement Security will hold a <u>hearing</u> to examine feeding a healthier America, focusing on current efforts and potential opportunities for Food is Medicine. This hearing was rescheduled from earlier this spring.
- On Thursday the Senate HELP Committee will hold a markup to consider several pieces of legislation, including <u>S.3679</u>, to reauthorize the Dr. Lorna Breen Health Care Provider Protection Act, <u>S.3765</u>, to amend the Public Health Service Act to reauthorize the Emergency Medical Services for Children program, <u>S.4351</u>, to amend the Public Health Service Act to reauthorize certain poison control programs, and <u>S.3775</u>, to amend the Public Health Service Act to reauthorize the BOLD Infrastructure for Alzheimer's Act, among others. The House Energy & Commerce Committee advanced most of these in March <u>IHPP summary</u>.

**House Appropriations:** On Wednesday the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies will hold a <u>hearing</u> to examine nutritious foods in the Supplemental Nutrition Assistance Program (SNAP).



**House Budget Committee:** On Thursday the House Budget Committee will hold a <u>hearing</u> titled "Breaking Up Health Care Monopolies: Examining the Budgetary Effects of Health Care Consolidation." Congressional Budget Office (CBO) Director of Health Analysis Dr. Chapin White will be testifying.\_

**Senate Appropriations Committee:** The Senate Appropriations Subcommittee on Labor-HHS will <u>hold</u> a hearing to examine proposed budget estimates and justification for fiscal year 2025 for the NIH.

**Senate Finance Committee**: On Thursday the Senate Finance Committee will <u>hold</u> a hearing to examine ways to support communities impacted by the fentanyl crisis, focusing on combating addiction through prevention and treatment.

**House Agriculture Committee:** On Thursday the House Agriculture Committee will hold a <u>markup</u> of the "Farm, Food, and National Security Act of 2024."

# **Regulatory Update**

The Office of Management and Budget (OMB) is currently 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).

# Medicaid

 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).

# **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 proposed rule 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. (5/20)

 2:30pm – HHS Meeting: Seniors Climate/Health Equity – The Department of Health and Human Services (HHS) holds a meeting of the National Advisory Committee on Seniors and Disasters to discuss and deliberate questions posed by the Administration for Preparedness and Response on climate and health equity. <u>Details</u>.

# <u>Tue. (5/21)</u>

- 10:00am CMS Meeting: Self-Management of Diabetes in Older Adults The Centers for Medicare and Medicaid Services (CMS) holds a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) to examine clinical endpoints pertinent to CMS in evaluating the efficacy and safety of new devices for self-management of type 1 and insulindependent type 2 diabetes in older adults. <u>Details</u>.
- **10:00am Hearing: Prescription Drug Market Competition** The Senate Judiciary Committee holds a hearing to examine competition in the prescription drug market, focusing on ensuring affordable and accessible medications. <u>Details</u>.
- 2:30pm Hearing: Food is Medicine Opportunities The Senate Health, Education, Labor, and Pensions Subcommittee on Primary Health and Retirement Security holds a hearing to examine feeding a healthier America, focusing on current efforts and potential opportunities for Food is Medicine. <u>Details</u>.

# Wed. (5/22)

- 10:00am FDA Meeting: Pediatric Oncology Cancer Drugs The Food and Drug Administration (FDA) holds a meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee to discuss perspectives relating to pediatric investigations of certain targeted cancer drugs with new active ingredients and its impact on pediatric cancer drug development to date. <u>Details</u>.
- 10:00am Hearing: NIST Priorities for 2025 The House Science, Space and Technology Committee holds a hearing on "Examining NIST's Priorities for 2025 and Beyond." Dr. Laurie Locascio, Under Secretary of Commerce for Standards and Technology and Director of the National Institute of Standards and Technology (NIST) will be testifying. <u>Details</u>.
- **10:00am Hearing: Nutritious Foods in SNAP –** The House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies holds a hearing to examine nutritious foods in the Supplemental Nutrition Assistance Program (SNAP). <u>Details</u>.



- 10:30am Hearing: FDA Regulation of Drugs, Biologics, and Devices The House Energy and Commerce Subcommittee on Health holds a hearing to examine FDA regulation of drugs, biologics, and medical devices, focusing on understanding what's working well and what challenges persist. FDA Directors for the Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health will be testifying. <u>Details</u>.
- 2:00pm Hearing: NIAID Oversight The House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic holds a hearing to examine the National Institute of Allergy and Infectious Diseases (NIAID) with NIAID Senior Scientific Advisor Dr. David Morens. <u>Details</u>.

# Thurs. (5/23)

- 9:00am NIH Meeting: Nursing Research The National Institutes of Health (NIH) holds a meeting of the National Institute of Nursing Research (NINR) for NINR Director Shannon Zenk's report, discussion of NINR Programs, and council open discussion. <u>Details</u>.
- 9:00am Hearing: Independent Medicine Challenges The House Ways and Means Subcommittee on Health holds a hearing to identify the financial and regulatory burdens facing independent medical providers and how continued challenges result in consolidated health care systems and barriers to patient care. <u>Details</u>.
- 9:30am Hearing: Older Americans Act Reauthorization The Senate Special Committee on Aging holds a hearing to examine the impact of the Older Americans Act and the upcoming reauthorization. <u>Details</u>.
- 10:00am CDC Meeting: National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases – The Centers For Disease Control and Prevention (CDC) holds a meeting of the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in People to discuss the VBD National <u>Strategy</u>. <u>Details</u>.
- **10:00am Hearing: Health Care Consolidation –** The House Budget Committee holds a hearing titled "Breaking Up Health Care Monopolies: Examining the Budgetary Effects of Health Care Consolidation." Congressional Budget Office (CBO) Director of Health Analysis Dr. Chapin White will be testifying. <u>Details</u>.
- 10:00am Hearing: NIH Appropriations The Senate Appropriations Labor-HHS Subcommittee holds a hearing to examine proposed budget estimates and justification for fiscal year 2025 for the NIH. <u>Details</u>.
- 10:00am Hearing: Combating Fentanyl Addiction Through Prevention and Treatment The Senate Finance Committee holds a hearing to examine ways to support communities impacted by the fentanyl crisis, focusing on combating addiction through prevention and treatment. <u>Details</u>.
- 10:00am Markup: Alzheimer's and Patient Care and Support The Senate Health, Education, Labor, and Pensions Committee holds a markup to consider several pieces of legislation, including <u>S.3679</u>, to reauthorize the Dr. Lorna Breen Health Care Provider Protection Act, <u>S.3765</u>, to amend the Public Health Service Act to reauthorize the Emergency Medical Services for Children program, <u>S.4351</u>, to amend the Public Health Service Act to reauthorize certain poison control programs, and <u>S.3775</u>, to amend the Public Health Service Act to reauthorize the BOLD Infrastructure for Alzheimer's Act, among others. <u>Details</u>.



- **12:00pm Markup: 2024 Farm Bill –** The House Agriculture Committee holds a markup of the "Farm, Food, and National Security Act of 2024." <u>Details</u>.
- 1:00pm Hearing: GAO's Report on Opportunities to Reduce Fragmentation, Overlap, and Duplication – The House Oversight and Accountability Subcommittee on Government Operations and the Federal Workforce holds a hearing to examine the findings and recommendations of the Government Accountability Office (GAO) 2024 <u>Report</u> on Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Financial Benefits. <u>Details</u>. This is the House version of the Senate hearing Victor covered this week <u>IHPP summary</u>. I suggest we skip due to bandwidth.
- 1:00pm Urban Institute Discussion: Child Tax Credit The Urban Institute holds a discussion on the impacts of providing cash assistance to low-income families with children and discuss how policymakers and researchers can leverage these insights to improve the well-being of vulnerable children, focusing on the upcoming 2025 expiration of the child tax credit enacted under the Tax Cuts and Jobs Act. Sen. Michael Bennet (D-CO) will deliver keynote remarks. <u>Details</u>.

#### Fri. (5/24)

 9:00am – FDA Meeting: Diabetes Insulin Product Discussion – The FDA holds a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee to discuss the safety and efficacy of biologics license application 761326 for NNC0148-0287 injection (insulin icodec), a long-acting insulin analog product, submitted by Novo Nordisk which will improve glycemic control in adults with diabetes mellitus. <u>Details</u>.

#### Additional Multi-Day Events

 May 21-May 22 – HHS Meeting: Global Antimicrobial Resistance – HHS holds a meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) to deliberate and vote on the Global Antimicrobial Resistance Working Group report to the Secretary of Health and Human Services. The remainder of the public meeting will include updates on AMR in conflict zones, the environment, and the voice of the patient. <u>Details</u>.

# 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 <u>here</u>.
- Impact Artificial Intelligence Policy Round Up In the Policy Hub Insight Bank here.



# Congressional Lookback

# <u>Fri. (5/17)</u>

- **The SFC** released a <u>white paper</u> that examined the Medicare PFS and policy options to support clinicians while improving chronic care. <u>Details</u>.
- Chair of the House Committee on Agriculture GT Thompson (R-PA) released a discussion draft of the Farm, Food, and National Security Act of 2024 for Farm Bill reauthorization. <u>Details</u>.

# <u> Thurs. (5/16)</u>

- The E&C Health Subcommittee convened a <u>markup</u> of 23 legislative proposals to strengthen the U.S. health care system. <u>Details</u>.
- Sens. Cassidy and Whitehouse introduced the bipartisan <u>Pay PCPs Act of 2024</u> to establish hybrid primary care payments under the Medicare program. <u>Details</u>.

# Weds. (5/15)

- The Bipartisan Senate AI Working Group unveiled a <u>comprehensive roadmap</u> for artificial intelligence policy in the United States Senate. <u>Details</u>.
- The House Education and Workforce <u>convened</u> a hearing with HHS Secretary Xavier Becerra to examine President Biden's FYC 2025 Budget for HHS. <u>Details</u>.

# Regulatory Lookback

# <u> Thurs. (5/16)</u>

• The GAO released its <u>14th annual report</u> identifying potential savings and efficiency improvements in federal government operations. <u>Details</u>.

# Weds. (5/15)

- HHS announced the release of a <u>national strategy</u> with recommendations developed by the <u>Task</u>
  <u>Force on Maternal Mental Health</u>. <u>Details</u>.
- **CMS** provided an <u>update</u> that it will not be finalizing its proposal related to the stacking of best prices that was included in the Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program proposed rule. <u>Details</u>.
- HHS released its <u>Plan for Promoting Responsible Use of Artificial Intelligence (AI) in Automated</u> <u>and Algorithmic Systems</u> by State, Local, Tribal, and Territorial Governments in Public Benefit Administration. <u>Details</u>.



# <u>Mon. (5/13)</u>

• **HHS OIG** conducted an <u>audit</u> to assess whether Medicaid State agencies were properly invoicing for and collecting rebates for physician-administered drugs under the Medicaid drug rebate program. <u>Details</u>.

Comment & Application Deadlines

- May 20: HHS OMH issued an <u>RFI</u> to solicit input for the development of a universal symbol informing people about the availability of language assistance services in health settings. <u>Details</u>.
- 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. <u>Details</u>.
- May 28: ONC published the draft 2024-2030 Federal Health IT <u>Strategic Plan</u>. <u>Details</u>.
- May 29: HRSA <u>announced</u> the opportunity to apply for base and matching funds under the 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 nation's cybersecurity posture. <u>Details</u>.
- June 6: SFC Chair Wyden (D-OR) and Ranking Member Crapo (R-ID) unveiled a <u>draft legislative</u> <u>proposal</u> aimed at tackling the persistent issue of prescription drug shortages in the United States. <u>Details</u>.
- June 7: The CDC is <u>seeking nominations</u> for membership on the Advisory Committee to the Director. Details.
- June 10: CMS released the FY 2025 IPPS and LTCH PPS proposed rule. <u>Details</u>.
- June 10: HUD released a proposed rule 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>.
- July 16: CMMI announced the Increasing Organ Transplant Access (IOTA) Model. Details.
- 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 <u>SNAP Fraud Framework Implementation Grant (FFIG)</u>. <u>Details</u>.
- **September 30:** The CDC is <u>seeking nominations</u> for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). <u>Details</u>.

