# Impact Health Policy Weekly

# Framing the Week

The House and Senate are both back in session this week, though just for a few days before many members join President Biden and foreign leaders in Normandy, France for a D-Day 80<sup>th</sup> Anniversary celebration. On Monday the House is scheduled to <u>vote</u> on multiple bills naming post offices before possibly taking up the first appropriations bill of the year, the fiscal year 2025 Military Construction and Veterans Affairs bill. The Senate also comes back into session on Monday with a nomination <u>vote</u>, which will be followed on Wednesday with a vote on the <u>Right to Contraception Act</u>, legislation introduced by Senators Ed Markey (D-MA) and Maize Hirono (D-HI) that will guarantee a woman's access to contraception. In a <u>letter</u> to his Senate colleagues, Senate Majority Leader Chuck Schumer (D-NY) promised there would be "more to come" in terms of reproductive rights legislation this month.

On a Committee level this week, the **Senate Health Education and Labor Committee** will also be focusing on access to reproductive health with a <u>hearing</u> focused on women's freedoms and access to abortions across America.

Meanwhile, the House Energy & Commerce Committee Oversight and Investigations Subcommittee will hold a hearing on Tuesday to explore recent trends and developments in the 340B drug pricing program. Last week Energy and Commerce Committee Republicans introduced the 340B Affording Care for Communities and Ensuring a Strong Safety-Net Act (340B ACCESS Act) that would establish additional oversight and transparency of the 340B program. A Senate bipartisan working group led by Senators John Thune (R-SD) and Debbie Stabenow (D-MI) has drafted their own legislation on the issue and is expected to officially introduce it in the coming weeks.

The House Appropriations Committee will continue their fast march towards completing all 12 Subcommittee bills by the August recess with the Subcommittee markups of the FY 2025 Homeland Security, DOD, State Department and Foreign Operations, and Financial Services bills.

Finally, the long-awaited *Improving Seniors' Timely Access to Care Act* (the Seniors' Act) is expected to be introduced in both the House and Senate this week. This bipartisan legislation seeks to address the overuse and abuse of prior authorization (PA) by Medicare Advantage (MA) plans. Introduced with great support in the past several Congresses, the bill was never enacted due to the bill's high cost. However, this year's bill has made changes to align with regulations finalized by CMS in 2023 and 2024 which should drastically reduce the score.

## 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).
- Medicare Shared Savings Program: A proposed rule titled, "Mitigating the Impact of Anomalous Increases in Billing on Medicare Shared Savings Program Financial Calculations."

#### 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 <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. (6/3)

- 10:00am Hearing: COVID-19 Pandemic Response The House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic holds a hearing with Dr. Anthony Fauci, Former Director at the National Institute of Allergy and Infectious Diseases regarding his role in America's public health response to the COVID-19 pandemic. Details.
- 12:00pm HITAC Meeting: Annual Report Workgroup The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to discuss program updates. Details.

# Tue. (6/4)

- 8:30am FDA Meeting: PTSD Drug Treatment Application The Food and Drug
  Administration (FDA) holds a meeting of the Psychopharmacologic Drugs Advisory Committee
  to discuss a new drug application for MDMA capsules, submitted by Lykos Therapeutics, for the
  proposed indication of treatment of post-traumatic stress disorder. <u>Details</u>.
- 10:00am Hearing: Abortion Access The Senate Health, Education, Labor, and Pensions Committee holds a hearing to examine women's freedoms, focusing on access to abortions across America. Details.
- 10:30am Hearing: 340B Drug Pricing Program Oversight The House Energy and Commerce Oversight and Investigations Subcommittee holds a hearing to explore recent trends and developments in the 340B drug pricing program. Details.
- 2:30pm Hearing: Al and Economic Growth The Senate Joint Economic Committee holds a
  hearing to examine artificial intelligence (Al) and its potential to fuel economic growth and
  improve governance. <u>Details</u>.

#### Wed. (6/5)

- 8:30am FDA Meeting: 2024-2024 Formula for COVID-19 Vaccines The Food and Drug Administration (FDA) holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss and make recommendations on the selection of strain(s) to be included in the 2024-2025 Formula for COVID-19 vaccines. <u>Details</u>.
- 10:00am Hearing: Federal Cybersecurity The Senate Homeland Security and Governmental Affairs holds a hearing to examine streamlining the Federal cybersecurity regulatory process, focusing on the path to harmonization. Details.
- 10:00am Hearing: Improving Services for Veterans at Home The Senate Special
   Committee on Aging and Veterans' Affairs Committee hold a joint hearing to examine veterans at home, focusing on improving services for veterans and their caregivers. <u>Details</u>.
- 11:00am HHS Meeting: Vital/Health Statistics Report to Congress The Department of Health and Human Services (HHS) holds a meeting of the National Committee on Vital and Health Statistics (NCVHS) for discussion of the NCVHS Report to Congress, including final recommendations. Details.
- 1:00pm Health Affairs Discussion: Reimagining Public Health Health Affairs holds a discussion on its June 2024 issue, Reimagining Public Health, where Health Affairs contributors set out to answer what might it look like to reimagine public health care and the systems that support the health of the community. Authors will present their work and engage in panel discussions, including on "The Dimensions of Public Health," and "The Public Health Workforce." Details.

#### Thurs. (6/6)

- 9:30am FDA Meeting: Drug Acts Financial Efficiency/Transparency The FDA holds a
  meeting to discuss the financial transparency and efficiency of the Prescription Drug User Fee
  Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments. <u>Details</u>.
- 9:30am Gladstone AI Discussion: Congressional AI Action Gladstone AI kicks off "Safety Forward" an artificial intelligence (AI) national security policy briefing series by providing analysis and commentary on Congressional AI action to date, highlighting strengths, gaps, and

- areas for improvement from a safety perspective. Policymakers, elected officials, and AI and national security experts will be participating. <u>Details</u>.
- 10:00am CDC Meeting: CDC Priorities The Centers for Disease Control and Prevention (CDC) holds a meeting of the Advisory Committee to the Director for an update on CDC priorities from the CDC Director, discussions on CDC's work to address equity and social determinants of health, lab readiness and response improvement efforts, and other program updates. <u>Details</u>.

# **Additional Multi-Day Events**

- June 5-June 6 HHS Meeting: HIV/AIDS Epidemic HHS holds a meeting of the Presidential Advisory Council on HIV/AIDS for panels on the state of HIV science, agencies' perspectives on ending the HIV epidemic, state-level system approaches from health departments and anti-LGBTQI+ laws and their impact nationally and globally. Details.
- June 6-June 7 Urban Institute Summit: Housing Justice The Urban Institute holds a summit on Advancing Housing Justice to showcase research from Urban's Housing Justice Hub and discuss narrative change efforts, equity measurement techniques, and emerging tools to help advance housing justice. <a href="Details">Details</a>.

## 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.

## Congressional Lookback

## Weds. (5/29)

• Reps. Bucshon, Carter, and Harshbarger introduced the <u>340B Affording Care for Communities</u> and Ensuring a Strong Safety-Net (<u>340B ACCESS</u>) Act. <u>Details</u>.

## Regulatory Lookback

#### Fri. (5/31)

- **CMS** published a <u>letter</u> sent to state Medicaid agencies regarding the extension of state reporting requirements on the unwinding of the Medicaid continuous enrollment condition. <u>Details</u>.
- **CMS** released a <u>SHO letter</u> describing 2025 updates to the Child and Adult Core Sets as well as additional information on mandatory reporting guidance. <u>Details</u>.

- The CBO released <u>preliminary results</u> of the potential impact of climate change on health and federal health care expenditure, with a specific focus on Medicare beneficiaries. <u>Details</u>.
- AHRQ issued an RFI on new strategies to advance interoperable, shareable, and reusable clinical decision support resources. Comments are due July 31. Details.

## Thurs. (5/30)

• **CMS** released an <u>RFA</u> detailing payment, care delivery, quality, and other policies for the ACO Primary Care Flex (ACO PC Flex) Model. <u>Details</u>.

## Weds. (5/29)

• The GAO <u>conducted</u> a study on Medicaid's EPSDT benefit, examining how managed care plans authorize services for children and how states oversee this process.

# Comment & Application Deadlines

- **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 3: AHRQ EPC issued a <u>request for supplemental evidence</u> and data submissions to inform its review on Management of Suicidal Thoughts and Behaviors in Youth. <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. 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>.
- July 16: CMMI announced the <u>Increasing Organ Transplant Access (IOTA) Model</u>. <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>. Details.



- 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.
- **July 31:** AHRQ issued an RFI on new strategies to advance interoperable, shareable, and reusable clinical decision support resources. Details.
- **September 30:** The CDC is <u>seeking nominations</u> for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). <u>Details</u>.