# Impact Health Policy Weekly

# Framing the Week

Congress is in full swing with two weeks to go before August recess. This week the Senate is expected to take up the National Defense Authorization Act, which will assuredly look very different from the controversial version the House debated last week. The House will be focusing on FAA reauthorization.

The House Energy and Commerce Committee may take up the PAHPA Reauthorization bill on Wednesday, after it narrowly passed out of the Health Subcommittee on party lines, though this could slip into next week. Democrats are upset the bill did not include drug shortage reforms. The Senate HELP Committee is scheduled to mark up their version of the PAHPA Reauthorization bill on Thursday.

Appropriations Markups continue this week as well. Last Friday the House Labor-HHS Subcommittee marked up their FY 2024 bill, which significantly cut funding for HHS agencies, including reducing CDC funding by \$1.6 billion and NIH funding by \$3.8 billion and eliminating funding for the Agency for Healthcare Research and Quality and gun violence research and prevention. A plethora of controversial provisions focused on abortion, social spending, DEI initiatives, and Critical Race Theory were also included. Full Committee markup has not yet been scheduled but is expected to be done before the end of the month. The Senate Appropriations Committee is expected to mark up their Labor-HHS bill on July 27.

# **Hearings and Markups**

- Senate HELP Committee- On Thursday, July 20, the Senate HELP Committee will mark up the Pandemic and All-Hazards Preparedness and Response Act.
- Senate Finance Committee-On Thursday, July 20, the Senate Finance Subcommittee on Health will hold a <a href="hearing">hearing</a> titled "The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System."
- House Energy and Commerce Committee- The Health Subcommittee will hold a hearing on Tuesday, July 18 titled "Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology."

# Regulatory Update

The Office of Management and Budget (OMB) is fiscal year 2024 Medicare payment final rules, including updates for acute care hospitals, inpatient psychiatric facilities, skilled nursing facilities, inpatient rehabilitation facilities, and hospice. Final action is not expected until November. Additionally, OMB is reviewing the following:

- Minimum staffing standards for long-term care facilities <u>Proposed rule</u> would address staffing requirements at long-term care facilities, including nursing homes.
- Medicaid and CHIP <u>Final rule</u> intended to streamline the eligibility and enrollment process for Medicaid and CHIP

# This Week in Health Policy

# Mon. (7/17)

4:15pm – O&A Committee Democrats Discussion: Medication Abortion Access – The
 Oversight and Accountability Committee Democrats hold a roundtable examining medication
 abortion access. Details.

# Tue. (7/18)

- 10:00am Hearing: Medicare Innovation The House Energy and Commerce Subcommittee on Health holds a hearing to examine Medicare coverage pathways for innovative drugs, medical devices, and technology, focusing on transparency around coverage determinations. <u>Details</u>.
- 10:00am Hearing: Compliance with Committee Oversight The House Judiciary Subcommittee on Responsiveness and Accountability To Oversight holds a hearing to examine the Department of Health and Human Services (HHS) and the Department of State's compliance to the Committee's document requests and subpoenas. Details.
- 12:30pm BPC Discussion: Child Care Partnerships The Bipartisan Policy Center (BPC)
  holds the final part in their event series on Early Head Start-Child Care Partnerships (EHS-CCP)
  with the Children's Equity Project to discuss how it helped communities stabilize child care
  partners during the pandemic, expand access to mental health services for children and families,
  and strengthen workforce development and retention. Details.
- 1:00pm CDC Meeting: CMS' Strategic Plan The Centers for Medicare and Medicaid Services (CMS) holds a Quarterly National Stakeholder Call to provide updates on CMS' recent accomplishments and how its cross-cutting initiatives are advancing CMS' Strategic Plan. Details.
- 2:00pm Hearing: DACA Medicaid Expansion The House Oversight and Accountability
  Subcommittee on Health Care and Financial Services holds a hearing to examine the effects of
  expanding Medicaid to DACA recipients on the border crisis. <u>Details</u>.

## Wed. (7/19)

- 9:30am Markup: Cybersecurity The Senate Homeland Security and Governmental Affairs
  Committee holds a business meeting to consider several cybersecurity related bills, among
  others. <u>Details</u>.
- 10:00am Hearing: Overregulation in Health Care The House Small Business Subcommittee on Oversight, Investigations, and Regulations holds a hearing titled "Burdensome Red Tape: Overregulation in Health Care and the Impact of Small Businesses." Details.
- 10:30am HITAC Meeting: Pharmacy Interoperability The Health Information Technology
  Advisory Committee (HITAC) holds a meeting of the Pharmacy Interoperability and Emerging
  Therapeutics Task Force to discuss program updates. <u>Details</u>.
- 2:00pm Hearing: Economic Impact of Diabetes The Senate Joint Economic Committee holds
  a hearing to examine the economic impact of diabetes and diabetes-related health
  complications, including the role of health and nutrition programs in diabetes prevention and
  pharmaceutical interventions. Details.

- 2:45pm Hearing: Vertical Mergers

   The Senate Judiciary Subcommittee on Competition,
  Policy, Antitrust, and Consumer Rights holds a hearing to examine trends in vertical merger
  enforcement. Details.
- **2:00pm NIST Meeting: Artificial Intelligence** The National Institute of Standards and Technology (NIST) holds a meeting of the National Artificial Intelligence Advisory Committee to discuss Working Group Chairs updates. <u>Details</u>.

#### Thurs. (7/20)

- 9:30am Hearing: Housing Accessibility for Older Adults The Senate Special Committee on Aging holds a hearing to examine housing accessibility and affordability for older adults and people with disabilities. Details.
- **10:00am Hearing: Transplant System** The Senate Finance Subcommittee on Health Care holds a hearing to examine the need to reform the U.S. organ transplant system. <u>Details.</u>
- 10:00am CSIS Discussion: National Cybersecurity Strategy The Center for Strategic and International Studies holds a discussion on the Department of Justice's implementation of President's Biden National Cybersecurity Strategy. Details.
- 10:30am Markup: Pandemic Preparedness The Senate Health, Education, Labor, and Pensions Committee holds a business meeting to consider its Pandemic and All-Hazards Preparedness and Response Act (PAHPA) reauthorization bill. <u>Details</u>.
- 2:00pm BPC Discussion: Legal Immigration Reform BPC holds a panel discussion on legal immigration reform issues and opportunities for legislative change. <u>Details</u>.
- **4:30pm Politico Discussion: Gene Therapy** Politico holds a discussion on the landscape of future health care gene therapies, including optimizing patient access and innovative payment and reimbursements structures that Congress and the Administration are debating. <u>Details</u>.

# **Additional Multi-Day Events**

- July 18-July 19 NIST Meeting: Internet of Things Report NIST holds a meeting of the
  Internet of Things Advisory Board on recommendations to be included in the Board's report for
  the IoT Federal Working Group. <u>Details</u>.
- July 19-July 20 HHS Meeting: Health Data Policy HHS holds a meeting of the National
  Committee on Vital and Health Statistics to discuss several health data policy topics, including a
  briefing on conversational artificial intelligence. <u>Details</u>.
- July 19-July 20 HHS Meeting: Human Research Protections HHS holds a meeting of the Secretary's Advisory Committee on Human Research Protections to discuss program updates, including an overview of the Food and Drug Administration (FDA) Draft Guidance on Decentralized Clinical Trials for Drugs, Biological Products, and Devices. <u>Details</u>.

#### Featured Analysis

- Impact Regulatory Outlook: 2023 Unified Agenda In the Policy Hub Insight Bank here.
- Impact Updated Chart: PBM Legislation Under Consideration In the Policy Hub Insight Bank here.
- Impact Tracker of COVID-19 PHE Flexibilities In the Policy Hub Insight Bank here
- Impact Health Policy Guide to the 118th Congress In the Policy Hub Insight Bank here.

• Impact Roundup of Surprise Billing and Transparency Updates—In the Policy Hub Insight Bank here.

# Congressional Lookback

# Thurs. (7/13)

• The House E&C Health Subcommittee convened a <u>markup</u> of 17 bills related to a wide array of health care-related issues. Details.

## Weds. (7/12)

- The CBO released its score of the PATIENT Act. Details.
- The SFC released a discussion draft that would establish PBM reporting requirements. Details.
- The Senate HELP Committee convened a <u>hearing</u> to assess the challenges posed by antimicrobial resistance (AMR). <u>Details</u>.

# Tues. (7/11)

• The House Committee on Education and Workforce introduced a <u>package of bills</u> aimed in increasing transparency in health care. <u>Details</u>.

## Regulatory Lookback

### Fri. (7/14)

 CMMI issued an RFI to inform the development of an episode-based payment model focused on improving beneficiary care and lowering Medicare expenditures. Responses are due August 17.
 Details.

#### Thurs. (7/13)

- CMS released the CY 2024 MPFS proposed rule. Comments are due September 11. Details.
- CMS released the CY 2024 OPPS proposed rule. Comments are due September 11. Details.
- SAMHSA announced a new <u>Harm Reduction Framework Draft</u> available to the public for comment. Comments are due August 5. <u>Details</u>.
- The USPSTF published a <u>final research plan</u> on screening for chronic kidney disease (CKD). <u>Details</u>.

# Mon. (7/10)

 CMMI released a <u>white paper</u> that retroactively analyzed previous model evaluations to determine the models' impacts on health <u>equity</u>. <u>Details</u>.

# Comment & Application Deadlines

- **July 21:** CMS recently opened a <u>public comment opportunity</u> related to cost measures for potential use in the Merit-Based Incentive Payment System (MIPS). <u>Details</u>.
- August 5: SAMHSA announced a new <u>Harm Reduction Framework Draft</u> available to the public for comment. <u>Details</u>.



- August 17: CMMI issued an RFI to inform the development of an episode-based payment model focused on improving beneficiary care and lowering Medicare expenditures. <u>Details</u>.
- August 23: The FDA issued <u>draft guidance</u> entitled: "Psychedelic Drugs: Considerations for Clinical Investigations. <u>Details</u>.
- August 25: CMS released the CY 2024 ESRD PPS proposed rule. Details.
- August 26: CMS released a notice with comment to establish the TCET pathway. Details.
- August 28: The FDA <u>issued</u> an RFI to assess whether in-home disposal products can mitigate
  the risk of nonmedical use or overdose of opioid analgesics. Submissions are due August 28.
  Details.
- **September 5:** CMS issued a <u>proposed rule</u> that describes the agency's proposed actions to remedy the payment for 340B drugs for calendar years (CYs) 2018 through 2022. <u>Details</u>.
- **September 5:** The CFPB and HHS issued an RFI on high-cost specialty financial products used to pay for health care. Details.
- **September 6:** The FDA <u>issued</u> a proposed rule to establish tobacco product manufacturing practice (TPMP) requirements. <u>Details</u>.
- **September 11**: HHS released a <u>proposed rule</u> to ensure short-term, limited duration insurance (STLDI) and fixed indemnity benefits coverage do not undermine consumer protections and requirements under the ACA. <u>Details</u>.
- September 11: CMS released the CY 2024 MPFS proposed rule. Details.
- September 11: CMS released the CY 2024 OPPS proposed rule. Details.
- September 29: The CDC <u>issued</u> a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). <u>Details</u>.
- November 17: The FDA <u>issued</u> a proposed rule to amend its <u>prescription drug labeling</u> regulations to require the inclusion Patient Medication Information (PMI). <u>Details</u>.