

Impact Health Policy Weekly

Framing the Week

The newly rebranded Impact Health Policy Partners is excited to share the [announcement](#) of our new CEO, Yvette Fontenot. **To celebrate these exciting developments and introduce you to Yvette, we are hosting a happy hour reception this Wednesday, June 7, from 5-7pm at [Bar Deco](#) in Washington.** We hope you will stop by for some drinks, apps, and good cheer. Please RSVP by emailing billy@impacthealthpolicy.com if you plan to attend.

Congressional Update

Both the House and Senate are in session this week, the first week of a three-week work period where both sides of the Capitol will be busy with hearings and appropriations markups (markups have not been scheduled but are expected to begin sometime this month).

Debt Ceiling Crisis Over: Last week the House and Senate managed to quickly move the Fiscal Responsibility Act through on a bipartisan basis, avoiding default on the national debt and preventing economic chaos. The President signed the bill over the weekend. In addition to lifting the debt ceiling for the next two years, the legislation solidifies that spending levels will be frozen at fiscal year (FY) 2023 levels for non-defense discretionary programs, with some adjustments for veteran's benefits and Biden priorities like the Moonshot Cancer program. Defense spending will be funded at the President's FY 24 request, which is a 3% increase. To calm Republican Senators that were concerned with what they considered to be low funding levels for DOD, Senate Majority Leader Chuck Schumer (D-NY) and Senate Minority Leader Mitch McConnell (R-KY) went on record stating they would support emergency supplemental funding later in the year to fund defense priorities, like aid for Ukraine, as well as funding for domestic disaster relief efforts and border security issues. Though it calmed Senators concerned with limited funding, getting a supplemental emergency funding package through the Republican controlled House will not be an easy process.

Hearings

House Energy & Commerce Committee: The E&C Subcommittee on Oversight will hold a hearing on Wednesday to examine the Centers for Disease Control and Prevention (CDC) 'Moving Forward Initiative', focusing on the lack of transparency around how the CDC developed and is implementing the initiative. [Details.](#)

Senate Finance Committee: On Thursday, the Senate Committee on Finance will hold a hearing to examine consolidation and corporate ownership in health care, focusing on trends and impacts on access, quality, and costs. [Details.](#)

Senate HELP Committee: Also on Thursday, the Senate Committee on Health, Education, Labor, and Pensions will hold a hearing to examine the American youth mental health crisis, focusing on causes and solution. [Details.](#)

Regulatory Update

The Office of Management and Budget (OMB) is currently reviewing the following rules.

- **Minimum staffing standards for long-term care facilities** – [Proposed rule](#) would address staffing requirements at long-term care facilities, including nursing homes.
- **340B Drug Pricing Program** – [Proposed rule](#) regarding potential remedies for safety-net hospitals affecting cost years 2018-2022. In *American Hospital Association v. Becerra*, the Supreme Court ruled in favor of safety-net hospitals that challenged Medicare reimbursement cuts for prescription drugs provided in outpatient settings.
- **Calendar year 2024 Medicare payment policies** – specifically, proposed updates to the [Physician Fee Schedule](#) and payment and policy updates for [hospital outpatient departments and ambulatory surgical centers](#), [home health agencies](#), and [end-stage renal disease facilities](#);
- **TCET Pathway** – [Proposed rule](#) that would establish criteria for an alternative coverage pathways to provide transitional coverage for emerging technologies (TCET) under Medicare; and
- **Short-Term Plans** – [Proposed rule](#) that would ensure short-term limited duration insurance includes protections for people with pre-existing conditions and other ACA protections.

This Week in Health Policy

Mon. (6/5)

- **9:30am – SAMHSA Meeting: Addiction Treatment** – The Substance Abuse and Mental Health Services Administration holds a meeting of the Interdepartmental Substance Use Disorders Coordinating Committee to discuss program updates and sections 1262 and 1263 of the Consolidated Appropriations Act, 2023, commonly known as the Mainstreaming Addiction Treatment Act and Medication Access and Training Expansion Act. [Details.](#)
- **2:00pm – ONC Webinar: Health IT** – The Office of the National Coordinator for Health Information Technology (ONC) holds a webinar to discuss with patient advocates and health IT experts how more immediate access to test results is changing the care paradigm for patients, and how providers are advancing communications with patients throughout the test ordering and result process. [Details.](#)
- **3:00pm – BPC Discussion: PEPFAR** – The Bipartisan Policy Center (BPC) holds a discussion focused on the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) 20-year anniversary since its authorization. The discussion will bring together key sectors that helped advance PEPFAR through the years. [Details.](#)

Tue. (6/6)

- **1:00pm – ITIF Discussion: Artificial Intelligence Regulation** – The Information Technology and Innovation Foundation hold a discussion focusing on the need for a new U.S. artificial intelligence (AI) regulator. [Details.](#)
- **3:00pm – 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.](#)

Wed. (6/7)

- **10:00am – Hearing: Opportunities for Modernization in Title IV** – The House Committee on Agriculture holds a hearing titled “Innovation, Employment, Integrity, and Health: Opportunities for Modernization in Title IV.” [Details.](#)
- **10:30am – Hearing: CDC Transparency and Reform** – The House Energy and Commerce Subcommittee on Oversight and Investigations holds a hearing to examine the Centers for Disease Control and Prevention (CDC) ‘Moving Forward Initiative’, focusing on the lack of transparency around how the CDC developed and is implementing the initiative. [Details.](#)

- **11:00am – Politico Summit: Health Care** – Politico holds a Health Care Summit with the theme “Checking the Pulse of America’s Health Care System.” Featured speakers include the Department of Health and Human Services Secretary Xavier Becerra, among others. [Details.](#)
- **3:00pm – Hearing: Artificial Intelligence** – The Senate Judiciary Committee holds a hearing to examine artificial intelligence (AI) and intellectual property, focusing on patents and competition. [Details.](#)
- **3:00pm – Hearing: Veterans’ Access to Long Term Care** – The Senate Committee on Veterans’ Affairs (VA) holds a hearing to examine veterans’ access to long term care. [Details.](#)

Thurs. (6/8)

- **9:30am – FDA Meeting: Prescription Drug User Fees** – The Food and Drug Administration (FDA) holds a meeting on “Financial Transparency and Efficiency of the Prescription Drug Use Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments.” [Details.](#)
- **10:00am – Hearing: Health Care Consolidation** – The Senate Committee on Finance holds a hearing to examine consolidation and corporate ownership in health care, focusing on trends and impacts on access, quality, and costs. [Details.](#)
- **10:00am – Hearing: Youth Mental Health Crisis** – The Senate Committee on Health, Education, Labor, and Pensions holds a hearing to examine the American youth mental health crisis, focusing on causes and solution. [Details.](#)
- **10:00am – Business Meeting: Controlled Substances Act** – The Senate Judiciary Committee holds a business meeting to consider the Cooper Davis Act ([S. 1080](#)) to amend the Controlled Substances Act to require electronic communication service providers and remote computing services to report to the Attorney General certain controlled substances violations. [Details.](#)
- **10:00am – BPC Discussion: Emerging Technology and the Workforce** –BPC holds a discussion focused on emerging technology’s role in shaping the workplace and workforce. Discussion topics include AI, automation, and the role of public policy in creating opportunities to maximize these technologies’ potential benefits while mitigating their potential risks. [Details.](#)
- **11:00am – LAN Discussion: Primary Care’s Role in Advancing Accountable Care** – The Health Care Payment and Learning Network (LAN) holds the second of its three-part LAN Spring Series. This discussion will feature leadership from the Centers for Medicare and Medicaid Services (CMS) and focus on CMS’s vision for a resilient, person-centered health system by strengthening primary care. In addition, the LAN will launch the new interactive Accountable Care Curve tool. [Details.](#)

Fri. (6/9)

- **10:00am – FDA Meeting: Leqembi Application Review** – FDA holds a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee to discuss supplemental biologics license application 761269/s-001, for LEQEMBI (lecanemab) solution for intravenous infusion, submitted by Eisai, Inc., for the treatment of early Alzheimer’s disease. [Details.](#)

Additional Multi-Day Events

- **June 7-June 8 – CMS Meeting: Health Equity Conference** – The Centers for Medicare and Medicaid Services (CMS) holds its inaugural CMS Health Equity Conference to discuss CMS’ leadership on recent developments, up-to-date research on health equity, and innovative solutions for community engagement efforts. [Details.](#)
- **June 8-June 9 – CDC Meeting: Health Care Infection Control Practices** – The Centers for Disease Control and Prevention (CDC) holds a meeting for the Healthcare Infection Control Practices Advisory Committee (HICPAC) to discuss updates on CDC’s activities for prevention of health care-associated infections and HICPAC workgroup updates. [Details.](#)

- **June 6-June 9 – HITAC Meeting: Health Data, Technology, and Interoperability Proposed Rule** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the HTI-1 Proposed Rule Task Force 2023 to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule. [Details.](#)

Featured Analysis

- **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

Regulatory Lookback

Fri. (6/2)

Thurs. (6/1)

- **CMS [announced](#)** that if the FDA grants traditional approval to Leqembi, the agency would provide broader Medicare coverage on the same day of approval. [Details.](#)

Weds. (5/31)

- **CMS [issued](#)** a final rule that makes regulatory changes to COVID-19 vaccination and testing requirements as part of the agency's transition out of the COVID-19 PHE. [Details.](#)
- **The FDA [issued](#)** a proposed rule to amend its prescription drug labeling regulations to require the inclusion Patient Medication Information (PMI). Comments are due November 17. [Details.](#)

Comment & Application Deadlines

- **June 5:** The USPSTF [is requesting](#) comment on a draft recommendation statement, draft evidence review, and draft modeling report on screening for breast cancer. [Details.](#)
- **June 5:** CMS [opened](#) a public comment opportunity related to Medicaid HCBS quality measure development. [Details.](#)
- **June 9:** CMS [released](#) the FY 2024 IPPS and LTCH PPS proposed rule. [Details.](#)
- **June 9:** The House Agriculture Committee leadership [launched](#) an online portal to gather feedback about the Farm Bill from non-committee members and the public. [Details.](#)
- **June 16:** HHS OCR [released](#) a proposed rule to modify HIPAA Privacy Rule to better protect sensitive information related to reproductive health care. [Details.](#)
- **June 20:** HHS ONC [issued](#) a proposed rule to revise and enhance the ONCE Health IT Certification Program. [Details.](#)
- **June 23:** CMS [released](#) a proposed rule to revise the definition of “lawfully present” in order to expand eligibility for health insurance coverage through the Exchange, Medicaid, and Basic

Health Program to recipients of the Deferred Action for Childhood Arrivals (DACA) program. [Details.](#)

- **June 30:** The NIH [issued](#) an RFI inviting input on research opportunities and best practices for Food is Medicine research program. [Details](#)
- **July 3:** CMS [released](#) a proposed rule aimed at strengthening access to and quality of care across Medicaid services. [Details.](#)
- **August 28:** The FDA [issued](#) 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 6:** The FDA [issued](#) a proposed rule to establish tobacco product manufacturing practice (TPMP) requirements. [Details.](#)
- **September 29:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details.](#)
- **November 17:** The FDA [issued](#) a proposed rule to amend its prescription drug labeling regulations to require the inclusion Patient Medication Information (PMI). [Details.](#)