

Impact Health Policy Weekly

Framing the Week

Happy Anniversary to the Affordable Care Act which was signed into law 14 years ago this week! The House and Senate are both in session this week as we once again countdown towards the expiration of the Continuing Resolution (CR) that is currently funding the last six fiscal year (FY) 2024 appropriations bills, including the bill that funds the Department of Health and Human Services. Five of the six bills appear ready to go but have been delayed over negotiations over immigration provisions in the Homeland Security Appropriations bill. The clock is ticking as House leadership has promised 72 hours for members to review legislation before a vote is scheduled and there will be some Senate Republicans that will want to offer amendments and have time to debate the large spending package. While a shutdown remains unlikely, even if text was released today, it leaves very little time to pass the final FY 2024 bills through both the House and Senate before the CR expires at midnight on Friday. This package covers funding for two-thirds of the federal government. The other six bills were passed and signed into law March 8.

Over the last week there has been a lot of discussion about possibly attaching additional health related bills to the omnibus budget package. Last Thursday Senate Finance Committee Chairman Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID) held a press conference with pharmacy leaders and pharmacists putting pressure on leadership to attach bipartisan pharmacy benefit manager (PBM) reforms to the budget bill. House Republican leadership is reluctant to add to the size of the package and so far have resisted adding any additional riders.

Though the hope is to finally wrap up FY 2024 at the end of the week, last week we moved on to FY 2025 when the President submitted his 7.3 trillion budget proposal to Congress (IHPP summary). The proposal focuses on lowering costs for American families, a cornerstone of President Biden's re-election campaign, including lowering the cost of prescription drugs, ensuring access to affordable health care, protecting and strengthen Social Security and Medicare, and fully funding federal nutrition assistance for women, infants, and children. Representatives from the Administration will continue to present and defend the budget proposal to Congress in hearings this week.

<u>Hearings</u>

House Appropriations Committee: On Tuesday the House Labor, Health and Human Services, Education Appropriations Subcommittee will hold a hearing to examine the President's FY 2025 budget request for the Department of Health and Human Services (HHS) with the HHS Secretary Xavier Becerra.

House Ways and Means Committee: On Tuesday the House Ways and Means Committee will hold a hearing on the President's FY 2025 budget request for HHS with HHS Secretary Xavier Becerra.

House Appropriations Committee: On Thursday the House Agriculture Appropriations Subcommittee will hold a <u>hearing</u> to examine the President's proposed budget request for FY 2025 for the Department of Agriculture (USDA) with the USDA Secretary Thomas Vilsack.

House Oversight and Accountability Committee: On Thursday the House Oversight and Accountability Cybersecurity, Information Technology, and Government Innovation Subcommittee will hold a hearing titled "White House Overreach on Artificial Intelligence (AI)."

House Oversight Select Committee on Coronavirus: On Thursday the House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic will hold a hearing titled "Assessing America's Vaccine Safety Systems, Part 2."

House Energy & Commerce Committee: On Thursday the House Energy and Commerce Health Subcommittee will hold a <u>hearing</u> to discuss the Food and Drug Administration's (FDA) proposed rule to regulate lab developed tests and alternative approaches to diagnostic regulation.

Regulatory Update

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

Medicare

- 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).
- Payment Update The proposed rules would make policy payment updates for <u>acute care</u>
 hospitals inpatient and long-term care hospitals, <u>hospice</u>, <u>inpatient psychiatric facilities</u>, <u>skilled</u>
 nursing facilities, and <u>inpatient rehabilitation facilities</u> (April 2024).
- Nursing Homes The <u>final rule</u> would establish minimum staffing standards for long-term care facilities and establish Medicaid institutional payment transparency reporting requirements (September 2026).

Medicaid

- Disproportionate Share Hospital Program The <u>final rule</u> would implement requirements under section 203 of the Consolidated Appropriations Act, 2021 (CAA), which relate to Medicaid shortfall and third-party payments (February 2024).
- Eligibility and Enrollment The <u>final rule</u> would implement changes to align enrollment and renewal requirements for most individuals in <u>Medicaid</u> and promote maintenance of coverage (February 2024).

Access to Care – A pair of final rule intended to access to care and quality outcomes for Medicaid
and CHIP beneficiaries enrolled in <u>managed care delivery systems</u> and <u>fee-for-service Medicaid</u>
(April 2024).

Commercial Insurance

- ACA Marketplace The <u>final rule</u> would make changes to regulations governing Affordable
 Care Act (ACA) Marketplace plans, insurance standards, and the risk adjustment program for
 plan year 2025 (not specified but likely April 2024).
- Short-Term Plans The <u>final rule</u> would modify definitions to ensure short-term, limited duration insurance and fixed indemnity benefits coverage do not undermine consumer protections and requirements under the Affordable Care Act (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).
- Reproductive Health Care Privacy The <u>final rule</u> would modify the HIPAA Privacy Rule to support reproductive health care privacy (March 20240.
- 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).
- **Disability** The <u>final rule</u> would revise regulations under section 504 of the Rehabilitation Act of 1973 to address discrimination on the basis of disability in HHS-funded programs and activities (April 2024)

This Week in Health Policy

Mon. (3/18)

3:00pm – Field Hearing: Emergency Medical Care – The House Ways and Means Committee holds a field hearing examining the challenges and opportunities surrounding recent investments in emergency care services and how to strengthen access to emergency care in America. Details.

Tue. (3/19)

• 10:00am – HITAC Meeting: Interoperability Standards – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Interoperability Standards Workgroup to discuss program updates. Details.

- 12:00pm Health Affairs Discussion: Medicare Value-Based Care Health Affairs holds a
 discussion with Dr. Douglas Jacobs, Chief Transformation Officer, Center for Medicare at the
 Centers for Medicare and Medicaid Services (CMS) on the Medicare value-based care strategy,
 as discussed in his latest article. Details.
- 12:00pm Politico Discussion: California's Prescription Drug Costs Politico holds a discussion on the challenges of affordable prescription drugs accessibility, focusing on challenges unique to California. Details.
- 2:00pm Axios Discussion: Future of AI Axios holds its third annual What's Next Summit featuring conversations on the future of AI, among other topics. Participants include Rep. Jay Obernolte (R-CA), Rep. Ted Lieu (D-CA), Transportation Secretary Pete Buttigieg, and Homeland Security Secretary Alejandro Mayorkas. <u>Details</u>.

Wed. (3/20)

- **10:00am Hearing: Nature of Climate Costs –** The Senate Budget Committee holds a hearing to examine the nature of climate costs. <u>Details.</u>
- 10:00am Hearing: President's HHS Budget Request for FY 2025 The House
 Appropriations Labor, Health and Human Services, Education Subcommittee holds a hearing to
 examine the President's proposed budget request for fiscal year (FY) 2025 for the Department
 of Health and Human Services (HHS) with the HHS Secretary Xavier Becerra. <u>Details</u>.
- 2:00pm Hearing: President's HHS Budget Request for FY 2025 The House Ways and Means Committee holds a hearing to examine the President's proposed budget request for FY 2025 for HHS with HHS Secretary Xavier Becerra. <u>Details</u>.
- 2:00pm Healthcare Leadership Council Discussion: Nutrition The Healthcare Leadership Council holds a discussion on programs that are improving the health of individuals and communities from beyond the walls of traditional clinical settings, with a focus on improving access to nutrition. Details.
- 2:30pm Hearing: Reproductive Freedom The Senate Judiciary Committee holds a hearing to examine post Dobbs America and reproductive freedoms. <u>Details</u>.

Thurs. (3/21)

- 10:00am Hearing: President's Budget Request for FY 2025 The Senate Finance Committee holds a hearing to examine the President's proposed budget request for FY 2025 with the Department of Treasury Secretary Janet Yellen. <u>Details</u>.
- 10:00am Hearing: President's USDA Budget Request for FY 2025 The House Appropriations Agriculture, Rural Development, Food and Drug Administration Subcommittee holds a hearing to examine the President's proposed budget request for FY 2025 for the Department of Agriculture (USDA) with the USDA Secretary Thomas Vilsack. <u>Details</u>.
- 10:00am Hearing: President's Budget Request for FY 2025 The House Budget Committee
 holds a hearing to examine the President's proposed budget request for FY 2025. <u>Details</u>.
- 10:00am Hearing: White House Action on AI The House Oversight and Accountability Cybersecurity, Information Technology, and Government Innovation Subcommittee holds a hearing titled "White House Overreach on Artificial Intelligence (AI)." <u>Details</u>.



- 10:00am Hearing: Diagnostic Test Regulation The House Energy and Commerce Health Subcommittee holds a hearing to discuss the Food and Drug Administration's (FDA) proposed rule to regulate lab developed tests and alternative approaches to diagnostic regulation. <u>Details</u>.
- 12:00pm ACL Meeting: Home/Community Based Services The Administration for Community Living (ACL) holds a meeting of the President's Committee for People With Intellectual Disabilities (PCPID) to discuss issues surrounding Home and Community Based Services to be examined in the Committee's Report to the President. Details.
- 12:00pm HHS Meeting: Catalytic Program on Utilizing the IRA The Department of Health and Human Services (HHS) holds a meeting as part of a "catalytic program" to support health care providers and safety net organizations in taking advantage of the tax credits, grants and other supports made available by the Inflation Reduction Act (IRA). This session will focus on other IRA opportunities. Details. AM covering meetings
- **2:00pm Hearing: Vaccine Safety Systems** The House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic holds a hearing titled "Assessing America's Vaccine Safety Systems, Part 2." <u>Details</u>.
- 2:30pm Hearing: President's Budget Request for FY 2025 Economic Outlook The House Appropriations Financial Services and General Government Subcommittee holds an oversight hearing to examine the President's proposed budget request for FY 2025 and economic outlook with the Department of Treasury Secretary Janet Yellen, and the Office of Management and Budget Director Shalanda Young. <u>Details</u>.

Fri. (3/22)

8:30am – NIH Meeting: Research Specific to Pregnant Women and Lactating Women – The
National Institutes of Health (NIH) holds a meeting of the National Institute of Child Health and
Human Development (NICHD) Task Force on Research Specific to Pregnant Women and
Lactating Women (PRGLAC) Implementation Working Group of Council to discuss updates
regarding the inclusion of pregnant women and lactating women in clinical trials. Details.

Additional Multi-Day Events

- Mar. 19-Mar. 20 HRSA Meeting: Health Service Future Program Priorities The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on the National Health Service Corps (NACNHSC) for the identification of NHSC priorities for future program issues and concerns; proposed policy changes by using the varying levels of expertise represented on the NACNHSC to advise on specific program areas, updates from clinician workforce experts and education and practice improvement in the training development of primary care clinicians. Details.
- Mar. 19-Mar. 20 CDC Meeting: International Diseases Classification Modification The
 Centers For Disease Control and Prevention (CDC) holds a meeting of the National Center for
 Health Statistics ICD-10 Coordination and Maintenance Committee for the presentation of
 proposed modifications to the International Classification of Diseases, Tenth Revision, Clinical
 Modification and ICD-10 Procedure Coding System. Details.
- Mar. 20-Mar. 21 HHS Meeting: Human Subjects Research HHS holds a meeting of the Secretary's Advisory Committee on Human Research Protections for a discussion of the draft recommendation, Ethical and Regulatory Considerations for the Inclusion of LGBTQI+

Populations in HHS Human Subjects Research and a discussion of considerations for uninformative research. 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.

Congressional Lookback

Fri. (3/15)

- MedPAC released its March 2024 Report to Congress. Details.
- MACPAC released its <u>March 2024 Report to Congress</u>. <u>Details</u>.

Thurs. (3/14)

- The SFC convened a <u>hearing</u> to examine President Biden's FY 2025 <u>budget for HHS. <u>Details</u>.
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- Sens. Cassidy (R-LA) and Carper (D-DE) introduced the <u>Delivering Unified Access to Lifesaving</u>
 Services (DUALS) Act of 2024. <u>Details</u>.

Weds. (3/13)

• The House W&M Committee held a <u>hearing</u> on improving access to care at home for rural and underserved communities. <u>Details</u>.

Tues. (3/12)

• The House E&C Health Subcommittee convened a <u>markup</u> of 19 legislative proposals that support patients and caregivers. <u>Details</u>.

Mon. (3/11)

- President Biden released his \$7.3 trillion <u>budget proposal</u> for FY 2025 which focuses on lowering costs for American families. <u>Details</u>.
- House and Senate Committees have made significant strides in addressing the integration of artificial intelligence (AI) and safeguarding sensitive data from foreign adversaries. <u>Details</u>.

Regulatory Lookback

Thurs. (3/14)

• The GAO released a <u>report</u> that examined the appeals and grievances data related to Medicaid Managed Care plans. <u>Details</u>.

Mon. (3/11)

• HHS <u>expanded the range of health care providers</u> eligible for advance payment under federal programs in response to a cyberattack on Change Healthcare. <u>Details</u>.

Comment & Application Deadlines

- March 21: The Senate HELP Committee issued a <u>request for information (RFI)</u> from stakeholders on the reauthorization of the Older Americans Act (OAA). <u>Details</u>.
- March 22: AHRQ EHC Program has an opportunity to support the development of a review entitled, "Evidence Map on Home and Community-Based Services". Details.
- March 22: HRSA <u>announced</u> \$8,750,000 for the Behavioral Health Integration (BHI) Evidence Based Telehealth Network Program (EB-TNP) grant program. <u>Details</u>.
- March 25: The USPSTF is requesting comment on a <u>draft recommendation statement</u> and draft evidence review on screening and supplementation for iron deficiency during <u>pregnancy</u>. <u>Details</u>.
- March 28: The NIH, through the Office of AIDS Research, issued an RFI to solicit input for the development of the FY 2026–2030 NIH Strategic Plan for HIV and HIV-Related Research. <u>Details</u>.
- April 1: The Senate 340B Bipartisan Working Group released a <u>discussion draft</u> for the SUSTAIN 340B Act. <u>Details</u>.
- April 2: HRSA announced a <u>notice of funding opportunity</u> under the State Maternal Health Innovation program. <u>Details</u>.
- April 12: SAMHSA <u>announced</u> \$9,995,000 for the Screening, Brief Intervention, and Referral to Treatment (SBIRT) grant program. <u>Details</u>.
- April 15: CMS released a <u>proposed rule</u> to strengthen oversight of accrediting organizations
 (AOs) by addressing conflicts of interest, establishing consistent standards, and updating the
 validation and performance systems. <u>Details</u>.
- April 15: SAMHSA <u>announced</u> \$5,400,000 for states and territories under the Provider's Clinical Support System grant program. <u>Details</u>.
- April 15: The FTC and HHS issued an RFI regarding market concentration among large health care group purchasing organizations (GPOs) and drug wholesalers. Details.
- April 19: The DOJ issued an <u>advance notice of proposed rulemaking</u> in response to the Executive Order of February 28, 2024, titled "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern." <u>Details</u>.
- 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</u>
 <u>Therapy Access Model</u>. Applications are due May 1. <u>Details</u>.
- 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>.