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# Impact Health Policy Weekly

## Framing the Week

The House and the Senate are both on a two-week spring recess after finally passing the last of the fiscal year (FY) 2024 appropriations bills over the weekend. Six months into the fiscal year, Congress passed a <u>minibus package</u> of six appropriations bills, including the Labor-HHS bill that funds the Department of Health and Human Services. President Biden <u>signed</u> the bill into law on Saturday.

Overall, \$116.8 billion in funding was provided for the Department of Health and Human Services, an increase of about \$955 million over last year. Most programs were flat funded or received modest increases with a couple of programs receiving cuts. Programs that received modest funding boosts include the National Institutes of Health, Biomedical Advanced Research and Development Authority, organ transplant system modernization and the 9-8-8 mental health crisis hotline.

Despite a last-minute push from members and advocates, the bill did not include a separate health care package that would have reformed pharmacy benefit manager and hospital billing practices.

Details on specific programs are below:

National Institutes of Health: The bill provides \$48.6 billion in base discretionary funding for the National Institutes of Health (NIH)—an increase of \$300 million in base funding over fiscal year 2023. ARPA-H receives a \$1.5 billion, the same as last year. Most of the funding increases go towards NIH priority programs, including \$120 million increase for the National Cancer Institute for cancer research; a \$75 million increase for mental health research; a \$100 million increase for Alzheimer's disease research; a \$10 million increase for opioid research; \$12.5 million for a new palliative care research program; a \$10 million increase for diabetes research; and a \$10 million increase for the IMPROVE initiative for research on maternal mortality.

**Mental Health:** The bill includes \$1 billion for the Mental Health Block Grant and \$153 million for the Behavioral Health Workforce Education and Training Program to support community-based clinical training and strengthen the mental health workforce. The bill also provides an \$18 million increase for the 988 Suicide Prevention Lifeline; continued \$385 million for Certified Community Behavioral Health Clinics; and \$98.8 million (a \$5 million increase) for the National Child Traumatic Stress Initiative. The bill also includes more than \$160 million in investments within the Department of Education to address the shortage of school-based mental health professionals in our nation's K-12 schools.

**Healthcare Workforce:** The bill includes a \$5 million increase for the Children's Hospital GME program, as well as a \$3 million increase for the National Health Service Corps; and a \$5 million increase for nursing training programs. HRSA's Graduate Medical Education program was flat funded.

**Organ Transplantation**: The bill increases funding for the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative by \$23 million to strengthen and reform the nation's organ donation and transplant system. This funding increase will allow HRSA to recompete the contract to run



the nation's organ allocation system and to potentially break up the current contract into multiple contracts. On a related note, the House Energy & Commerce Committee sent a <u>letter</u> HRSA requesting information on how the OPTN contract solicitation plan will support fair and competitive practices during the contracting process, promote data transparency and patient safety, and ensure system security and operability. A separate <u>letter</u> was sent to the United Network for Organ Sharing (UNOS), the current contractor, regarding the UNOS IT system security and operability, issues with patient safety and equity, and conflict-of-interest concerns.

**Pandemic Preparedness and Biodefense:** The bill includes \$3.6 billion for the Administration for Strategic Preparedness and Response (ASPR), including a \$65 million increase for the Biomedical Advanced Research and Development Authority (BARDA) and \$10 million to establish ongoing funding for industrial base manufacturing and supply chain activities to help ensure that critical resources in the public health supply chain—including raw materials, medical countermeasures, and ancillary supplies—are manufactured in the United States.

**Public Health Infrastructure:** The bill also includes \$350 million (same as FY 2023) to support public health infrastructure and capacity, and the public health workforce at the state and local level to improve preparedness and respond to emerging public health threats.

Agency for Healthcare Quality and Research: AHRQ received a \$4.5 million decrease in funding from last year, however it was stated that not less than \$13,500,000 is to be used for Long COVID research.

The full explanatory statement can be found <u>here</u>; the House Committee's summary can be found <u>here</u>; and the Senate Committee's summary can be found <u>here</u>.

# Regulatory Update

The Office of Management and Budget (OMB) completed reviewing the FY 2025 <u>inpatient rehabilitation</u> <u>facilities</u>. OMB is also reviewing the following rules:

#### Medicare

- Alternative Payment Models The proposed rule 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> <u>hospitals inpatient and long-term care hospitals</u>, <u>hospice</u>, <u>inpatient psychiatric facilities</u></u>, and <u>skilled nursing 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 Medicaid 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).
- 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).

## **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 Medicaid-participating 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 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).
- **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

# <u>Tue. (3/26)</u>



• **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. <u>Details</u>.

## Wed. (3/27)

- 9:00am SAMHSA Meeting: Serious Mental/Emotional Illness The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee to provide information on federal efforts related to serious mental illness and serious emotional disturbance. <u>Details</u>.
- 10:00am USPTO Meeting: AI and Intellectual Property The United States Patent and Trademark Office (USPTO) holds a meeting of the Artificial Intelligence (AI)/Emerging Technologies (ET) Partnership to discuss insights regarding the intersection of intellectual property (IP) and AI/ET. <u>Details</u>.

#### <u> Thurs. (3/28)</u>

- **1:00pm AHP Discussion: Policy Opportunities for Dually Eligible Individuals** The Alliance for Health Policy (AHP) holds a discussion on the role of Medicare, Medicaid, and the private sector in providing care for dually eligible populations and to present policy efforts and strategies to improve care for that population. The executive director of the Medicaid and CHIP Payment and Access Commission (MACPAC) Kate Massey will be participating. <u>Details</u>.
- 2:00pm CDC Meeting: Health Equity Science The Centers for Disease Control and Prevention (CDC) holds a meeting of the Office of Health Equity (OHE) to discuss using health equity science and data for action. OHE will share additional information about the <u>Principles of</u> <u>Health Equity Science for Public Health Action</u>. <u>Details</u>.
- 2:00pm PEPC Discussion: Physician Experience in CMMI Models The Partnership to Empower Physician-Led Care (PEPC) holds a webinar highlighting the independent physician experience in CMS Innovation Center Models. CMS Innovation Center Chief Strategy Officer Purva Rawal will be participating. <u>Details</u>.

## Fri. (3/29)

 12:00pm – US News and World Report Discussion: Drug Shortages – The U.S. News and World Report holds a discussion on regulatory changes and tools that could increase visibility into the supply chain regarding persistent drug shortages and the need to forecast potential risks and weak points earlier. Panelists will discuss efforts to ramp up domestic production of generic drugs and explore the role advanced manufacturing and AI can play in alleviating drug shortages over the long term. <u>Details</u>.

#### Additional Multi-Day Events

 Mar. 25-Mar. 26 – HHS Meeting: Physician-Focused Payment Models – The Department of Health and Human Services (HHS) holds a meeting of the Physician-Focused Payment Model Technical Advisory Committee for deliberation and voting on proposals for physician-focused payment models submitted by individuals and stakeholder entities, including on developing and implementing performance measures for Population-Based Total Cost of Care (PB-TCOC) models. <u>Details</u>.



 Mar. 27-Mar. 28 – HHS Meeting: HIV/AIDS Treatment – HHS holds a meeting of the Presidential Advisory Council on HIV/AIDS to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective HIV diagnosis, treatment, prevention, and quality care services. Topics for discussion include ending the HIV epidemic in Texas, addressing the needs of Black & Brown cisgender women, and addressing the needs of new immigrants particularly in the LatinX community. <u>Details</u>.

## Featured Analysis

- Impact Roundup of January Behavioral Health Actions In the Policy Hub Insight Bank <u>here</u>.
- Impact Chart of Key Provisions of Legislative Proposals on Health Care Price Transparency Requirements – In the Policy Hub Insight Bank <u>here</u>.
- 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

#### <u> Thurs. (3/21)</u>

- The House W&M Committee convened a <u>hearing</u> with HHS Secretary Xavier Becerra to examine President Biden's FY 2025 budget for HHS. <u>Details</u>.
- The House E&C Health Subcommittee convened a <u>hearing</u> to examine diagnostic test regulation and the FDA <u>proposed rule</u> to make explicit that lab developed tests (LDTs) are medical devices. <u>Details</u>.
- The House Oversight and Accountability Coronavirus Pandemic Subcommittee convened its <u>second</u> session of a two-part hearing series to evaluate the effectiveness of vaccine safety reporting and injury compensation systems post-COVID-19 vaccine rollout. <u>Details</u>.
- The House Appropriations Ag-Rural Development-FDA Subcommittee held a hearing with USDA Secretary Vilsack to discuss the President Biden's FY 2025 budget. <u>Details</u>.

## Weds. (3/20)

- The House E&C Committee convened a <u>markup</u> of 28 bills covering a range of topics including energy, climate, grid security, environment, manufacturing, critical materials, health, and communications technology. <u>Details</u>.
- The House Appropriations Labor-HHS-Education Subcommittee convened a <u>hearing</u> with HHS
  Secretary Xavier Becerra to examine President Biden's FY 2025 budget for HHS. <u>Details</u>.

## Regulatory Lookback



# <u>Thurs. (3/21)</u>

• The HHS OCCHE held a presentation to discuss the Office's Catalytic Program on Utilizing the Inflation Reduction Act. <u>Details</u>.

# <u>Weds. (3/20)</u>

- HRSA <u>announced</u> the opportunity to apply for base and matching funds under the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program. Applications are due May 29. <u>Details</u>.
- **HRSA** <u>announced</u> the availability of funding under the Maternal and Child Health Services Block Grant program. Applications are due June 15. <u>Details</u>.

# <u>Tues. (3/19)</u>

• **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. Applications are due June 17. <u>Details</u>.

## <u>Mon. (3/18)</u>

 President Biden issued an <u>executive order</u> entitled "Advancing Women's Health Research and Innovation" aimed at transforming women's health research across the life span at the NIH. <u>Details</u>.

## Comment & Application Deadlines

- 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 pregnancy. <u>Details</u>.
- March 28: The NIH, through the Office of AIDS Research, issued an <u>RFI</u> 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 proposed rule 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 <u>RFI</u> regarding market concentration among large health care group purchasing organizations (GPOs) and drug wholesalers. <u>Details</u>.
- 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>.
- 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 15: HRSA <u>announced</u> the availability of funding under the Maternal and Child Health Services Block Grant program. <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>.