

Impact Health Policy Weekly

Framing the Week

Happy July 4th! The House and Senate are both on recess this week for the holiday. We hope you all have a wonderful Independence Day celebration!

Prior to recessing, the House had a busy week last week passing three of the fiscal year (FY) 2025 appropriations bills by mostly partly line votes on the floor, and moving the last five bills through Subcommittee, including the Labor-HHS-Education bill. The overall funding level for the Labor-HHS bill is \$24.6 billion (11%) less than last year, which resulted in some drastic cuts. HHS received \$109.5 billion, a decrease of \$7.5 billion, or 6.4 percent, below the FY 2024 level and \$9.7 billion below the 2025 Administration request. CDC, HRSA, and the Administration on Children and Families all received cuts, while programs such as the Agency for Healthcare Research and Quality and Title X Family Planning, the Healthy Start Program, and the Ending the HIV Epidemic programs were eliminated. The Democratic summary of the bill can be found [here](#), and the Republican summary is [here](#). The bill is scheduled to go to the full Committee on July 10. The Senate has not yet begun marking up FY 25 bills, but it is safe to assume that the elimination of programs and controversial riders that have been included in the House bills will not survive in the Senate.

Supreme Court Chevron Ruling:

On Friday, in a [6-3 decision](#) the Supreme Court reversed a 1984 decision known as the “Chevron deference” that allowed federal agencies, not the courts, leeway to implement laws that were ambiguous or lacked specificity. The 1984 decision was based on the idea that experts employed by federal agencies have more knowledge and expertise than federal judges when it came to complex regulations. With this ruling, however, the power is returned to the courts thereby substantially weakening federal agencies. This ruling could have a major impact on complex technical health care regulations including FDA drug and medical device approvals, Medicare reimbursement, and drug pricing.

Healthcare stakeholder organizations such as the American Academy of Pediatrics, American Cancer Society, American Public Health Association and others [submitted an amicus brief](#) prior to the decision warning of chaos for health programs if *Chevron* was overturned.

The decision is not retroactive, so previous court rulings that used the Chevron deference will not be overturned, but going forward we can expect that courts will increasingly take up cases involving an agency’s interpretation of ambiguous laws. In fact, there has been some speculation that this ruling could open the door to legal challenges for some of the more controversial federal rules recently put out by HHS, such drug price negotiation, the nursing home staffing rule and the LDT rule.

Regulatory Update

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

Medicare

- **Calendar Year (CY) Payment Updates** – The CY 2025 proposed rule for [Medicare Physician Fee Schedule and hospital outpatient departments and ambulatory surgical centers](#) (June 2024).
- **Fiscal Year (FY) Payment Updates** – The FY 2025 final rules for [hospitals and long-term care hospitals](#), and [skilled nursing facilities](#) (August 2024).

Medicaid

- **Drug Rebate Program** – The [final rule](#) would establish 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 Medicaid-participating providers and suppliers (was set for December 2023).
- **Tobacco Products** – The [final rule](#) would prohibit the sale of tobacco products to persons younger than 21 years of age (was set for April 2024).
- **Retail Pharmacy Standards** – The [final rule](#) would require pharmacies and vendors to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version 10 (was set for February 2024).

This Week in Health Policy

Thurs. (7/4)

- **Holiday – Independence Day**

Additional Multi-Day Events

- **July 1-July 2 – HHS Meeting: AA and NHPI Equity** – The Department of Health and Human Services (HHS) holds a meeting of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders to discuss recommendations by the Commission's six subcommittees on ways to advance equity, justice, and opportunity for Asian American, Native Hawaiian, and Pacific Islander (AA and NHPI) communities. [Details](#).

Featured Analysis

- **Impact Mental Health Legislative Update** – In the Policy Hub Insight Bank [here](#).
- **Impact Roundup of Behavioral Health Administrative 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 Artificial Intelligence Policy Round Up** – In the Policy Hub Insight Bank [here](#).

Congressional Lookback

Thurs. (6/27)

- **The House W&M Committee** convened a [markup](#) of four bills related to access to breakthrough devices, multi-cancer diagnostics, prescription digital therapeutics, remote monitoring devices with an artificial intelligence component, medically tailored meals, and obesity treatment. [Details](#).

Weds. (6/26)

- **The House W&M Health Subcommittee** convened a [hearing](#) to discuss ways to improve and expand value-based care. [Details](#).
- **House E&C Leadership** formally introduced the [American Privacy Rights Act \(APRA\)](#), federal privacy legislation aimed at establishing national data privacy rights. [Details](#).

Regulatory Lookback

Fri. (6/28)

- **The Biden Administration** released an [agenda](#) to lower costs across various sectors. [Details](#).
- **CMS** released a [proposed rule](#) to mitigate the impact of significant, anomalous, and highly suspect billing activity involving intermittent urinary catheters on financial calculations in CY 2023 for ACOs participating in the MSSP. Comments are due July 29. [Details](#).
- **CMMI** released an [RFA](#) for the Cell and Gene Therapy Access Model. Applications are due February 25. [Details](#).

Thurs. (6/27)

- **SCOTUS** ruled to dismiss [Moyle v. United States](#), reinstating a District Court ruling that requires hospitals to provide abortions in medical emergencies in Idaho. [Details](#).
- **CMS** released its CY 2025 end-stage renal disease (ESRD) prospective payment system (PPS) [proposed rule](#). Comments are due August 26. [Details](#).
- **HHS OIG** [conducted](#) a study to assess how states monitor maltreatment in residential facilities for children in foster care. [Details](#).

Weds. (6/26)

- **CMS** released a [notice of funding opportunity \(NOFO\)](#) for the Transforming Maternal Health (TMaH) Model. Applications are due September 20. [Details](#).

- **CMS** issued the CY 2025 home health prospective payment and rate update [proposed rule](#). Comments are due August 26. [Details](#).
- **The FDA** issued [draft guidance](#) entitled “Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.” Comments are due September 26. [Details](#).

Tues. (6/25)

- **SAMHSA** issued [guidance](#) on available federal funding provided by the Bipartisan Safer Communities Act (BSCA) for supporting LGBTQI+ youth mental health. [Details](#).
- **SAMHSA** is [seeking](#) applications for the Women’s Behavioral Health Technical Assistance Center (Women’s BH TAC) program for fiscal year 2024. Applications are due August 20. [Details](#).

Mon. (6/24)

- **CMS and ONC** released a [final rule](#) to establish disincentives for providers who are determined to have committed information blocking. [Details](#).

Comment & Application Deadlines

- **July 10:** The GAO is [seeking nominations](#) for the Physician-Focused Payment Model Technical Advisory Committee. [Details](#).
- **July 11:** HHS OMH issued an [RFI](#) on how community health workers can enhance cultural competency in public health educational campaigns. [Details](#).
- **July 12:** CMS is seeking [nominations](#) for a Technical Expert Panel (TEP) to support the expansion of the CMS’ Maternal Morbidity Structural Measure ([MMSM](#)) and the CMS’ [Birthing-Friendly Hospital Designation](#). [Details](#).
- **July 29:** CMS released a [proposed rule](#) to mitigate the impact of significant, anomalous, and highly suspect billing activity involving intermittent urinary catheters on financial calculations in CY 2023 for ACOs participating in the MSSP. [Details](#).
- **July 31:** AHRQ issued an [RFI](#) on new strategies to advance interoperable, shareable, and reusable clinical decision support resources. [Details](#).
- **August 12:** The CFPB issued a [proposed rule](#) aimed at eliminating medical bills from most credit reports. [Details](#).
- **August 17:** CMS released a [notice of funding opportunity](#) for the Expanding Access to Women’s Health Grant. [Details](#).
- **August 20:** SAMHSA is [seeking](#) applications for the Women’s Behavioral Health Technical Assistance Center (Women’s BH TAC) program for fiscal year 2024. [Details](#)
- **August 26:** CMS issued the CY 2025 home health prospective payment and rate update [proposed rule](#). [Details](#).

- **August 26:** CMS released its CY 2025 end-stage renal disease (ESRD) prospective payment system (PPS) [proposed rule](#). [Details](#).
- **September 20:** CMS released a [notice of funding opportunity \(NOFO\)](#) for the Transforming Maternal Health (TMaH) Model. [Details](#).
- **September 26:** The FDA issued [draft guidance](#) entitled “Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.” [Details](#).
- **September 30:** The CDC is [seeking nominations](#) for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details](#).
- **February 25:** CMMI released an [RFA](#) for the Cell and Gene Therapy Access Model. [Details](#).