

## Impact Health Policy Weekly

### Framing the Week

The House and Senate are both back in session this week, with a full agenda to tackle over the 11 legislative days before the government runs out of funding on September 30. The Senate will be taking up the first appropriations “minibus” package this week which will include the Committee passed Agriculture, Military Construction-VA, and Transportation bills.

On the House side, the Department of Defense Appropriations bill may see floor action this week, followed by Homeland Security and State-Foreign Ops next week. Over 300 amendments have been filed on the DOD bill, including several “culture war” focused amendments.

A recently introduced bipartisan package may also be squeezed in this month. Leadership from the Energy and Commerce (E&C), Ways and Means (W&M), and Education and Workforce Committees introduced the Lower Costs, More Transparency Act ([Impact Health summary](#)). The bill largely includes previously marked up and advanced legislation from the three Committees and features provisions that will:

- Increase transparency of hospital prices, clinical diagnostic laboratory test prices, imaging prices, ambulatory surgical center prices, health coverage prices, and pharmacy benefit manager (PBM) practices;
- Provide parity in Medicare payments for hospital outpatient department services furnished off-campus;
- Prohibit spread pricing in Medicaid;
- Reauthorize for Community Health Centers, the Teaching Health Center GME program, National Health Service Corps; and the Special Diabetes Program;
- Delay Disproportionate Share Hospital (DSH) reductions under Medicaid; and
- Increase plan fiduciary access to health data and requiring hidden fee disclosures.

**House Energy & Commerce:** On Thursday, the House Energy and Commerce Committee Health Subcommittee will hold a [hearing](#) on Thursday on drug shortages. This will focus on Chair Cathy McMorris Rodgers’ [proposal](#) and four other bills from both sides of the aisle that address the drug shortages facing America. Committee Democrats had pushed to include a drug shortage provision in the Committee’s PAHPA Reauthorization bill ([Impact Summary](#)) that passed in July, but the majority argued it wasn’t the appropriate vehicle. Later in the month it is reported that the Oversight and Investigations subcommittee will hold an IRA focused hearing and the Health Subcommittee will hold a hearing on Medicare innovation.

**Other Hearings:** As noted below, Congress will convene four hearings – three in the Senate and one in the House – on artificial intelligence to inform legislation establishing guardrails for AI and oversight

and enforcement mechanisms. The House Oversight Select Subcommittee on the Coronavirus Pandemic will convene a hearing to examine COVID-19 pandemic's effect on the doctor-patient relationship.

### Regulatory Update

The Office of Management and Budget (OMB) completed reviewing the first of [two final rules](#) intended to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP and the Basic Health Program. The first final rule expected in September 2023 will remove barriers and facilitate enrollment of new applicants, particularly those dually eligible for Medicare and Medicaid. The second final rule expected in February 2024 will implement changes to align enrollment and renewal requirements for most individuals in Medicaid and promote maintenance of coverage.

OMB is also reviewing the following rules:

- **CMS Enforcement of State Compliance with Medicaid Reporting and Renewal Requirements** –The [interim final rule](#) would establish rules regarding CMS enforcement of states' compliance with reporting requirements and renewal requirements during the period that begins on July 1, 2023 and ends on June 30, 2024. The interim final rule may codify [existing guidance](#) and provide more details on how CMS may enforce the requirements. The interim final rule was not included in the Spring 2023 Unified Agenda.
- **Food and Drug Administration (FDA) Regulation of Laboratory-Developed Tests (LDTs)** – [Proposed rule](#) would make explicit that LDTs are devices under the Federal Food, Drug, and Cosmetic Act and subject to FDA regulation.
- **Annual Rulemaking for Commercial Insurers** – Proposed rules for the [CY 2025 Policy and Technical Changes to Medicare Advantage and Part D](#) (expected in October 2023) and [CY 2025 Notice of Benefit and Payment Parameters](#) (expected in November 2023)
- **Surprise Billing Regulations** – A [proposed rule](#) to amend requirements for the independent dispute resolution (IDR) process, as well as a [proposed rule](#) to set fees for IDR. Due to legal challenges, the IDR process is [temporarily suspended](#) for all disputes.
- **Over-the-Counter Contraception** – A request for information regarding coverage of over-the-counter preventive products arrived at OMB for review last week. The RFI was not included in the Unified Agenda. It stems from President Biden's [Executive Order](#) on Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services, which requires HHS, Labor, and Treasury to pursue actions increasing access to affordable OTC contraception. The first and only FDA-approved OTC oral contraceptive will be available in early Q1 2024.

**Mon. (9/11)**

- **10:30am – NIH Meeting: NIAID Reports** – The National Institutes of Health (NIH) holds a meeting of the NIAID National Advisory Allergy and Infectious Diseases Council to discuss program updates and reports. [Details.](#)
- **1:00pm – HHS Meeting: Disability Discrimination** – The Health and Human Services (HHS) Department Office for Civil Rights (OCR) holds a meeting to discuss OCR’s proposed rule to update HHS’ regulations implementing Section 504 of the Rehabilitation Act, which prohibits disability discrimination by recipients of federal funding. [Details.](#)
- **3:00pm – Urban Institute Discussion: AI in Health Care** – The Urban Institute holds a discussion on addressing current challenges to building equitable AI in health care. [Details.](#)

**Tue. (9/12)**

- **9:00am – HRSA Meeting: Telehealth** – The Health Resources and Services Administration (HRSA) holds a National Telehealth Conference to discuss telehealth best practices, including the expansion of broadband connectivity to improve health equity and integrating telehealth into standard care. HRSA Administrator Carole Johnson and the Centers for Medicare and Medicaid Services (CMS) Deputy Administrator Meena Seshamani are scheduled to attend. [Details.](#)
- **9:00am – NIH Meeting: Nursing Research** – NIH holds a meeting of the National Institute of Nursing Research to discuss research updates, including artificial intelligence consortium to advance health equity and researcher diversity. [Details.](#)
- **10:00am – CDC Meeting: COVID-19 Vaccines** – The Centers for Disease Control and Prevention (CDC) hold a meeting of the Advisory Committee on Immunization Practices (ACIP) to discuss COVID-19 vaccines, including recommendation votes. [Details.](#)
- **11:00am – BPC Discussion: Paid Family Leave** – The Bipartisan Policy Center holds a discussion on the role that paid family leave can play in helping non-working adults return to the workforce. [Details.](#)
- **12:00pm – KFF Discussion: Medicare Drug Price Negotiations** – The Kaiser Family Foundation (KFF) holds a discussion to examine the legal arguments in the drug industry’s challenges to the Medicare Drug Price Negotiation Program and how they intersect with the policy goals of the legislation. [Details.](#)
- **2:30pm – Hearing: AI Regulation** – The Senate Judiciary Subcommittee on Privacy, Technology, and the Law holds an oversight hearing to examine AI, focusing on legislation. [Details.](#)
- **2:30pm – Hearing: AI Transparency** – The Senate Commerce, Science, and Transportation Subcommittee on Consumer Protection, Product Safety, and Data Security holds a hearing to examine the need for transparency in AI. [Details.](#)

**Wed. (9/13)**

- **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. [Details.](#)
- **12:00pm – AACR Briefing: Cancer Research** – The American Association for Cancer Research holds a briefing to unveil the “AACR Cancer Progress Report 2023.” [Details.](#)

**Thurs. (9/14)**

- **9:00am – Hearing: Member Day** – The House Ways and Means Committee holds a Member Day hearing. [Details.](#)
- **10:00am – Hearing: AI Regulation** – The Senate Homeland Security and Governmental Affairs Committee holds a hearing to examine governing AI through acquisition and procurement. [Details.](#)
- **10:00am – Hearing: Drug Shortages** – The House Energy and Commerce Subcommittee on Health holds a hearing to examine the root cause of generic drug shortages. [Details.](#)
- **10:00am – Hearing: Doctor-Patient Relationship** – The House Oversight and Accountability Select Coronavirus Pandemic Subcommittee holds a hearing to examine to COVID-19 pandemic’s effect on the doctor-patient relationship. [Details.](#)
- **11:00am – CDC Meeting: AI/Long-term Health Care Data Collection** – The CDC holds a meeting of the National Center for Health Statistics’ Board of Scientific Counselors to discuss the role of artificial intelligence in NCHS programs and an update on long-term health care data collection. [Details.](#)
- **1:00pm – Hearing: AI Regulation** – The House Oversight and Accountability Subcommittee on Cybersecurity, Information Technology, and Government Innovation holds a hearing to examine how federal agencies are harnessing AI. [Details.](#)
- **1:00pm – HITAC Meeting: Annual Report Workgroup** – HITAC holds a meeting of the Annual Report Workgroup to discuss program updates. [Details.](#)
- **1:30pm – Brookings Discussion: AI Regulation** – The Brookings Institute holds a discussion on frontier AI systems and how to proactively regulate them. [Details](#)
- **1:30pm – AEI Discussion: Drug Pricing** – The American Enterprise Institute (AEI) holds a webinar to discuss alternatives that would balance pharmaceutical product innovation with fiscal prudence while deploying the principles of managed care. [Details.](#)
- **2:00pm – Hearing: Inflation Reduction Act Review** – The House Oversight and Accountability Health Care and Financial Services Subcommittee holds a hearing to examine the first anniversary of the Inflation Reduction Act. [Details.](#)
- **2:00pm – BPC Discussion: AI Governance** – The Bipartisan Policy Center holds a discussion on artificial intelligence policy issues being considered in Congress and the White House, including the impact of data privacy policy measures on AI governance. [Details.](#)
- **3:00pm – Health Affairs Discussion: CMMI GUIDE Model** – Health Affairs holds a policy spotlight with the Director of the Center for Medicare and Medicaid Innovation (CMMI) to discuss

the Guiding an Improved Dementia Experience (GUIDE) model, and CMMI's strategy refresh that's informing future model development. [Details.](#)

### Additional Multi-Day Events

- **Sep. 11-Sep. 12 – FDA Meeting: Oral Phenylephrine** – The Food and Drug Administration (FDA) holds a meeting of the Nonprescription Drugs Advisory Committee to discuss new data regarding the 'Generally Recognized as Safe and Effective' status of oral phenylephrine as a nasal decongestant that have become available since FDA last examined the issue. [Details.](#)
- **Sep. 12-Sep. 13 – CMS Meeting: ICD-10 Procedure Codes** – CMS holds a meeting of the ICD-10 Coordination and Maintenance Committee to discuss new technology add-on payment (NTAP)-related ICD-10 procedure codes. [Details.](#)
- **Sep. 12-Sep. 13 – DEA Meeting: Telemedicine** – The Drug Enforcement Administration (DEA) holds a public listening session to receive comments from health care practitioners, advocates, and patients to inform DEA's regulations on prescribing controlled substances via telemedicine. [Details.](#)
- **Sep. 12-Sep. 13 – HHS Meeting: Dietary Guidelines** – HHS holds a meeting of the 2025 Dietary Guidelines Advisory Committee to detail progress made on the guidelines. [Details.](#)

### 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 118<sup>th</sup> 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

#### Fri. (9/8)

- **House leadership** introduced the [Lower Costs, More Transparency Act.](#) [Details.](#)
- **MedPAC** convened virtually for Day Two of its [September 2023 public meeting](#) and held sessions on Medicare's Acute Care Hospital at Home Program and ambulatory surgical centers. All Impact Health session summaries are available on Policy Hub [here.](#)

#### Thurs. (9/7)

- **MedPAC** convened virtually for Day One of its [September 2023 public meeting](#) and held sessions on Commission's work plan and Medicare Advantage. All Impact Health session summaries are available on Policy Hub [here](#).

#### **Weds. (9/6)**

- **Sen. Cassidy (R-LA)** released a [white paper](#) on artificial intelligence (AI) discussing AI's potential benefits and risks to society. Feedback is due September 22. [Details](#).

#### Regulatory Lookback

#### **Thurs. (9/7)**

- **HHS** issued a [proposed rule](#) to amend the regulations at section 504 which protect against discrimination based on disability by recipients of financial assistance through HHS programs or activities. Comments are due November 13. [Details](#).

#### **Weds. (9/6)**

- **CMS** opened a [public comment opportunity](#) related to Medicaid HCBS quality measure development, reliability, and usability. Comments are due September 21. [Details](#).

#### **Tues. (9/5)**

- **CMMI** announced the [State Advancing AHEAD Model](#) to address unsustainable health care cost growth, poor population health, and disparities in health outcomes. Applications are due March 6. [Details](#).

#### Comment & Application Deadlines

- **September 11:** HHS released a [proposed rule](#) to ensure short-term, limited duration insurance (STLDI) and fixed indemnity benefits coverage do not undermine consumer protections and requirements under the ACA. [Details](#).
- **September 11:** CMS issued a [proposed rule](#) that describes the agency's proposed actions to remedy the payment for 340B drugs for calendar years (CYs) 2018 through 2022. [Details](#).
- **September 11:** CMS released the CY 2024 MPFS [proposed rule](#). [Details](#).
- **September 11:** CMS released the CY 2024 OPPS [proposed rule](#). [Details](#).
- **September 20:** CMS [issued](#) draft part one guidance on a select set of topics for the *Maximum Monthly Cap on Cost-Sharing Payments Program*. [Details](#).
- **September 21:** CMS opened a [public comment opportunity](#) related to Medicaid HCBS quality measure development, reliability, and usability. [Details](#).

- **September 22:** Sen. Cassidy (R-LA) released a [white paper](#) on artificial intelligence (AI) discussing AI's potential benefits and risks to society. [Details.](#)
- **September 25:** The USPSTF is requesting comment on a [draft recommendation](#) statement and draft evidence review on primary care interventions to prevent child maltreatment. [Details.](#)
- **September 29:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details.](#)
- **October 6:** CISA and FEMA are collaborating to [provide](#) \$374.9 million in grants to enhance cybersecurity for state and local governments, responding to increasing threats to critical infrastructure and public safety. [Details](#)
- **October 10:** The EEOC issued an [NPRM](#) to implement the Pregnant Workers Fairness Act. [Details.](#)
- **November 13:** HHS issued a [proposed rule](#) to amend the regulations at section 504 which protect against discrimination based on disability by recipients of financial assistance through HHS programs or activities. [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.](#)
- **November 30:** CMMI released a [Request for Application](#) detailing payment, care delivery, quality, and other policies for the Making Care Primary (MCP) Model. [Details.](#)
- **March 6:** CMMI announced the [State Advancing AHEAD Model](#) to address unsustainable health care cost growth, poor population health, and disparities in health outcomes. [Details.](#)