

Impact Health Policy Weekly

Framing the Week

It is officially October, and the government remains in operation after a surprising and dramatic weekend. After weeks of trying, and failing, to pass a Continuing Resolution (CR) with drastic spending cuts and controversial riders to appease the House Freedom Caucus, House Speaker Kevin McCarthy (R-CA) gave up on wooing the most conservative faction of his party and introduced a clean CR to keep the government in operation until November 17. The measure passed with a huge bipartisan majority in the House (335-91) and in the Senate (88-9) and avoided a government shutdown with just hours to spare. The CR further includes funding for disaster relief, as well as a 45-day extension for key health programs that were set to expire on September 30, including community health centers, the National Health Service Corps, teaching health centers and graduate medical education programs. The stopgap measure also includes a delay of the Medicaid disproportionate share hospital (DSH) pay cuts until the end of the CR, temporary extension of the Special Diabetes Program for Type I Diabetes and Special Diabetes Program for Indians, and full reauthorization of the Animal Drug User Fee Amendments (ADUFA) through fiscal year 2028. The bill did not extend authorization for the SUPPORT Act, the Children's GME Program, some maternal health programs, or the Pandemic and All-Hazards Response Act. It also does not include funding for Ukraine, despite pleas from the White House and support from most of the Senate.

Though the passage of the CR was a major concession on the part of House Republican leadership, it only delays the budget crises for another six weeks. Bringing the two bodies into consensus on an overall spending package remains a challenge. The overall funding totals between the House and Senate are a sticking point as the Senate bills are funded at the levels agreed to in the Fiscal Responsibility Act (also known as the bipartisan debt ceiling deal), with an additional \$13+ billion in emergency spending. The House, on the other hand, used the debt ceiling deal as a starting point, and then cut an additional \$119 billion while simultaneously rescinding \$115 billion in recent spending. If a November shutdown is to be avoided, and an FY 2024 spending package finalized, Speaker McCarthy will need to work with the Democrats again.

This week the House plans to continue work on passing the 12 individual appropriations bills, with the Energy & Water and Legislative Branch bills being next in line. However, progress could be sidelined as Rep. Matt Gaetz (R-FL) has stated that he will introduce a motion to vacate to strip Speaker McCarthy of his leadership position. Advancing a clean CR with bipartisan support marginalized and angered the most conservative faction of his party. As a result, it is expected McCarthy will be forced to fight to keep control of his party and the House.

Regulatory Update

The Office of Management and Budget (OMB) recently completed the review of a [proposed rule](#) that would make explicit that laboratory-developed tests (LDTs) are devices under the Federal Food, Drug, and Cosmetic Act and subject to FDA regulation ([Impact Summary](#)).

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.
- **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)
- **Annual CY 204 Medicare Payment Updates** – Final rules for the [CY 2024 Home Health Prospective Payment System](#) and the [CY 2024 Physician Fee Schedule](#).
- **340B Program** – Final rule on the [Hospital Outpatient Prospective Payment System: Remedy for 340B-Acquired Drugs Purchased in Cost Years 2018-2022](#).
- **Surprise Billing Regulations** – A [proposed rule](#) to amend requirements for the independent dispute resolution (IDR) process. Due to legal challenges, the IDR process is [temporarily suspended](#) for all disputes.
- **Conscience Rights in Health Care** – [Final rule](#) to safeguard the rights of federal conscience and religious nondiscrimination while protecting access to care, including abortion.
- **Skilled Nursing Facilities** – [Final rule](#) to require the disclosure of certain ownership, managerial, and other information regarding Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities. Interestingly, the Unified Agenda forecasted action in February 2026.

Other Policy Updates

The Departments of Labor, Health and Human Services, and the Treasury released [Frequently Asked Questions](#) (FAQs Part 61) clarifying that the **Departments are enforcing the requirement that plans and issuers publish a machine-readable file related to prescription drugs**, established in the Transparency in Coverage Final Rules (TiC Final Rules). Though the requirement took effect on January 1, 2022, the Department did not enforce it due to concerns that it conflicted with transparency requirements in the Consolidated Appropriations Act, 2021 (CAA).

The Departments have determined that prescription drug reporting requirements of CAA require disclosure of “different and additional” information than required in the TiC Final Rules. Therefore, the Departments are rescinding prior policies in which the Departments had deferred enforcement and established an enforcement safe harbor for requirements in the TiC Final Rules.

Regarding next steps, the Departments plan to release guidance with technical requirements and an implementation timeline to support compliance with this policy change. The Departments do not plan to engage in any rulemaking in the near term. The Departments will address enforcement decisions under the relevant requirements of the TiC Final Rules on a case-by-case basis.

This FAQ follows recent Congressional action to codify the Transparency in Coverage regulations. The House's bipartisan transparency package, the Lower Costs, More Transparency Act ([H.R. 5378](#)), includes provisions to codify the rate and payment information transparency requirements, which are inclusive of prescription drug rates. The bill was slated for a vote early last week, but it was unexpectedly cancelled.

Roundup of Recent OIG and GAO Reports

The Department of Health and Human Services (HHS) Office of the Inspector General (OIG) and the Government Accountability Office (GAO) released several reports and audits as part of their oversight of HHS's response to the COVID-19 pandemic. These reports are summarized below.

- **OIG report on whether states that received enhanced Medicaid funding met federal requirements:** The Families First Coronavirus Response Act (FFCRA) provided a temporary increase of 6.2 percentage points to states' federal medical assistance percentage (FMAP) rates in Medicaid. To qualify for the increase, states had to meet certain requirements including maintaining eligibility no more restrictive than the beginning of 2020, not charging premiums higher than those at the beginning of 2020, covering COVID-19 testing and treatment, and not terminating individuals from Medicaid under the continuous enrollment requirement. OIG selected four states (New York, Florida, Texas, and Minnesota) that received the FMAP increase to examine whether they met the federal requirements.
 - **Findings:**
 - None of the four states completely complied with the continuous enrollment requirement of the FFCRA:
 - Texas and Minnesota terminated coverage for 26,915 enrollees for unallowable reasons and New York, Florida, and Minnesota terminated coverage for 220,113 enrollees for potentially unallowable reasons due to a lack of support or documentation.
 - Minnesota may have inappropriately charged some enrollees cost-sharing for COVID-19 testing or treatment.
 - **Recommendations:** OIG recommends that the Centers for Medicare and Medicaid Services (CMS):
 - Work with the four states to determine what amount, if any, of the funding they received should be refunded; and
 - Work with Minnesota to determine whether enrollees were responsible for cost-sharing, and if so, work with Minnesota to make sure enrollees are reimbursed.
- **GAO report on HRSA oversight of the Provider Relief Fund (PRF):** The PRF was created to compensate and support providers for expenses or losses attributable to the COVID-19 pandemic. HRSA issued more than \$92 billion in payments between April and July 2020 and continued to make payments until June 2023 when the remaining funds were rescinded. GAO

developed this report to describe PRF distributions, examine HRSA's efforts to ensure that payments were only distributed to eligible providers in correct amounts, examine HRSA's efforts to ensure payments were used for their intended purposes, and examine the status of HRSA's recovery of funds.

- **Findings:**
 - HRSA conducted pre-payment reviews to verify provider eligibility and review the financial information on applications.
 - HRSA also conducted post-payment reviews of distributed payments, although 21 reviews have remained open since September 2022 which HRSA said it will not close until all related PRF were issued.
 - HRSA has experienced delays in closing reviews because they require "extensive" discussions and collaborations with other agencies.
 - HRSA is also conducting audits on a sample of providers to verify that they used their PRF payments according to federal requirements and is using provider reporting to identify payments that went unused.
 - As of June 2023, HRSA identified 321 providers that did not use PRF payments according to requirements.
 - HRSA has recovered nearly half of the \$2.6 billion in payments to noncompliant providers, overpayments, and unused payments that it identified, and has established time frames to recover the rest by April 2024.
 - **Recommendation:** GAO had planned to recommend that HRSA establish timeframes to recover the remaining payments that were identified, but HRSA addressed this recommendation before the report was published.
- **OIG report on telehealth use by Home Health Agencies (HHAs) during COVID-19:** OIG developed this report to determine whether home health services furnished via telehealth early in the pandemic were provided and billed according to Medicare requirements. CMS revised regulations during the pandemic to allow HHAs to use telehealth services with additional requirements for documentation.
 - **Findings:** Out of OIG's sample of 200 claims, only four had telehealth and none of these four fully complied with Medicare requirements.
 - OIG determined that the errors were due to HHAs being unfamiliar with the new requirements for telehealth.
 - **Recommendation:** OIG notes that in the 2023 Home Health Prospective Payment System final rule, CMS instructed HHAs to report telehealth services as separate line items with one of two specific G-codes. OIG recommends that CMS monitor HHA reporting of the new G-codes to determine whether additional guidance is necessary.
 - **OIG report on CDC Epidemiology and Labor Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) program:** The Centers for Disease Control and Prevention (CDC) ELC program provided \$10 billion in American Rescue Plan funding to 64 recipients to support COVID-19 screening testing for teachers, staff, and students at K-12 schools. The funding was intended to help schools reopen and remain open.
 - **Findings:**

- CDC provided oversight and technical assistance to the ELC recipients in implementing the COVID-19 screening testing programs by utilizing recipient data and periodic outreach.
- Challenges that schools faced in implementing the ELC screening testing programs including:
 - Lack of interest from schools and communities;
 - Limitations on the costs that were allowable under the terms and conditions of the awards;
 - Insufficient school staffing and resources; and
 - Issues with vendors or contractors.
- **OIG Review of health care staffing shortages during the pandemic:** HHS OIG worked with the Department of Defense (DoD), Department of Justice (DOJ), and Department of Veterans Affairs (VA) under the Pandemic Response Accountability Committee (PRAC) to develop a report on personnel shortages within four programs: DoD Medical Treatment Facilities, DOJ Federal Bureau of Prisons, Veterans Health Administration Facilities, and Medicare- and Medicaid-Certified Nursing Homes.
 - **Common themes across all Departments include:**
 - Nurses and medical officers were the most common positions with shortages;
 - A limited labor pool, noncompetitive pay, COVID-19 requirements, and a challenging hiring process were the most commonly reported factors that contributed to shortages;
 - A decrease in patient access to care and patient satisfaction, and an increase in personnel work hours were the most commonly reported impacts of shortages; and
 - Monetary incentives were the most commonly reported strategy to recruit and retain personnel.
 - **Findings from OIG on HHS nursing homes:**
 - 35 of the 50 non-statistically selected nursing homes for the report experienced a staffing shortage at some point before the pandemic, and all 50 experienced a staffing shortage during the pandemic.
 - From May 2020 through September 2022, 80 percent of all nursing homes reported a staffing shortage, although shortages varied by state.
 - Contributing factors to staff shortages in nursing homes included:
 - Increased job demands;
 - Noncompetitive pay;
 - Fear of COVID-19;
 - Increased COVID-19 protocols;
 - Limited labor pool; and
 - Exposure to COVID-19.
 - 26 of the nursing homes reported that shortages impacted nursing home residents by reducing or stopping restorative care, reducing physical rehabilitation services, and sending residents who needed wound care to the hospital.

- Officials said that the shortages and lower level of care caused a decline in the physical and mental health of patients.
- To address the shortage, nursing homes engaged in various efforts to recruit and retain staff including monetary incentives, training and educational opportunities, flexible schedules, and mental health support.
- CMS also enacted several emergency waivers to nursing home requirements for staff training, the performance of specific tasks, and administrative reporting requirements.

This Week in Health Policy

Mon. (10/2)

- **11:00am – Brookings Discussion: AI in the Workforce** – Brookings Institution holds a discussion with the U.S. Equal Employment Opportunity Commission (EEOC) Chair Charlotte Burrows to discuss how the agency has been addressing how to identify and mitigate bias in the use of artificial intelligence (AI) in recruitment, hiring retention, promotion, performance tracking, and dismissal. [Details.](#)

Tue. (10/3)

- **1:00pm – Duke Margolis Discussion: Medicare Accountable Care** – The Duke-Margolis Center for Health Policy holds a discussion on Medicare’s transition to accountable care relationships. Meena Seshamani, Deputy Administrator and Director for the Centers for Medicare and Medicaid Services (CMS) and Elizabeth Fowler, Deputy Administrator and Director for the Centers for Medicare and Medicaid Innovation (CMMI) will be panelists. [Details.](#) **LT**
- **1:00pm – Health Affairs Discussion: Structural Racism in Health** – Health Affairs holds a discussion on the relationship between structural racism, health, and health care with new research and perspectives on the politics of racism and how it is ingrained in health research and society. [Details.](#)

Wed. (10/4)

- **10:30am – HITAC Meeting: Pharmacy Interoperability** – HITAC holds a meeting of the Pharmacy Interoperability and Emerging Therapeutics Task Force to discuss program updates. [Details.](#)
- **12:00pm – NIH Meeting: Maternal Health** – The National Institutes of Health (NIH) holds a meeting of the Health Equity Research Outreach (HERO) Lecture Series to discuss efforts by the Communities Improving Maternal Health Alliance to improve maternal health outcomes by decreasing health disparities. [Details.](#)

- **3:30pm – Hearing: VA Accountability** – The Senate Veterans’ Affairs Committee holds a hearing to examine VA accountability and transparency, focusing on care and benefits for veterans. [Details.](#)

Thurs. (10/5)

- **8:30am – FDA Meeting: Influenza Virus Vaccines Strain Selection** – The Food and Drug Administration (FDA) holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss the Strain Selection for the Influenza Virus Vaccines for the 2024 Southern Hemisphere Influenza Season. [Details.](#)
- **9:00am – PunchBowl News Discussion: Opioid Crisis** – PunchBowl News holds a discussion with Sen. Shelley Moore Capito (R-WV) on measures to address the opioid crisis. [Details.](#)
- **9:00am – National Academies Discussion: Reproductive Health Data Needs** – The National Academies of Sciences, Engineering, and Medicine hold a discussion focused on the data available to measure the cascading effects of the Dobbs v. Jackson Women’s Health Organization Supreme Court Decision on health, equity, and society. [Details.](#)
- **10:00am – Hearing: Cost of Government Shutdown** – The Senate Budget Committee holds a hearing to examine the costs of a government shutdown. [Details.](#)
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [Details.](#)

Additional Multi-Day Events

- **Oct. 4-Oct. 5 – PCORI Meeting: Women’s Health/Mental Health/Telehealth** – PCORI holds its annual meeting featuring sessions on the latest research and important findings on a range of topics including creating pathways to optimal health for women and telehealth treatment in the post-pandemic environment. [Details.](#)
- **Oct. 5-Oct. 6 – Autoimmune Association Meeting: Autoimmunity** – The Autoimmune Association holds its third annual Autoimmune Community Summit to discuss pressing topics that impact the autoimmune community. [Details.](#)

Featured Analysis

- **Impact Artificial Intelligence Policy Round Up** – In the Policy Hub Insight Bank [here.](#)
- **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 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

Thurs. (9/28)

- **The SFC** formally introduced the [Modernizing and Ensuring PBM Accountability \(MEPA\) Act](#). [Details](#).

Tues. (9/26)

- **Senate HELP Ranking Member Cassidy** announced a [request for stakeholder input](#) to inform reforms to the CDC. Comments are due October 20. [Details](#).

Regulatory Lookback

Fri. (9/29)

- **The FDA** issued a [proposed rule](#) to make explicit that LDTs are devices. Comments due December 2. [Details](#).
- **The Tri-Departments** issued an [RFI](#) regarding commercial coverage of over-the-counter (OTC) preventive products. [Details](#).
- **CMS** is seeking [nominations](#) for a Technical Expert Panel (TEP) to support the development and evolution of quality measures for the Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP). Nominations are due October 11. [Details](#).
- **CMS** released [new Medicaid information](#) and questions for public comment on mental health parity. Comments are due December 4. [Details](#).
- **The CBO** [estimates](#) CMMI increased federal spending by \$5.4 billion from 2011 through 2020. [Details](#).

Thurs. (9/28)

- **SAMHSA** announced [\\$42.6 million](#) in Strategic Prevention Framework – Partnerships for Success (SPF-PFS) grants for 17 states and 60 communities across the country. [Details](#).
- **The Biden Administration** has unveiled nearly [\\$115 million in funding](#) for three new cancer research initiatives and the establishment of a nationwide health innovation network called ARPANET-H. [Details](#).
- **The USDA** announced a new pilot Nutrition Hub under the Agricultural Science Center of Excellence for Nutrition and Diet for Better Health ([ACEND for Better Health](#)) initiative. [Details](#).

Weds. (9/27)

- HHS announced [a series of initiatives](#) and funding totaling more than \$103 million aimed at addressing the maternal health crisis in the United States. [Details](#).

Tues. (9/26)

- The USDA released a [final rule](#) to lower the threshold for the Community Eligibility Provision (CEP) for no-cost school meals. [Details](#).

Comment & Application Deadlines

- **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](#).
- **October 11:** CMS is seeking [nominations](#) for a Technical Expert Panel (TEP) to support the development and evolution of quality measures for the Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP). [Details](#).
- **October 20:** Senate HELP Ranking Member Cassidy announced a [request for stakeholder input](#) to inform reforms to the CDC. [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](#).
- **December 2:** The FDA issued a [proposed rule](#) to make explicit that LDTs are devices. [Details](#).
- **December 4:** CMS released [new Medicaid information](#) and questions for public comment on mental health parity. [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](#).