

Impact Health Policy Weekly

Framing the Week

Congress is in recess until after the elections on November 12, but there are increasing calls for them to return early and pass emergency funding to cover the disasters caused by Hurricanes Helene and Milton in Florida, North Carolina, South Carolina, Georgia, Tennessee and Virginia. In recent weeks President Joe Biden has called on lawmakers to return to Capitol Hill “immediately” to provide additional funding, and last Wednesday Democrats on the House Small Business Committee put out a [statement](#) urging Speaker Mike Johnson (R-LA) to “call the House back into session so we may begin to work on, a bipartisan basis, the SBA’s request for additional disaster funding.”

State officials are still assessing the damage, and the Administration is working on submitting an official request to Congress detailing what resources are needed to help affected states. Speaker Johnson has insisted that Congress will provide additional funds upon return in November and that the Federal Emergency Management Agency (FEMA) has the resources necessary until then.

Prior to recessing, Congress included in the Continuing Resolution (CR) a provision that allowed FEMA to tap into an additional \$20.3 billion. FEMA officials have indicated that they currently have \$11 billion of those funds remaining, and that should last them until Congress returns in November and passes additional emergency funding. Congress did not, however, include any additional funding for the Small Business Administration’s (SBA) disaster loan program, that provides disaster victims with low-interest loans to help with expenses such as home repair or replacement, personal property, vehicles, mitigation, business losses, and working capital for individuals, small businesses, and most private nonprofits. It has been reported that the SBA will run out of funding well before the Congress is scheduled to reconvene. Democrats on the Small Business Committee stated that they are looking for other ways to support the disaster loan program, “including the reprogramming of appropriated funds, to ensure there is no gap in service”, but SBA has said it can’t make new loans without additional funding from Congress.

It is unlikely that Congressional leadership will call Congress back early to pass additional funding, but emergency assistance has jumped to the top of a long list of to-do items for when Congress does return post-election.

So far, the Biden-Harris Administration has approved [more than \\$1.8 billion](#) in assistance for hurricane response and recovery efforts, including over \$911 million for those affected by Hurricane Helene and over \$620 million for those affected by Hurricane Milton from FEMA. Other federal agencies are taking steps to support health care providers in affected areas, including the following:

- The Centers for Medicare and Medicaid Services (CMS) is [providing certain flexibilities](#) related to provider and supplier fee-for-service (FFS) Medicare debt due to Hurricane Helene:
 - **Accelerated and advance payments:** Payments may be granted at the National Provider Identifier (NPI) or Provider Transaction Access Number (PTAN) level in amounts equal to

a percentage of the preceding 90 days of claims and will be repaid through automatic recoupment from Medicare claims for 90 days following issuance. This applies to Medicare providers/suppliers in good standing that are located in or furnishing services within a FEMA designated disaster area.

- **Flexibility for existing extended repayment schedules (ERS):** Those repaying debt under an ERS at the maximum 60-month term may restructure the payment schedule for two payments during the approved period without additional financial documentation. Those repaying debt under an ERS for less than a 60-month term may request an additional two months be added. The two months will be interest only payments, or \$0 payments, with remaining payment adjusted.
- **Disrupted debt communications:** Providers/suppliers may request demand letters be rescinded and reissued when mail service has been reestablished if a letter regarding repayment or overpayment is not received due to Postal Service delivery disruptions.
- The Food and Drug Administration (FDA) announced [temporary policies](#) for compounding certain parenteral drug products due to the impact of the hurricanes on one of the nation's largest manufacturers of certain intravenous and peritoneal dialysis solutions, the Baxter International's North Cove facility. The guidance describes the agency's regulatory and enforcement priorities regarding the compounding for parenteral drugs by [outsourcing facilities](#) and [pharmacy compounders](#), and the policies will remain in effect only for the duration of the supply disruption.

Additionally, the FDA has conducted scientific and regulatory assessments to facilitate the [temporary importation](#) of intravenous and peritoneal fluids, and to date, has provided regulatory discretion for 23 different product lines at five international Baxter facilities.

- CDC issued a [Health Alert Network Advisory](#) (HAN) regarding disruptions in availability of peritoneal dialysis and intravenous solutions from the Baxter International's North Cove facility in North Carolina, due to Hurricane Helene. The HAN provides recommendations for health care providers, pharmacists, health care facilities, dialysis facilities, and state and local health departments.
- The Administration for Strategic Preparedness and Response (ASPR) has deployed approximately 370 medical, public health, and disaster response personnel to support North Carolina communities as part of the government-wide response to the devastation caused by the hurricane. Additionally, ASPR has deployed approximately 150 responders, along with medical equipment and supplies, to help protect the delivery of health care services in Florida.

Regulatory Update

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

Medicare

- **Physician Payment** – The [final rule](#) would make changes to the Medicare physician fee schedule for calendar year 2025 (November 2024).
- **Outpatient Payment** – The [final rule](#) would make changes to the Medicare hospital outpatient prospective payment system for calendar year 2025 (November 2024).
- **Home Health** – The [final rule](#) would make changes to the Medicare home health prospective payment system for calendar year 2025 (November 2024).
- **ESRD** – The [final rule](#) would make changes to the Medicare End-Stage Renal Disease (ESRD) payment system for calendar year 2025 (November 2024).
- **Medicare Advantage** – The [proposed rule](#) would make policy and technical changes to the Medicare Advantage, Medicare Prescription Drug Benefit, and Medicare Cost Plan Programs, and PACE for contract year 2026 (September 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).
- **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).
- **Organ Transplants** – The [final rule](#) would establish a new mandatory Medicare payment model, the Increasing Organ Transplant Access Model (IOTA Model), that would test whether performance-based incentive payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with end-stage renal disease (ESRD) while preserving or enhancing the quality of care and reducing Medicare expenditures.

This Week in Health Policy

Mon. (10/21)

- **9:00am – FDA Meeting: Smoking Cessation Priorities** – The Food and Drug Administration (FDA) holds a meeting entitled “Advancing Smoking Cessation: FDA and NIH Priorities.” Jointly convened by FDA and the National Institutes of Health (NIH), this public meeting will address the need for novel smoking cessation products to help individuals of all ages, including underserved and vulnerable populations, stop smoking. [Details.](#)
- **9:30am – HHS Meeting: Alzheimer’s Research/Care/Services** – The Department of Health and Human Services (HHS) holds a meeting of the Advisory Council on Alzheimer’s Research, Care, and Services to hear updates from federal agencies on activities during the last quarter and from panels organized by the clinical care and risk reduction subcommittees and to discuss dementia care from different perspectives, including those of providers, people with lived experience, and

CMMI Guiding an Improved Dementia Experience Model participants, as well as how to bridge gaps in service delivery. [Details.](#)

- **1:00pm – CMS Meeting: Hospital Price Transparency Machine-Readable File 2025 Requirements** – The Centers for Medicare and Medicaid Services (CMS) holds a webinar to discuss the new hospital price transparency requirements before becoming effective January 1, 2025. The requirements include incorporating additional elements into the standard machine-readable format, including an estimated allowed amount and information on modifiers and prescription drugs. [Details.](#)

Tue. (10/22)

- **8:30am – The Hill Discussion: 2025 Medicare Drug Benefit** – The Hill holds a discussion on the upcoming changes to the Medicare prescription-drug benefits for 2025, including a \$2,000 cap on out-of-pocket prescription-drug costs and a new program designed to help enrollees spread out their medication costs over the course of the calendar year. [Details.](#)
- **9:00am – CDC Meeting: CDC Priority Updates** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the CDC's Advisory Committee to the Director (ACD) to discuss updates on priorities from CDC Director Mandy Cohen, discussions on strategic science and impact, artificial intelligence, childhood immunization coverage and efforts to address lagging rates, and updates from the ACD Data and Surveillance Workgroup. [Details.](#)

Wed. (10/23)

- **1:30pm – Brookings Discussion: Medicare Performance and Options for Reform** – The Brookings Institution holds two panel discussions that will take stock of how Medicare's two insurance systems are performing today and how policymakers could make each work better. The first panel will examine the current performance of both sides of the Medicare program. The second panel will examine options for reform and discuss how reforms to traditional Medicare and Medicare Advantage could fit together. Paul Masi, executive director of the Medicare Payment Advisory Commission (MedPAC), participates in the performance panel. [Details.](#)
- **2:00pm – R Street Institute Discussion: Harm Reduction-Informed Solutions to the Overdose Crisis** – The R Street Institute holds a discussion with parents about why and how they have channeled their loss of a child to overdose into support for evidence-based, harm reduction-informed solutions to the overdose crisis. [Details.](#)

Thurs. (10/24)

- **10:00am – BPC Discussion: Housing Affordability** – The Bipartisan Policy Center (BPC) holds a joint event with the National Housing Crisis Task Force—a project of Accelerator for America and the Nowak Metro Finance Lab at Drexel University—on local and state best practices to increase housing affordability in collaboration with the federal government. Experts and policymakers will discuss a plan for innovative solutions in land use, construction, capital, regulation, and housing delivery. [Details.](#)
- **12:00pm – NIH Meeting: AIDS Strategic Plan/HIV Research Priorities** – The National Institutes of Health (NIH) holds a meeting of the Office of the Director for a report from the Office of Aids Research Director Diana Finzi, update on the development of the NIH Strategic Plan and Research priorities for HIV research. [Details.](#)

- **2:00pm – ASTP Meeting: Information Blocking** – The Assistant Secretary for Technology Policy (ASTP) holds “office hours” to answer questions on the information blocking regulations. [Details.](#)

Additional Multi-Day Events

- **Oct 21-Oct 22 – HRSA Meeting: HIV/Viral Hepatitis/STD Prevention/Treatment** – HRSA holds a meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment to discuss issues related to re-engaging people with HIV out of care (including data-to-care strategies and overcoming barriers to care), the use of long-acting injectables for HIV care and treatment and increasing access to mental health services for people with HIV and STDs. [Details.](#)
- **Oct 21-Oct 22 – HHS Meeting: Dietary Guidelines Scientific Report Findings** – HHS holds a Scientific Report Meeting of the 2025 Dietary Guidelines Advisory Committee to review and discuss the scientific findings and advice included in its scientific report. [Details.](#)
- **Oct 22-Oct 23 – HRSA Meeting: Migratory/Seasonal Agricultural Worker Health** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on Migrant Health (NACMH) to discuss migratory and seasonal agricultural worker health, including impacts of heat and wildfire smoke, farmworker data, and best practices for fostering partnerships between farmworkers, health centers, growers, and community organizations. [Details.](#)
- **Oct 22-Oct 23 – PCORI Meeting: Annual Meeting** – The Patient-Centered Outcomes Research Institute (PCORI) holds the 2024 PCORI Annual Meeting to explore innovative strategies for engaging diverse communities and hear about the latest in PCORI-funded comparative clinical effectiveness research (CER). [Details.](#)
- **Oct 23-Oct 24 – CDC Meeting: Immunization Practices** – The CDC holds a meeting of the Advisory Committee on Immunization Practices to discuss chikungunya vaccines, COVID-19 vaccines, cytomegalovirus vaccine, Human papillomavirus vaccines, influenza vaccines, meningococcal vaccines, mpox vaccines, pneumococcal vaccines, Respiratory Syncytial Virus vaccines for adults, RSV vaccines for maternal and pediatric populations, and the adult and child/adolescent immunization schedules. [Details.](#)

Featured Analysis

- **Insights for Impact: the 340B Drug Pricing Program**– In the Policy Hub Insight Bank [here.](#)
- **Impact 2024 Election Outlook and 2025 Congressional Preview** – In the Policy Hub Insight Bank [here.](#)
- **Impact Preview of Lame Duck Health Package** – In the Policy Hub Insight Bank [here.](#)
- **Impact Chart of PBM Legislation** – In the Policy Hub Insight Bank [here.](#)
- **Impact Regulatory Outlook: Spring 2024 Unified Agenda** – In the Policy Hub Insight Bank [here.](#)
- **Making Sense of the New Landscape for Health Policy After Recent Supreme Court Decisions** – In the Policy Hub Insight Bank [here.](#)

Congressional Lookback

Thurs. (10/17)

- **The Senate HSGAC Permanent Subcommittee on Investigations** released a [report](#) entitled “Refusal of Recovery: How MA Insurers Have Denied Patients Access to Post-Acute Care. [Details.](#)

Regulatory Lookback

Fri. (10/18)

- **The FCC** [voted unanimously](#) to require all wireless carriers to implement georouting for calls to the 9-8-8 Suicide & Crisis Lifeline. [Details.](#)
- **HHS OIG** released a [summary](#) of the top unimplemented recommendations. [Details.](#)
- **The USDA** released a [report](#) on SNAP participation in FY 2022. [Details.](#)

Weds. (10/16)

- **HRSA** [announced](#) \$19 million to enhance maternal health across 15 states, addressing the urgent public health challenge of rising maternal mortality rates and significant disparities. [Details.](#)

Comment & Application Deadlines

- **October 29:** CMS is [seeking nominations](#) for a TEP to assist in the development and maintenance of electronic clinical quality measures (eCQMs). [Details.](#)
- **October 29:** CMS seeks [comments](#) on its implementation of mental health parity in Medicaid and CHIP managed care plans.
- **November 1:** HHS announced an [Interim Final Rule](#) (IFR) to implement the 2024 revisions to the Uniform Administrative Requirements for Federal Financial Assistance (Uniform Guidance) under 2 CFR Part 200. [Details.](#)
- **November 12:** CMS released the HHS Notice of Benefit and Payment Parameters for [2026 proposed rule](#). [Details.](#)
- **December 9:** CMMI released an [RFI and a sample list](#) of prescription drugs that the agency intends to include in its \$2 Drug List Model. [Details.](#)
- **February 25:** CMMI released an [RFA](#) for the Cell and Gene Therapy Access Model. [Details.](#)
- **February 25:** CMMI released a [NOFO](#) to apply for Cooperative Agreement funding to support states’ participation in the Cell and Gene Therapy (CGT) Access Model. [Details.](#)