

Impact Health Policy Weekly

Framing the Week

The House and Senate have both recessed until after the November elections, though the Supreme Court starts a new term today. The Court is still weighing what cases they will take up over the 8-month term. One case not on the docket, but that could have the most important repercussions, is if the Supreme Court decides to weigh into the outcome 2024 Presidential election. Below we have summarized several health care and public health cases that the Court has agreed to hear this term.

- **Gun Violence Prevention** – In [*Garland v. VanDerStok*](#), the Supreme Court will decide whether the Biden-Harris Administration’s [rule](#) issued by the Bureau of Alcohol, Tobacco and Firearms to regulate “ghost guns” – a firearm without a serial number that can be made from scratch or with a kit – under the Gun Control Act. The U.S. Court of Appeals for the Fifth Circuit and a district judge blocked the rule. The rule requires “ghost guns” to be subject to the same regulations that apply to commercially manufactured, fully assembled firearms, such as background checks, serial numbers ([fact sheet](#)). It is part of President Biden’s [comprehensive gun crime reduction strategy](#). Oral arguments are on October 8.
- **Gender Affirming Care-** In [*U.S. v. Skrmetti*](#) the Supreme Court will decide whether Tennessee [Senate Bill 1](#), which prohibits all medical treatments intended to allow “a minor to identify with, or live as, a purported identity inconsistent with the minor’s sex” or to treat “purported discomfort or distress from a discordance between the minor’s sex and asserted identity,” violates the equal protection clause of the 14th Amendment. Over the past three years, 26 Republican-controlled states have passed laws restricting gender-affirming care for minors. Most of the laws ban puberty blockers, hormone treatment and surgery for those under 18. Some include provisions that allow those already receiving treatment to continue. If the court strikes down Tennessee’s law states would no longer be able to ban gender-affirming care outright.
- **Medicare DSH Calculation** – In [*Advocate Christ Medical v. Becerra*](#), the Supreme Court will decide how the Department of Health and Human Services (HHS) can calculate Medicare disproportionate share hospital (DSH) payments. Hospital groups submitted an [amicus brief](#) arguing the current method for counting supplemental security income eligible recipients in the Medicare DSH payment formula conflicts with a 2022 Supreme Court ruling in *Becerra v. Empire Health Foundation*. They contend the calculation undercounts the number of SSI-eligible populations, resulting in an estimated loss in DSH payments of about \$1 billion per year. The U.S. Court of Appeals for the D.C. Circuit and a district judge ruled in favor of HHS. Oral arguments are on November 5.

Regulatory Update

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

- **Medicare Appeals** – The [final rule](#) would establish new appeals processes for Medicare beneficiaries who have an inpatient hospital admission changed to outpatient by a hospital, and meet other conditions.

OMB is also 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).

Private Insurance

- **Preventive Services** – The [proposed rule](#) is titled, “Enhancing Coverage of Preventive Services under the Affordable Care Act.” It was not included in the latest Unified Agenda.

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.

Other Updates

Last week, the Department of Agriculture (USDA) [announced](#) an investment of \$1.7 billion for purchase of locally and regionally produced food through the Commodity Credit Corporation for emergency food assistance. \$1.2 billion will go to food to be delivered to schools, child care facilities, and food banks. The remaining \$500 million will be used to purchase domestic commodities for emergency food providers. USDA emphasizes that the purchases will also help farmers find new markets and recover from supply chain disruption.

This Week in Health Policy

Mon. (10/7)

- **9:00am – FDA Meeting: FDA Reorganization and Human Foods Program** – The Food and Drug Administration (FDA) holds a meeting of the Science Board to the FDA Advisory Committee to receive an update from the New Alternative Methods Subcommittee and to hear details about FDA's reorganization scheduled for implementation on October 1, 2024, that includes significant updates to the Office of the Chief Scientist and the creation of a unified Human Foods Program.. [Details.](#)
- **11:00am – HITAC Meeting: Annual Report Workgroup** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to discuss program updates. [Details.](#)

Tue. (10/8)

- **8:00am – NIH Meeting: Women's Health Updates** – The National Institutes of Health (NIH) holds a meeting of the Advisory Committee on Research on Women's Health (ACRWH) to discuss Technology, Engineering, and Innovation in Women's Health Research. [Details.](#)
- **12:00pm – Hudson Institute Discussion: Drug Patents** – The Hudson Institute holds a discussion on the state of play concerning the empirical evidence on the connection between drug patents and drug prices and whether officials are engaging in evidence-based policymaking on this issue. [Details.](#)
- **2:00pm – TFAH Discussion: Strengthening Public Health** – Trust for America's Health (TFAH) holds a national briefing of its latest report: *Pathway to a Healthier America: A Blueprint for Strengthening Public Health for the Next Administration and Congress*. Former Department of Health and Human Services (HHS) secretaries Michael Leavitt and Kathleen Sebelius will be participating. [Details.](#)

Thurs. (10/10)

- **8:00am – Axios Discussion: Acute Pain Treatment Innovation** – Axios holds a discussion with policymakers and medical experts about the challenges in the current acute pain treatment landscape. [Details.](#)

- **8:00am – FDA Meeting: Influenza Virus Vaccine Strain Selection** – FDA holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss three separate topics: the strain selection for the influenza virus vaccines for the 2025 southern hemisphere influenza season; pandemic preparedness for highly pathogenic avian influenza virus including considerations for vaccine composition for (H5) vaccines; and an overview of the research programs in the Laboratory of Pediatric & Respiratory Viral Diseases and the Laboratory of DNA Viruses. [Details.](#)
- **10:00am – NIST Meeting: AI Advisory Committee Update** – The National Institute of Standards and Technology (NIST) holds a meeting of the National Artificial Intelligence Advisory Committee (NAIAC) to report working group findings, identify actionable recommendations, and receive public briefings. [Details.](#)
- **1:00pm – Urban Institute Discussion: Telecommunication/Equity** – Urban Institute holds a discussion to highlight how access to digital infrastructure can facilitate equitable outcomes across policy sectors, featuring current investments via the US Department of Commerce’s Internet for All initiative and programs from other federal agencies, including the Department of Agriculture, HHS, the Small Business Administration, and the Department of Education. [Details.](#)
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [Details.](#)

Fri. (10/11)

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Featured Analysis

- ***NEW* 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.](#)

Regulatory Lookback

Fri. (9/20)

- **CMS** released the HHS Notice of Benefit and Payment Parameters for [2026 proposed rule.](#) Comments are due November 12. [Details.](#)
- **The CBO** released [report](#) entitled that discusses the underlying factors that contribute to prescription drug prices and examines a set of policy approaches that aim to reduce such prices. [Details.](#)

- OMB recently released a [new memorandum](#) offering guidance on the responsible acquisition of artificial intelligence (AI) solutions by U.S. federal agencies. [Details.](#)
- The HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP) is seeking input through an [RFI](#) to help shape the 2026–2030 National HIV/AIDS Strategy. Comments are due December 6. [Details.](#)
- HHS OIG [released](#) a report emphasizing the urgent need for enhanced oversight of remote patient monitoring (RPM) Medicare. [Details.](#)

Thurs. (10/3)

- HHS OIG [conducted](#) a study on maternal health care access in Medicaid managed care, highlighting critical gaps in a landscape marked by disparities and poor outcomes. [Details.](#)
- The GAO released a [report](#) highlighting the ongoing crisis of drug misuse in the United States and identifying key areas for improvement under the [2024 National Drug Control Strategy](#). [Details.](#)

Weds. (10/2)

- CMS issued [final guidance](#) for the initial price applicability year (IPAY) 2027 and for the effectuation of the maximum fair price (MFP) in 2026 and 2027. [Details.](#)

Tues. (10/1)

- CMS issued an [interim final action with comment period \(IFC\)](#) in response to an appellate court decision in *Bridgeport Hosp. v. Becerra*. [Details.](#)
- CMS issued a [report \(fact sheet\)](#) which reviews the Acute Hospital Care at Home (AHCAH) initiative. [Details.](#)

Mon. (9/30)

- The ASTP/ONC [released](#) its final 2024-2030 *Federal Health Information Technology (IT) Strategic Plan*. [Details.](#)

Comment & Application Deadlines

- **October 7:** CMS issued an [RFI](#) seeking information on AI technologies that can improve health care outcomes and service delivery. [Details.](#)
- **December 6:** The HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP) is seeking input through an [RFI](#) to help shape the 2026–2030 National HIV/AIDS Strategy. [Details.](#)
- **November 12:** CMS released the HHS Notice of Benefit and Payment Parameters for [2026 proposed rule](#). [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](#).