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Impact Health Policy Weekly

Framing the Week

Health Policy to Watch. Congress is in recess, with the House returning on August 31 and the Senate returning September 14. During this August period, Impact Health Policy Partners will provide a series of brief policy outlooks examining key priority areas likely to shape the health policy landscape this fall. This week, we are examining artificial intelligence (AI) and LGBTQ+ health.

Artificial Intelligence

Congress is entering the fall with a growing slate of bipartisan AI legislation, but the unresolved debate over federal preemption remains a major obstacle to a broader national framework. Reps. Jay Obernolte (R-CA) and Lori Trahan (D-MA) are advancing pieces of their Great American AI Act (GAAIA) through more targeted legislation, including the bipartisan FRONTIER Act (H.R. 9925), which would establish federal transparency, incident-reporting, risk-management, and independent-assessment requirements for frontier AI developers while preempting certain overlapping state requirements. The House Science Committee has also advanced ten bipartisan AI bills addressing NIST standards, AI research infrastructure, cybersecurity, workforce development, and model documentation. However, key Democrats remain wary of preemption, and Democratic proposals from Sens. Mark Warner (D-VA) and Edward Markey (D-MA) instead emphasize worker protections, consumer safety, health care oversight, data-center impacts, and preserving state authority (Impact summary). The White House is continuing discussions with Senate Republicans on a federal framework that could preempt some state AI laws, but it remains unclear whether a package can secure sufficient bipartisan support before the end of the year.

On the regulatory side, federal agencies are beginning to translate broader AI policy into more concrete health care and consumer-protection frameworks. FDA recently released a discussion paper seeking feedback on how generative AI-enabled medical devices should be evaluated, including possible competency-based premarket review, risk-proportionate postmarket monitoring, and approaches for addressing foundation models, agentic AI, performance drift, and model modifications. CMS is separately examining how AI should affect Medicare payment and care delivery through the CY 2027 Physician Fee Schedule. The agency is seeking comment on whether generative and agentic AI should change how primary care and care-management services are valued, how productivity gains should be reflected in payment, and whether AI could support technology-enabled Annual Wellness Visits. CMS is also proposing a new MIPS improvement activity for responsible clinical AI use and is moving toward a distinct Software as a Medical Service (SaMS) payment framework for algorithm-driven clinical services.

The FTC is also positioning existing federal consumer-protection law as a potential tool for AI oversight. Its proposed policy statement would clarify how Section 5 of the FTC Act could apply when AI systems

intentionally alter outputs to advance undisclosed ideological, political, or other objectives and suggests that conflicting state requirements could in some circumstances be impliedly preempted. Despite the growing activity, significant AI policy changes are unlikely to be finalized in the near term. Congressional Republicans and the White House continue to prioritize a uniform federal framework that preempts certain state AI laws, while Democrats are generally emphasizing testing, disclosure, worker and consumer protections, and preserving a role for states. Any broader federal framework will likely require elements of both approaches, and reaching that compromise before the midterm elections will be difficult. Similarly, the recent FDA and CMS actions are largely proposals or requests for stakeholder feedback that are more likely to inform future policymaking than produce an immediate regulatory framework.

LGBTQ+ Health

The federal policy landscape for gender-affirming care continues to evolve across funding, regulatory, and enforcement fronts, as the Trump administration uses multiple federal authorities to restrict access while litigation challenges the scope of those efforts. Most recently, the administration finalized Medicaid and CHIP funding restrictions for gender-affirming care for minors, escalated federal scrutiny of providers and billing practices, and secured an appellate ruling allowing the Department of Justice (DOJ) to proceed with its investigation of a gender-affirming care provider. Additionally, a federal district court blocked the administration from removing gender-affirming care from key Affordable Care Act (ACA) consumer protections, while DOJ abandoned an appeal seeking access to sensitive patient records at UPMC Children's Hospital of Pittsburgh. Taken together, these developments underscore the administration's increasingly broad use of federal funding and enforcement authorities to restrict gender-affirming care, while court decisions continue to produce mixed outcomes and constrain some of those efforts.

Medicaid and CHIP Funding Restrictions. CMS finalized a much anticipated final rule prohibiting federal Medicaid funding for gender-affirming care for individuals under 18 and federal CHIP funding for individuals under 19 (IHPP Summary). The rule takes effect October 12, 2026. Although states could continue covering care with state-only funds, the loss of federal matching dollars could make coverage more difficult to sustain, particularly for low-income patients. We expect to see state decisions on whether to maintain coverage with state-only funds in the coming weeks. The rule represents a significant expansion of the administration's use of federal health care financing to restrict access to gender-affirming care.

Expanded Federal Enforcement and Provider Scrutiny. HHS released a report titled *Wolves in White Coats: How Doctors and Hospitals Pushed and Profited from the Fraud of "Gender Medicine,"* on August 13, alleging potential improper billing and financial incentives associated with gender-affirming care for minors (press release). The report identified millions of dollars in claims for puberty blockers and recommended additional review of providers' billing practices. Following the report's release, Vice President J.D. Vance and HHS Secretary Robert F. Kennedy Jr. referred providers identified in the report to DOJ and HHS's Office of Inspector General for possible investigation. The report could provide a basis for additional enforcement or policy action, similar to the administration's use of its May 2025 HHS report, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices*, to support subsequent policy efforts.

DOJ Investigations of Providers. On August 14, a divided Ninth Circuit panel reversed a lower-court decision that had blocked a DOJ subpoena issued to QueerDoc, a telehealth provider specializing in gender-affirming care for minors. The ruling allows DOJ's investigation to proceed and could have

implications for federal investigations of gender-affirming care providers. In contrast, DOJ separately moved to dismiss its appeal of a lower-court decision blocking subpoenas for sensitive medical records from transgender patients at UPMC Children's Hospital of Pittsburgh. Together, the cases illustrate the mixed outcomes in the administration's efforts to use federal investigative authorities to scrutinize gender-affirming care providers.

ACA Protections for Gender-Affirming Care. A federal district court in Massachusetts ruled that HHS and CMS did not follow required procedures when attempting to remove gender-affirming care from the ACA's essential health benefits (EHB). The ruling preserves EHB protections for gender-affirming care, including limits on out-of-pocket costs, for now. The decision limits the administration's ability to remove gender-affirming care from these ACA consumer protections and means the administration cannot categorically strip the care of EHB status without further regulatory action that complies with the ACA's requirements.

Regulatory Update

Recently Arrived at OMB

- **Organ Procurement.** Final Rule: Amendments to Rules Governing Organ Procurement Organizations
- **Nutrition.** Proposed Rule: Enhancing Electronic Benefit Transfer (EBT) Card Security Measures

All other pending regulations can be found here.

This Week in Health Policy

An overview of upcoming events is included below. Events highlighted in orange are those that we will be covering in detail:

Mon. (8/24)

- **9:30am – CMS Meeting: Hospital Outpatient Payment** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting of the Advisory Panel on Hospital Outpatient Payment to discuss the clinical integrity of the Ambulatory Payment Classification groups and their associated weights, which are major elements of the Medicare Hospital Outpatient Prospective Payment System and the Ambulatory Surgical Center payment system. Details.

Tue. (8/25)

- **10:00am – FDA Meeting: Nonhealing Chronic Wounds** – The Food and Drug Administration (FDA) holds a meeting to hear directly from patients, caregivers, and other stakeholders about experiences with nonhealing chronic wounds and their treatment. Discussions will focus on the health and daily impacts of chronic wounds, patients' current approaches to treatment and wound care, and factors patients consider when deciding whether to participate in clinical trials. Details.
- **3:00pm – CMS Meeting: Geo AHEAD** – CMS holds a webinar on the Geo AHEAD Participation Perspectives (GAPP) Survey, related to the AHEAD (States Advancing All-Payer Health Equity Approaches and Development) Model. Details.

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Wed. (8/26)

- **2:00pm – Justice in Aging Discussion: Public Charge Final Rule** – Justice in Aging holds a discussion on the Department of Homeland Security's (DHS) new public charge final rule, which takes effect September 18, 2026, and changes how immigration officers assess whether certain immigrants may become primarily dependent on the government for support. Details.

Featured Analysis

- **Medicaid Round-Up: H.R. 1 Implementation and Program Integrity** – In Policy Hub here.
- **AI Policy Roundup** – In Policy Hub here.
- **2026 Regulatory Outlook** – In Policy Hub here

Regulatory Lookback

Fri. (8/20)

- **HHS** released an RFI on the adequacy of the categories used in federal vaccine recommendations. Comments are due September 20. Details.

Thurs. (8/18)

- Following the Supreme Court's June 30 decision in *Trump v. Barbara*, **the Trump administration** has continued pursuing restrictions on birthright citizenship through new executive action, while the legal boundaries of that effort remain contested. Details.

Wed. (8/17)

- **CMS** released guidance clarifying its expectations for the impacted payers that must report certain prior authorization metrics beginning this year pursuant to the 2024 Interoperability and Prior Authorization final rule. Details.
- **CMS** launched QualTech, a new industry engagement initiative seeking technology solutions to improve patient safety, expand Medicare Annual Wellness Visits, modernize digital quality measurement, and make hospital quality information more accessible. Submissions are due September 4. Details.
- **NSF** released 12 new notices of funding opportunity providing more than $1.5 billion for foundational research across the sciences and engineering, including opportunities supporting artificial intelligence (AI), advanced computing, bioengineering, biotechnology, materials, quantum information science, and other emerging technologies. Details.

Tues. (8/16)

- **HHS, HUD, ONDCP, and ACF** announced a series of actions advancing the Trump Administration's "Treatment First" approach to homelessness, addiction, mental illness, and family stability. Details.

- **NIST** released an initial public draft of NIST AI 200-2, The TEVV-Athlon Framework for Evaluating AI Systems. Comments are due October 6. Details.
- **The FDA Digital Health Center of Excellence** released a discussion paper and request for feedback on potential regulatory approaches for generative artificial intelligence (GenAI)-enabled medical devices. Comments are due October 19. Details.

Mon. (8/17)

- **The DOJ** finalized the creation of the National Fraud Enforcement Division. Details.

Litigation Highlights

Judge Temporarily Blocks HHS from Implementing New Ideological Conditions on Teen Pregnancy Prevention Program Funding But Refrains from Restoring Funding that was Terminated: On August 19, in *Hennepin County, Minnesota v. U.S. Department of Health and Human Services*, a federal judge in Washington issued a preliminary injunction blocking HHS from imposing new conditions on Teen Pregnancy Prevention Program grants, including requirements that recipients emphasize abstinence and limit contraception-focused education. The court found the new criteria unreasonable or inadequately explained, including concerns that HHS was attempting to reimpose requirements previously rejected by the courts. The injunction prevents HHS from applying the new criteria while the litigation proceeds, but the judge declined to restore tens of millions of dollars in funding already terminated, finding it unclear whether he had authority to do so. The litigation remains ongoing, and the parties must submit proposed next steps by September 1, 2026.

Case Tests Legality of State Laws Funding Medicaid Through Employer Fees: On August 20, in *Restaurant Law Center et al. v. Binder et al.*, business and industry groups filed suit challenging New Jersey's new Medicaid law that requires employers with 50 or more employees to pay the state an annual fee when their employees or employees' dependents are enrolled in Medicaid. NJ expects the law to generate approximately $145 million per year, with funds used to support Medicaid at a time when states face significant federal Medicaid funding cuts under the One Big Beautiful Bill (H.R. 1). The plaintiffs' arguments are multifaceted and include claims that the law is preempted by ERISA. The case could have broader implications for states seeking alternative mechanisms to finance Medicaid as federal funding reductions under H.R. 1 take effect.

For additional information regarding legal developments, please see our litigation tracker.

New Comment & Application Deadlines

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- **September 20:** HHS released an RFI on the adequacy of the categories used in federal vaccine recommendations. Details.
- **October 6:** NIST released an initial public draft of NIST AI 200-2, The TEVV-Athlon Framework for Evaluating AI Systems. Details.

- **October 19:** The FDA Digital Health Center of Excellence released a discussion paper and request for feedback on potential regulatory approaches for generative artificial intelligence (GenAI)-enabled medical devices. Details.

All open comment and application deadlines can be found here.