

## Impact Health Policy Weekly

### Framing the Week

**Big Picture.** The House is in recess this week. The Senate is focused on advancing the nomination of Jay Clayton to serve as director of national intelligence and reauthorizing FISA. Key health committees are teeing up legislation if an opportunity for a legislative vehicle emerges.

### Health Policy to Watch

1. The [Senate Committee on Health, Education, Labor and Pensions](#) will mark up eight bills on Wednesday, including two aimed at **increasing access to generics and biosimilars and one on the drug application process**. A pair of bills are related to transplants – reauthorization of bone marrow/umbilical cord blood **transplant program** and organ transplant discrimination prevent. The remaining bills are reauthorizations of **Healthy Start, breast health education program, and research on therapies for ALS**.
2. **Budget reconciliation 3.0** is a possibility, though there is more skepticism in the Senate. [House Budget Committee Chairman Arrington](#) is pushing for a package to fund defense and target fraud. The [Heritage Foundation](#) is also calling for 3.0 addressing fraud as well as affordability. A [coalition of HSA companies](#) are also pushing for expanded availability of the tax-advantaged accounts.
3. Reps. John Joyce (R-PA), Greg Murphy (R-NC) and Kim Schrier (D-WA) plan to formally introduce their **bipartisan Medicare physician reform legislation** by the end of the month. In the meantime, the Doc Caucus continues to welcome feedback on their [discussion draft](#).

### Regulatory Update

#### Completed OMB Review

- **Nutrition.** [Proposed Rule](#): Supplemental Nutrition Assistance Program: Changes in Federal-State Administrative Cost Sharing

#### Recently Arrived at OMB

- **New Drugs.** [Notice](#): Expedited Investigational New Drug Pilot Program; Request for Information
- **Discrimination.** [Final Rule](#): Rescinding Guidelines for Eliminating Discrimination and Denial of Services on the Basis of Race, Color, National Origin, Sex, and Handicap in Vocational Education Programs

#### Pending OMB Review

#### Coverage and Payment:

- **Medicaid Tax Waivers.** [Proposed Rule](#): Amending the Indirect Hold Harmless Threshold of Health Care-Related Taxes
- Security Act
- **Managed Care.** [Proposed Rule](#): Strengthening the Integrity of Medicaid and CHIP Managed Care, Financing, and Access to Care
- **Medicare.** Proposed Rules: CY 2027 policy changes and payment rates for [hospital outpatient departments](#), [physicians](#), [home health providers](#), and [ESRD facilities](#)
- **Marketplace.** [Proposed Rule](#): Exchange Pre-Enrollment Eligibility Verification
- **ERISA.** [Proposed Rule](#): Default Electronic Disclosures by Group Health Plans Under ERISA
- **Short-Term Insurance.** [Proposed Rule](#): Short-Term, Limited-Duration Insurance

#### Prescription Drugs

- **340B.** [Prerule](#): Notice Regarding 340B Rebate Model Pilot Program
- **PBM Compensation.** [Notice](#): Request for Information: Pharmacy Benefit Manager Compensation and Data Collection

#### Nutrition

- **Work Requirements.** [Proposed Rule](#): Supplemental Nutrition Assistance Program: Modification to Work Requirements for Able-Bodied Adults
- **Categorical Eligibility.** [Proposed Rule](#): Supplemental Nutrition Assistance Program: Reforming Categorical Eligibility
- **WIC.** [Final Rule](#): Special Supplemental Nutrition Program for Women, Infants and Children (WIC): WIC Online Ordering and Transactions and Food Delivery Revisions to Meet the Needs of a Modern, Data-Driven Program
- **Milk.** [Final Rule](#): Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Increase to the Maximum Monthly Allowance of Milk for Child, Pregnant, and Breastfeeding Participants

#### Other Issues

- **Pharmaceuticals.** [Notice](#): Oncology Pharmaceuticals: Streamlined Nonclinical Safety Studies for Biologics and Conjugated Products
- **Immigration.** [Interim Final Rule](#): Unaccompanied Children Program Foundational Rule; Update to Include Proof of Identity and Income Verification Standards
- **Medication-Assisted Treatment.** [Final Rule](#): Implementation of the SUPPORT Act: Dispensing and Administering Controlled Substances for Medication-Assisted Treatment
- **HIPAA.** [Final Rule](#): HIPAA Privacy Rule: Changes to Support Coordinated Care and Individual Engagement and Reduce Regulatory Burdens
- **Discrimination.** [Final Rule](#): Rescinding Portions of Department of Health and Human Services Title VI Regulations to Conform More Closely with the Statutory Text and to Implement Executive Order 14281

### 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:

#### **Tue. (6/16)**

- **12:30pm – HHS Meeting: Combating Anti-Microbial Resistance** – The Department of Health and Human Services (HHS) holds a meeting the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) to inform the 2026-2031 National Action Plan on Combating Antibiotic Resistant Bacteria. [Details.](#)

#### **Wed. (6/17)**

- **10:00am – Markup: Organ Transplant and Generic and Biosimilar Competition** – The Senate Health, Education, Labor, and Pensions Committee holds a markup to consider a package of bipartisan health care bills, including legislation on organ transplant nondiscrimination for individuals with disabilities ([S.1782](#)), reauthorization of several public health programs (Healthy Start, stem cell research, breast health awareness, and ALS initiatives), and measures to promote generic and biosimilar competition through patent transparency reforms, citizen petition changes ([S.3014](#)), and streamlined biosimilar interchangeability requirements ([S.1954](#)). [Details.](#)
- **3:30pm – Hearing: China’s Impact on Older Americans’ Health** – The Senate Special Committee on Aging holds a hearing to examine China's toll on older Americans' health, finances, and security. [Details.](#)

#### **Thurs. (6/18)**

- **8:30am – FDA Meeting: Influenza Vaccine Safety/Effectiveness** – The Food and Drug Administration (FDA) holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss and make recommendations on the safety and effectiveness of MFLUSIVA (Influenza Vaccine, mRNA), manufactured by Moderna TX Inc., with a requested indication in Biologics License Application STN 125869/0 for the prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine, in persons 50 years of age and older. [Details.](#)
- **2:00pm – Health Affairs Discussion: 340B and Medicare Drug Price Negotiation** – Health Affairs holds a discussion on how the 340B and Medicare Drug Price Negotiation programs intersect, with a focus on 340B transparency gaps, duplicate discounts, and evolving policy. [Details.](#)

#### **Fri. (6/19)**

- **Holiday – Juneteenth**

#### **Additional Multi-Day Events**

- **June 15-June 16 – HHS Meeting: Physician-Focused Payment Model Proposals** – HHS holds a meeting of the Physician-Focused Payment Model Technical Advisory Committee to discuss targeting improvements in patient safety through alternative payment models. [Details.](#)
- **June 17-June 18 – AI, Pediatric Care, Medical Education** – US News and World Report holds its Healthcare of Tomorrow Conference for discussions on how artificial intelligence (AI) is transforming care, bolstering pediatric care, and how medical education is evolving. The Centers for Medicare and Medicaid Services (CMS) Administrator, Dr. Mehmet Oz, CMS Chief Medical Officer, Dr. Dora Hughes, and the National Institutes of Health (NIH) Director, Dr. Jay Bhattacharya, are participating. [Details.](#)

### Featured Analysis

- **Reproductive Health Roundup** – In Policy Hub [here.](#)
- **FDA Policy Roundup** – In Policy Hub [here.](#)
- **Behavioral Health Roundup** – In Policy Hub [here.](#)
- **Innovation Center Model Portfolio Overview** – In Policy Hub [here.](#)

### Congressional Lookback

#### Wed. (6/10)

- **The House Appropriations Committee** [advanced](#) the Fiscal Year (FY) 2027 Labor, Health and Human Services, Education, and Related Agencies Appropriations Bill following a lengthy markup marked by sharp partisan disagreements over federal spending priorities. [Details.](#)
- **The House Energy and Commerce Subcommittee on Health** convened a [legislative hearing](#) to explore several policies to increase transparency in the health care sector regarding rates and payments, discounted cash prices, ownership, overhead costs, and use of prior authorization. [Details.](#)

#### Tues. (6/9)

- **The House Education & Workforce (E&W) Subcommittee on Workforce Protections** held a hearing on supporting locum tenens providers, advance practice clinicians who work as independent contractors. [Details.](#)

### Regulatory Lookback

#### Fri. (6/12)

- **CMS** released a proposed rule to codify key policies governing the Medicare Drug Price Negotiation Program beginning with Initial Price Applicability Year (IPAY) 2029 and subsequent years. [Details.](#)

- **HRSA** released a 30-day Paperwork Reduction Act (PRA) notice outlining data collection requirements for its proposed 340B Rebate Model Pilot Program. [Details.](#)
- **CMS** issued a request for information to gather input on possible future notice and comment rulemaking to revise the “typical employer standard” for the scope of Essential Health Benefits. [Details.](#)
- **CMS** released a final rule with comment to strengthen oversight of accrediting organizations (AOs) by addressing conflicts of interest, establishing consistent standards, updating the validation and performance systems. [Details.](#)

#### **Thurs. (6/11)**

- **The U.S. Supreme Court** is entering the final weeks of its 2025-2026 term, with 20 cases still awaiting decisions. [Details.](#)
- **CMS** issued a letter to State Medicaid Directors previewing the policy changes the agency expects to make in an upcoming proposed rule regarding budget neutrality requirements for Medicaid Section 1115 demonstration projects. [Details.](#)

#### **Wed. (6/10)**

- **The Medicare Trustees** released their annual report on the projected financial status of the Hospital Insurance (HI) and Supplemental Medicare Insurance (SMI) trust funds. [Details.](#)
- **CMS** established the new Office of Health Technology and Products (OHTP) to lead and oversee CMS health technology modernization, digital products, and transformation of platforms and services supporting CMS programs. [Details.](#)

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

- **The Department of Health and Human Services (HHS)** issued a request for information (RFI) on substance use research and policies that can improve the continuum of prevention, treatment, and recovery for behavioral health conditions. [Details.](#)

#### **Mon. (6/8)**

- **Secretary of HHS Robert F. Kennedy Jr., and Secretary of the Department of Education, Linda McMahon** **announced** that eight accreditors, assessors, and medical organizations will increase nutrition requirements for medical education, evaluation, and residency. [Details.](#)

#### **Litigation Highlights**

The **Supreme Court** is entering the final weeks of its 2025-2026 term, with 20 cases still awaiting decisions. The remaining rulings are expected by late June or early July. Pending decisions could reshape citizenship rights, federal immigration policy, transgender protections, presidential authority over independent agencies, election administration, and gun regulations. A summary of cases in these areas is available [here](#).

Recent lower court developments include:

- **Court Strikes Down Multiple Trump Administration Changes to ACA Marketplaces:** In [City of Columbus v. Defendants](#), a federal judge struck down multiple components of the Affordable Care Act program integrity rule including the \$5 monthly fee charged to ACA premium recipients who are who are automatically reenrolled in ACA marketplace coverage. The judge also blocked the provision that created stricter income verification requirements, finding that the administration could not support its claim that the change would decrease fraudulent enrollments in marketplace coverage. Other challenged provisions were upheld. The federal court will issue a separate order this week detailing out the ruling will be implemented.
- **Judge Temporarily Blocks DOJ Subpoena for Gender-Affirming Care Records:** On June 9, in [Z.A., et al. v. Lucile Salter Packard Children's Hospital at Stanford](#), a federal judge [temporarily blocked](#) enforcement of a Department of Justice grand jury subpoena seeking patient records from a provider of gender-affirming care for transgender youth and extended the hospital's response deadline to June 25. The case challenges the administration's expanded effort to obtain sensitive medical records through grand jury subpoenas after courts limited similar requests made through administrative processes.
- **Federal Court Invalidates \$100,000 H-1B Visa Fee:** On June 8, in a [lawsuit](#) brought by a coalition of 20 states challenging the Trump administration's \$100,000 fee on new H-1B visas, a federal judge [struck down](#) the fee as an unauthorized tax imposed without congressional approval. The court held that the administration exceeded its authority under federal immigration law and violated the Administrative Procedure Act, and the administration has indicated it will appeal.

For additional information regarding legal developments, please see our [litigation tracker](#).

#### Comment & Application Deadlines

- **June 15:** CMS released a [proposed rule](#) to advance interoperability and improve prior authorization for prescription drugs. [Details](#).
- **June 25:** The Advanced Research Projects Agency for Health (ARPA-H) announced the Intelligent Generator of Research (IGoR) initiative to modernize how biomedical research is conducted by addressing persistent inefficiencies in speed, coordination, and reproducibility. [Details](#).
- **June 29:** The Food and Drug Administration (FDA) issued a notice proposing to exclude three widely used GLP-1 therapies – semaglutide, tirzepatide, and liraglutide – from the 503B Bulks List. [Details](#).
- **June 29:** The Housing and Urban Development Department (HUD) issued a proposed rule to replace references to “gender” and “gender identity” with “sex” in program language. [Details](#).
- **June 30:** FDA issued a Request for Information (RFI) seeking input on how obesity affects drug pharmacokinetics and pharmacodynamics during development. [Details](#).

- **July 5:** The Department of Health and Human Services issued a request for information (RFI) on substance use research and policies that can improve the continuum of [prevention](#), treatment, and recovery for behavioral health conditions. [Details.](#)
- **July 10:** The Departments of Labor, Health and Human Services, and Treasury announced a proposed rule to allow employers to provide standalone fertility benefits. [Details.](#)
- **July 13:** OMB issued a sweeping proposed rule revising the government-wide Uniform Guidance governing Federal financial assistance. [Details.](#)
- **July 15:** HRSA released a 30-day Paperwork Reduction Act (PRA) notice outlining data collection requirements for its proposed 340B Rebate Model Pilot Program. [Details.](#)
- **July 15:** CMS issued a request for information to gather input on possible future notice and comment rulemaking to revise the “typical employer standard” for the scope of Essential Health Benefits. [Details.](#)
- **July 31:** The ACL announced the [launch of Phase 1](#) of the ACL Caregiver AI Prize Competition. [Details.](#)
- **July 31:** CMS released an interim final rule on how states will need to implement their community engagement programs required by H.R. 1. [Details.](#)