

Wynne Health Group Weekly



FRAMING THE WEEK

As the Supreme Court's decision to overturn *Roe v. Wade* continues to alter the abortion landscape in the coming weeks and months, reproductive rights will remain a top priority for Democrats. With President Biden in Europe for meetings on the Russia-Ukraine war and international relations, a formal Executive Order to shore up access to abortion appears unlikely in the near term. In the meantime, the White House issued a [brief statement](#) on Friday announcing two actions to protect access to abortion: (1) directs the Attorney General to ensure persons seeking abortion would be allowed to cross state lines to do so; and (2) directs Secretary of Health and Human Services (HHS) to identify ways to increase access to mifepristone for medication abortion. WHG discusses these directives as part of the [set of six actions](#) the Administration could take in response to the Supreme Court's decision.

Before departing for Europe on Saturday, the President [signed](#) into law two bipartisan bills, delivering legislative victories to both parties on key issues – gun safety, mental health, and nutrition:

- **Bipartisan Safer Communities Act (S. 2938)**, which contains provisions to restrict access to firearms, increase access to mental health services, protect victims of domestic violence, and enhance school safety (WHG summary [here](#)). The bill was first introduced last week and then swiftly passed by both the Senate and the House.
- **Keep Kids Fed Act of 2022 (S. 2089)**, which extends school meal flexibilities, allows waivers related to the Summer Food Service Program (SFSP) and Seamless Summer Option (SSO) during the summer months, increases reimbursement rates for the 2022-2023 school year by an additional 15 cents per breakfast and 40 cents per lunch, and provide enhanced support to the Child Adult Care Feeding Program.

Ahead of its recess next week, the House will convene hearings on top priorities, including oversight of Medicare Advantage and bills to improve public health. The Senate is in recess this week and will return July 11.

Medicare Advantage

On Tuesday, the House Energy & Commerce (E&C) Subcommittee on Oversight and Investigations is [convening](#) to examine the quality of care Medicare beneficiaries are receiving through Medicare Advantage (MA) plans as well as the fiscal sustainability of the MA program. The hearing is partly in response to a recent HHS Office of Inspector General (OIG) [report](#) which found that MA plans sometimes deny care despite the prior authorization requests meeting Medicare coverage rules (WHG summary [here](#)).

This suggests Congress may be interested in taking action on MA prior authorization, as several members in both the House and the Senate have already signed on to [bipartisan legislation](#) that would place requirements on MA plans to improve their prior authorization processes. Alternatively, Congress could pressure the Centers for Medicare & Medicaid Services (CMS) to address this issue under its own authority,

which the agency appears prepared to do via [rulemaking later this fall](#). E&C Republicans had invited CMS Administrator to testify at the hearing, though the Administrator does not appear on the witness list.

Additional MA-related issues to be discussed at the hearing include beneficiaries' access to specialty care within MA provider networks; the higher rates of MA spending compared to that of traditional Medicare; racial and ethnic disparities of care among MA plans with higher star ratings; the MA quality bonus program; and MA network adequacy, among other issues. Current witnesses include officials from the HHS OIG, the Medicare Payment Advisory Commission (MedPAC), and the Government Accountability Office (GAO).

Public Health

On Wednesday, the House Energy and Commerce Committee will convene a [hearing](#) to discuss a slate of bills aimed at improving public health through increased access to health care services and biomedical research. The agenda includes a mix of bipartisan bills as well as bills with only Democratic or Republican support.

- Improve access to health care services through innovative delivery models, such as mobile medical clinics, telehealth, community health workers, trauma systems
 - Bipartisan support
 - **Maximizing Outcomes through Better Investments in Lifesaving Equipment for (MOBILE) Health Care Act (H.R. 5141)**, introduced by Reps. Susie Lee (D-NV) and Richard Hudson (R-NC). The Senate Health, Education, Labor and Pensions Committee recently approved an identical bill ([S. 958](#))
 - **Rural Telehealth Access Task Force Act (H.R. 8169)**, introduced by Reps. Greg Pence (R-IN) and Angie Craig (D-MN)
 - Democratic support only
 - **Building a Sustainable Workforce for Healthy Communities Act (H.R. 8151)**, introduced by Rep. Raul Ruiz (D-CA)
 - **Improving Trauma Systems and Emergency Care Act (H.R. 8163)**, introduced by Rep. Tom O'Halleran (D-AZ)
- Expand research on maternal health uterine fibroids, childhood therapies
 - Bipartisan support
 - **NIH Implementing a Maternal Health and Pregnancy Outcomes Vision for Everyone (IMPROVE) Act of 2022 (H.R. 7565)**, introduced by Reps. Lauren Underwood (D-IL) and Jaime Herrera Beutler (R-WA)
 - **Pediatricians Accelerate Childhood Therapies (PACT) Act of 2021 (H.R. 3773)**, introduced by Reps. John Joyce (R-PA) and Kim Schrier (D-WA)
 - Democratic support only
 - **Stephanie Tubbs Jones Uterine Fibroid Research and Education Act of 2021 (H.R. 2007)**, introduced by Rep. Yvette Clarke (D-NY)
- Strengthen security protections for biomedical research in the United States
 - Bipartisan support
 - **Protect America's Biomedical Research Enterprise Act of 2021 (H.R. 6305)**, introduced by Reps. Richard Hudson (R-NC) and David Trone (D-MD)
 - Republican support only
 - **Fix Nondisclosure of Influence in Health Research Act (H.R. 5442)**, introduced by Rep. John Curtis (R-UT)
 - **Protecting the Integrity of our Biomedical Research Act of 2021 (H.R. 5478)**, introduced by Rep. John Curtis (R-UT)

- Increase diversity in clinical trials funded by the National Institutes for Health
 - **NIH Clinical Trial Diversity Act of 2022 (H.R. 7845)**, introduced by Rep. Robin Kelly (D-IL)

THIS WEEK IN HEALTH POLICY

Mon. (6/27)

- **11:00am – NIH Meeting: Cancer** – The National Institutes of Health (NIH) National Cancer Institute holds a meeting of the Frederick National Laboratory Advisory Committee to discuss program updates. [Details.](#)

Tue. (6/28)

- **8:30am – FDA Meeting: COVID-19 Vaccines** – The food and Drug Administration (FDA) holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss whether and how the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified. [Details.](#)
- **10:30am – ONC Meeting: Adopted Standards** – The Office of the National Coordinator of Health Information Technology (ONC) holds a meeting of the Health Information Technology Advisory Committee (HITAC) Adopted Standards Taskforce to make recommendations on ONC-adopted standards and implementation specifications. [Details.](#)
- **11:00am – Hearing: MA** – The House Committee on Energy and Commerce Subcommittee on Oversight and Investigations holds a hearing titled, “Protecting America’s Seniors: Oversight of Private Sector Medicare Advantage (MA) Plans.” [Details.](#)

Wed. (6/29)

- **8:00am – FDA Meeting: Cellular, Tissue, and Gene Therapies** – FDA holds a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee to discuss products for the treatment of retinal disorders. [Details.](#)
- **11:00am – Hearing: Public Health** – The House Committee on Energy and Commerce Subcommittee on Health holds a legislative hearing titled, “Investing in Public Health: Legislation to Support Patients, Workers, and Research” to discuss 11 public health bills. [Details.](#)
- **12:00pm – NIH Meeting: Cancer** – The NIH National Cancer Institute holds a meeting of the National Cancer Institute of Research Advocates to discuss program updates. [Details.](#)
- **12:00pm – AHP Panel: FDA Approval** – The Alliance for Health Policy (AHP) holds a panel discussion titled, “FDA Approval Pathways 101.” [Details.](#)

Additional Multi-Day Events

- **June 28-June 29 – 9:00am – HRSA Meeting: National Health Service Corps** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on the National Health Service Corps to discuss program updates. [Details.](#)

FEATURED WHG ANALYSIS

- ***NEW* WHG A Suite Of Potential Executive Actions For A Post-Roe World** – In the Policy Hub Insight Bank [here.](#)
- **WHG Round-up of Recent Actions Related to the PHE Declaration** – In the Policy Hub Insight Bank [here.](#)
- **WHG Tracker of COVID-19 PHE Flexibilities** – In the Policy Hub Insight Bank [here.](#)

- **WHG Memo on PBM Regulatory and Legislative Landscape** – In the Policy Hub Insight Bank [here](#).
- **WHG Memo on Possible CMMI Action on Drug Pricing** – In the Policy Hub Insight Bank [here](#).
- **WHG Roundup of Recent Telehealth Policy** – In the Policy Hub Insight Bank [here](#).
- **WHG 2022 Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Thurs. (6/23)

- **The House Education and Labor Committee Civil Rights and Human Services Subcommittee** [held](#) a hearing on the policy priorities of the USDA FNS. [Details](#).

Weds. (6/22)

- **Sens. Shaheen (D-NH) and Collins (R-ME)** [introduced](#) the Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act. [Details](#).

REGULATORY LOOKBACK

Fri. (6/24)

- **The White House** released Biden-Harris Administration's [Blueprint for Addressing the Maternal Health Crisis](#) – a government-wide approach to improve maternal health and outcomes in the United States. [Details](#).
- **The USDA FNS** [issued](#) a proposed rule to revise data collection in SNAP to remove language that allows race and ethnicity data to be collected by observation when not provided. [Details](#).
- **HHS** [issued](#) a request for information on ways to strengthen primary care in the U.S. Responses are due August 1. [Details](#).

Thurs. (6/23)

- **MACPAC** [released](#) an issue brief on directed payments in Medicaid managed care. [Details](#).
- **The FDA** [issued](#) draft guidance on considerations for rescinding breakthrough therapy designation (BTD). Comments are due August 23. [Details](#).

Weds. (6/22)

- **CMS** [announced](#) that COVID-19 vaccines will be covered without cost-sharing for children aged six months to five years enrolled in Medicaid and CHIP. [Details](#).
- **The FDA** [announced](#) plans for a proposed rule that would establish a maximum nicotine level to reduce the addictiveness of cigarettes. [Details](#).

Tues. (6/21)

- **CMS** [released](#) its CY 2023 ESRD prospective payment system (PPS) proposed rule. Comments are due August 27. [Details](#).
- **The FTC** [announced](#) that it intends to increase enforcement against healthcare industry conduct that block patients' access to competing low-cost drugs. [Details](#).

COMMENT & APPLICATION DEADLINES

- **June 27:** FNS [announced](#) \$5 million in grant funding for Process and Technology Improvement Grants in SNAP. [Details](#).
- **June 27:** SAMHSA [announced](#) \$55 million in grant funding for Tribal Opioid Response Grants. [Details](#).
- **July 1:** CMS [announced](#) the nomination period is now open for Wave 5 of the MACRA clinician expert workgroups. [Details](#).
- **July 3:** The FDA [released](#) proposed rules to prohibit menthol in cigarettes and characterizing flavors in cigars. [Details](#).

- **July 5:** AHRQ [released](#) a notice of request for nominations for members of the National Advisory Council for Healthcare Research and Quality. [Details.](#)
- **July 7:** The FDA [issued](#) draft guidance on cybersecurity in medical devices and quality system considerations. [Details.](#)
- **July 11:** The GAO [announced](#) a request for nominations for the Physician-Focused Payment Model Technical Advisory Committee (PTAC). [Details.](#)
- **July 13:** CMS [issued](#) an IFC to implement a maximum OOP and cost sharing limits in MA. [Details.](#)
- **July 15:** HHS and USDA [announced](#) the intention to establish the 2025 Dietary Guidelines Advisory Committee and solicit nominations for membership. [Details.](#)
- **July 15:** The OASH and OMH [announced](#) a NOFO titled, “*Community-Driven Approaches to Address Factors Contributing to Structural Racism in Public Health.*” [Details.](#)
- **July 15:** The OASH and OMH [announced](#) a funding opportunity to promote equitable access to language services in Health and Human Services. [Details.](#)
- **July 17:** The FDA [issued](#) draft guidance on risk management plans to mitigate the potential for drug shortages. [Details.](#)
- **July 22:** The GAO [issued](#) a request for nominations for the Health Information Technology Advisory Committee (HITAC). [Details.](#)
- **August 1:** The USDA [announced](#) a \$20 million cooperative agreement opportunity to improve participation and retention in the WIC program. [Details.](#)
- **August 1:** HHS [issued](#) a request for information on ways to strengthen primary care in the U.S. Responses are due August 1. [Details.](#)
- **August 16:** CMS [issued](#) the cycle year (CY) 2023 home health prospective payment system and rate update proposed rule. [Details.](#)
- **August 23:** The FDA [issued](#) draft guidance on considerations for rescinding breakthrough therapy designation (BTD). [Details.](#)
- **August 27:** CMS [released](#) its CY 2023 ESRD prospective payment system (PPS) proposed rule. [Details.](#)
- **September 17:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details.](#)
- **October 1:** The CDC [seeks](#) nominations for the CDC/Health Resources & Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHACHSPT). [Details.](#)

WHG Contacts for Inquiries

Alyssa Llamas: alyssa@wynnehealth.com; (562) 207-8807

Josh LaRosa: josh@wynnehealth.com; (703) 309-4248

Erin Slifer: erin@wynnehealth.com; (410) 984-4552

Billy Wynne: billy@wynnehealth.com; (202) 309-0796

