

Wynne Health Group Weekly



FRAMING THE WEEK

Lawmakers continue to chip away at their to-do list. Yesterday, the bipartisan group led by Sen. Chris Murphy (D-CT) announced a framework to reduce gun violence and increase mental health resources. The Senate Health, Education, Labor and Pensions (HELP) Committee will vote on a slate of bills, including its legislation to reauthorize Food and Drug Administration (FDA) user fee programs. The House Appropriations Committee will begin marking up FY 2023 appropriations bills.

As for COVID-19, the Biden Administration is preparing to distribute vaccines for children under the age of 5, which could be available as soon as next week. The path forward for a bipartisan \$10 billion COVID-19 emergency supplemental package remains unclear.

Lastly, the Supreme Court of the United States may issue its decision on *Dobbs v. Jackson Women's Health Organization* this week. The Biden Administration is considering executive orders to bolster abortion access if *Roe v. Wade* is overturned.

Gun Violence and Mental Health

Senate Majority Leader Chuck Schumer (D-N) [announced](#) that he would hold a floor vote as soon as the legislative text of the [bipartisan framework](#) is finalized, which includes proposals to reduce gun violence and increase mental health resource. The bill is expected to pass.

- **Mental Health:** Expands the [Certified Community Behavioral Health Clinic model](#); increases investments in mental health and suicide prevention programs, including school-based mental health and supportive services; and provides funding to increase access to mental and behavioral health services for youth and families in crisis via telehealth;
- **Gun Reform:** Provides resources to states and tribes to create “red flag” laws, which would authorize courts to issue an order allowing law enforcement to temporarily confiscate firearms; requires background checks for buyers under 21 years of age to review juvenile and mental health records; increases enforcement of licensing requirements; and increase penalties for “straw purchasing”;
- **School Safety:** Provides funding for school safety resources for primary and secondary schools; and
- **Protections for Victims of Domestic Violence:** Requires convicted domestic violence abusers and individuals subject to domestic violence restraining orders to be included in the National Instant Criminal Background Check System, which is used to conduct background checks on people who want to purchase a firearm.

FDA User Fees

Tomorrow, the Senate HELP Committee will [mark-up](#) the **Food and Drug Administration (FDA) Safety and Landmark Advancements (FDASLA) Act**. The bipartisan FDA reauthorization bill, introduced by Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC), also includes provisions to increase biosimilar and generic competition, modernize the accelerated approval pathway, establish a new test product category and regulatory framework for in vitro clinical tests, and require opioids be dispensed with a safe, in-home disposal system ([WHG summary](#)). The mark-up, originally scheduled for last week, was postponed due to disagreements over the manager's amendment (WHG summary forthcoming). Last week, the House passed the **Food and Drug Amendments of 2022 (H.R. 7667)**, its version of an FDA user fee reauthorization package in a largely bipartisan vote of 392-28 ([WHG summary](#)).

In addition, the Senate HELP Committee will also vote on several bipartisan health bills:

- **Maximizing Outcomes through Better Investments in Lifesaving Equipment for (MOBILE) Health Care Act (S. 958)**, introduced by Sens. Jacky Rosen (D-NV) and Susan Collins (R-ME), would increase access to primary health care services in rural and underserved communities;
- **Cardiovascular Advances in Research and Opportunities Legacy Act (H.R. 1193)**, unanimously passed by the House, would authorize \$20 million for each of FYs 2022 through 2026 for research on valvular heart disease; and
- **Early Hearing Detection and Intervention Act of 2022 (S. 4052)**, introduced by Sens. Rob Portman (R-OH) and Maggie Hassan (D-NH), would reauthorize the program for early detection, diagnosis, and treatment regarding deaf and hard-of-hearing newborns, infants, and young children for FYs 2023 through 2027.

Appropriations

In the absence of an agreement on a budget resolution for FY 2023 between the two chambers, the House adopted a “**deeming resolution**” ([H. Res. 1151](#)) along party lines last Wednesday. The deeming resolution would cap discretionary spending for the upcoming fiscal year at approximately \$1.6 trillion, which aligns with President Biden's FY 2023 budget request ([WHG summary](#)). With the goal of floor votes before the August recess, the House Appropriations Committee is [scheduled](#) to begin marking up FY 2023 appropriations bills this week.

- **Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill** subcommittee markup is on June 15, and the full committee markup is on June 23;
- **Labor, Health and Human Services, Education, and Related Agencies bill** subcommittee markup is on June 23, and full committee markup is on June 30; and
- **Transportation, and Housing and Urban Development, and Related Agencies bill** subcommittee markup is on June 23, and full committee markup is on June 30.

Top appropriators in both chambers have met several times but have not yet announced an agreement on topline numbers for FY 2023 government funding. Due in part to time constraints and political factors, Congress may pursue a continuing resolution, level-funding the government possibly through the end of the calendar year and creating a must-pass vehicle for other legislative priorities. With the Senate Appropriations Committee Chairman Pat Leahy (D-VT) and Ranking Member Richard Shelby (R-AL) both retiring, there will be great momentum to pass a final funding package before the end of the Congress.

COVID-19

The Biden Administration is preparing the rollout of COVID-19 vaccines for children under the age of 5, in anticipation of the FDA and Centers for Disease Control and Prevention (CDC) authorizing and recommending the vaccine this week. According to an [operation plan](#) released last week, the Administration has made 10 million vaccine doses available for states, tribes, territories, community health centers, federal pharmacy partners, and others to pre-order. In addition to working with providers, hospitals,

pharmacies, and public health departments, the Administration is also leveraging federal programs and collaborating with community partners to reach parents and families, especially in communities that have been disproportionately affected by the pandemic. Federal programs include the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) program; Head Start Program; Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program; federal housing programs; and Medicaid and CHIP.

On Wednesday (June 15), the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will [meet](#) to discuss emergency use authorization (EUA) of COVID-19 vaccines for young children. FDA Commissioner is expected to decide whether to grant EUA to Moderna's vaccine for children six months through five years of age and Pfizer-BioNTech vaccine for children six months through four years of age shortly after the meeting. On Friday and Saturday (June 17 and 18), the CDC's Advisory Committee on Immunization Practices (ACIP) is [scheduled](#) to vote on recommendations on the use of these vaccines. The CDC Director is also expected issue a recommendation soon after.

On Thursday, the Senate HELP Committee will [question](#) senior officials about the federal response to COVID-19. The panel, who last appeared together before the Committee in January, features CDC Director Rochelle Walensky, Chief Medical Advisor Anthony Fauci, FDA Commissioner Robert Califf, and Assistance Secretary for Preparedness and Response Dawn O'Connell.

We anticipate they will urge Congress to provide additional COVID-19 supplemental funding to help sustain the federal response, especially through the fall when a second round of boosters for most adults could be recommended. The path forward for a [bipartisan \\$10 billion COVID-19 emergency supplemental package](#) remains unclear due to a dispute over the CDC's decision to [reverse](#) the Trump-era "Title 42 policy," though it is still in effect due to a [district court order](#). The bill would support the domestic COVID-19 response – specifically, the purchase of vaccines, therapeutics, and tests, as well as research and development of vaccines for emerging variants.

Abortion Access

The Supreme Court of the United States is scheduled to issue opinions today (June 13) and Wednesday (June 15), which is expected to include a decision on *Dobbs v. Jackson Women's Health Organization*, which involves a Mississippi law that prohibits nearly all abortions after the 15th week of pregnancy. According to a [leaked draft](#) published by Politico, the Supreme Court 's decision would overturn *Roe v. Wade*, effectively eliminating the constitutional right to abortion. Last month, the Senate failed to pass the Women's Health Protection Act of 2022 ([S. 4132](#)), which would prohibit government restrictions on the provision of, and access to, abortion services.

President Biden has said, without offering any details, that the White House is considering executive orders to bolster abortion rights, though any administrative actions are limited. Senate HELP Committee Chair Murray and Sen. Elizabeth Warren (D-MA) led 23 of their Democratic colleagues in a [letter](#) suggesting the President consider the following executive actions:

- Increase access to medication abortion;
- Provide vouchers for travel, child care services, and other forms of support for individuals seeking abortion care in other states;
- Establish a reproductive health ombudsman at the Department of Health and Human Services (HHS) that would educate the public and analyze data collected by HHS about access to reproductive services;
- Enforce "Free Choice of Provider" requirements that guarantee Medicaid beneficiaries have the ability to seek family planning services from their provider of choice;
- Clarify protections for sensitive health and location data related to reproductive health; and
- Use federal property and resources to increase access to abortion for military personnel and their families, federal employees, and individuals in the custody of federal agencies.

THIS WEEK IN HEALTH POLICY

Mon. (6/13)

- **10:00am – NQF Meeting: Rural Health** – The National Quality Forum (NQF) Rural Health Advisory Group holds a measure set review meeting to review proposed measures related to rural health. [Details.](#)

Tue. (6/14)

- **9:00am – PCORI Meeting: Strategic Plan** – The Patient-Centered Outcomes Research Institute (PCORI) holds a meeting of the Board of Governors to discuss the strategic plan. [Details.](#)
- **10:00am – Hearing: Nutrition Programs** – The House Agriculture Committee holds a hearing titled, “A 2022 Review of the Farm Bill: Stakeholder Perspectives on Non-Supplemental Nutrition Assistance Program (SNAP) Department of Agriculture (USDA) Nutrition Programs.” [Details.](#)
- **10:00am – Mark-Up: FDA** – The Senate Health, Education, Labor & Pensions (HELP) Committee holds a mark-up of two bills, including the “Food and Drug Administration (FDA) Safety and Landmark Advancements Act (S. 4348).” [Details.](#)
- **10:30am – ONC Meeting: Interoperability** – The Office of the National Coordinator for Health Information Technology (ONC) holds a meeting of the Interoperability Standards Workgroup to discuss how to improve interoperability. [Details.](#)
- **12:00pm – NIH Meeting: Heart, Lungs, and Blood** – The National Institutes of Health (NIH) National Heart, Lung, and Blood Institute holds a meeting of the National Heart, Lung, and Blood Advisory Council to discuss program policies and issues. [Details.](#)
- **12:30pm – SAMHSA Meeting: Women’s Health** – The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Advisory Committee for Women’s Services to discuss the impact of COVID-19 on behavioral health needs of women and children. [Details.](#)
- **1:00pm – NQF Meeting: PRO/PM** – NQF holds a technical expert panel to discuss patient-reported outcome performance measures (PRO/PMs). [Details.](#)

Wed. (6/15)

- **10:00am – Mark-Up: FDA** – The Senate Health, Education, Labor & Pensions (HELP) Committee holds a mark-up of two bills, including the “Food and Drug Administration (FDA) Safety and Landmark Advancements Act (S. 4348).” [Details.](#)
- **10:00am – Hearing: Gun Violence** – The Senate Judiciary Committee holds a hearing titled, “Protecting America’s Children From Gun Violence.” [Details.](#)
- **10:00am – NQF Meeting: Health Equity** – The NQF Measure Application Partnership (MAP) Health Equity Advisory Group holds a measure set review meeting to discuss proposed measures related to health equity. [Details.](#)
- **11:00am – CDC Meeting: Radiation** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Advisory Board on Radiation and Worker Health to provide advice to the Secretary. [Details.](#)
- **11:30am – BPC Event: 988 Crisis Line** – The Bipartisan Policy Center (BPC) holds a webinar titled, “988: Answering the Call.” [Details.](#)
- **2:30pm – Hearing: Infant Formula and Consolidation** – The Senate Judiciary Committee Competition Policy, Antitrust, and Consumer Rights Subcommittee holds a hearing titled, “Baby Formula and Beyond: The Impact of Consolidation on Families and Consumers.” [Details.](#)

Thurs. (6/16)

- **10:00am – Hearing: Federal COVID-19 Response** – The Senate Health, Education, Labor & Pensions (HELP) Committee holds a hearing titled, “An Update on the Ongoing Federal Response to COVID-19: Current Status and Future Planning.” [Details.](#)
- **10:00am – ONC Meeting: Health IT** – ONC holds a meeting of the Health Information Technology Advisory Committee (HITAC) to discuss ongoing projects. [Details.](#)

- **12:00pm – NIH Meeting: Diabetes** – The NIH holds a meeting of the Diabetes Mellitus Interagency Coordinating Committee titled, “National Clinical Care Commission Report Perspectives from Federal Partners to Prevent and Control Diabetes and its Complications.” [Details.](#)

Fri. (6/17)

- **8:45am – FDA Meeting: Psychopharmacologic Drugs** – The Food and Drug Administration (FDA) holds a meeting of the Psychopharmacologic Drugs Advisory Committee to provide advice and recommendations to the FDA on regulatory issues. [Details.](#)
- **12:00pm – AHP Event: HCBS** – The Alliance for Health Policy (AHP) holds a webinar titled, “What’s Next in Home and Community-Based Services?” [Details.](#)

Additional Multi-Day Events

- **June 13-June 15 – 1:00pm – NIH Meeting: Cancer** – The NIH National Cancer Institute holds a meeting of the National Cancer Advisory Board and Board of Scientific Advisors to hear the Director’s report and other presentations. [Details.](#)
- **June 14-June 15 – 11:00am – HRSA Meeting: Maternal and Infant Health** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Infant and Maternal Mortality to discuss program updates. [Details.](#)
- **June 14-June 15 – 8:30am – FDA Meeting: COVID-19 Vaccines for Children** – The FDA Vaccines and Related Biological Products Advisory Committee holds a meeting to discuss the request to amend emergency use authorization (EUA) of the Moderna COVID-19 vaccine to include children under 17 years of age and to amend the EUA of Pfizer-BioNTech’s COVID-19 vaccine to include children under 5 years of age. [Details.](#)
- **June 14-June 15 – 12:00pm – NIH Meeting: Child Health** – The NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development holds a meeting of the National Advisory Child Health and Human Development Council to hear the Director’s report and other presentations. [Details.](#)

FEATURED WHG ANALYSIS

- **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.](#)

LEGISLATIVE LOOKBACK

Thurs. (6/9)

- **The House of Representatives [passed](#)** the Food and Drug Amendments Act of 2022 by a vote of 392-28. [Details.](#)

Weds. (6/8)

- **The House Agriculture Committee Nutrition, Oversight, and Department Operations Subcommittee [held](#)** a hearing on the Farm Bill. [Details.](#)

REGULATORY LOOKBACK

Fri. (6/10)

- **The GAO** [issued](#) a request for nominations for the Health Information Technology Advisory Committee (HITAC). Nominations are due July 22. [Details](#).
- **MACPAC** [released](#) a new issue brief on the experiences of lesbian, gay, bisexual, and transgender Medicaid beneficiaries with accessing care. [Details](#).

Weds. (6/8)

- **The FTC** [announced](#) it is launching an inquiry into pharmacy benefit manager (PBM) practices. [Details](#).
- **HHS OIG** [released](#) the Semiannual Report to Congress providing which provides an overview of the Agency's activities from October 2021 through March 2022. [Details](#).
- **The GAO** [announced](#) a request for nominations for the Physician-Focused Payment Model Technical Advisory Committee (PTAC). Nominations are due July 11. [Details](#).

Tues. (6/7)

- **CMS** outlined via a blogpost its updated national quality strategy, "A Person-Centered Approach to Improving Care." [Details](#).

Mon (6/6)

- **The USDA** [announced](#) it is offering nationwide waivers to increase access to infant formula made available by Operation Fly Formula for participants of WIC. [Details](#).
- **The USDA FNS** [announced](#) that \$39 million in Reach and Resiliency grants has been awarded to 38 state agencies to improve the reach of the Emergency Food Assistance Program. [Details](#).
- **CMS** [announced](#) the nomination period is now open for Wave 5 of the MACRA clinician expert workgroups. Nominations are due July 1. [Details](#).
- **CMS** updated [guidance](#) revising COVID-19 data reporting requirements for psychiatric and rehabilitation hospitals. [Details](#).

COMMENT & APPLICATION DEADLINES

- **June 13:** The FDA [issued](#) draft guidance on diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations in clinical trials. [Details](#).
- **June 14:** HRSA [announced](#) the availability of \$226.5 million in American Rescue Plan (ARP) funding to launch the new Community Health Worker Training Program (CHWTP). [Details](#)
- **June 14:** SAMHSA [released](#) a notice of funding opportunity (NOFO) for Rural Opioid Technical Assistance Regional Centers. [Details](#).
- **June 16:** AHRQ [released](#) a request for supplemental evidence and data submissions to inform its review, "Pharmacotherapy for Adults with Alcohol-Use Disorders in Outpatient Settings: Systemic Review Update." [Details](#).
- **June 17:** The AHRQ [released](#) a NOFO applicants to disseminate and implement PCRO findings into innovative, evidence-based interventions to reduce healthcare disparities in chronic health conditions. [Details](#).
- **June 18:** HHS released an RFI to help develop the 2022 Environmental Justice Strategy and Implementation Plan. [Details](#).
- **June 18:** SAMHSA [announced](#) \$1.5 billion in Fiscal Year (FY) 2022 State Opioid Response (SOR) grant funding to assist states and territories. [Details](#).
- **June 20:** The FDA [issued](#) a request for comments on providing mail-back envelopes and education on safe disposal for opioid analgesics dispensed in an outpatient setting. [Details](#).
- **June 24:** HHS is [seeking nominations](#) for members on the [National Vaccine Advisory Committee](#). Nominations are due June 24. [Details](#).
- **June 24:** The CDC released a solicitation of nominations for appointment of individuals to serve as members of the Community Preventive Services Task Force (CPSTF). [Details](#).
- **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:** 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.](#)
- **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

