

Wynne Health Group Weekly



FRAMING THE WEEK

With Congress in recess this week, we provide a status update on top health issues, including gun violence, mental health, COVID-19 and public health, health care costs, and Food and Drug Administration (FDA) user fees, as well as government funding. Overall, lawmakers have made some progress, with several marked-up bills awaiting floor votes. When Congress returns next week, lawmakers will have about eight weeks, including a weeklong recess, to deliver legislative victories before the August recess. As the midterm elections in November near, both parties are increasingly less likely to come together on any bipartisan legislation.

Gun Violence

In response to the horrific shootings in Uvalde, Texas; Laguna Woods, CA; Buffalo, New York; and many others across the country, a bipartisan group of nine senators – four Republicans and five Democrats – led by Sen. Chris Murphy (D-CT) are working on gun reform. One potentially viable policy option is “red flag” legislation, which would allow family members or law enforcement to petition to temporarily remove firearms from a gun owner who could pose a threat. Nineteen states have enacted red flag laws, also known as “Extreme Risk laws,” though they vary on who could file a petition, [according](#) to Everytown for Gun Safety. For example, some states allow family members and law enforcement to file petitions, while others only allow law enforcement.

Last year, the House passed two major measures that appear unlikely to pass in the Senate: the **Enhanced Background Checks Act of 2021** ([H.R. 1446](#); [Everytown fact sheet](#)) and the **Bipartisan Background Checks Act of 2021** ([H.R. 8](#); [Everytown fact sheet](#)), both of which would close loopholes in background checks. However, limited changes to background checks appear to be on the negotiating table for senators.

On Thursday, the House Judiciary Committee is expected to advance the **Protecting Our Kids Act** – a package of eight bills that would raise the age to purchase semi-automatic rifles from 18 to 21 and stiffens penalties for gun trafficking, among other gun control measures. House Democratic leaders plan to hold a vote on the package early next week. While the omnibus package is anticipated to pass the House, it is unlikely to advance in the Senate. The bipartisan bill currently being negotiated in the Senate would be more likely to get to the President’s desk for signature.

Along with Sen. Murphy, the bipartisan group includes Sens. Joe Manchin, Richard Blumenthal (D-CT), Kyrsten Sinema (D-AZ), Martin Heinrich (D-NM), Susan Collins (R-ME), Lindsey Graham (R-SC), Pat Toomey (R-PA), and Bill Cassidy (R-LA). Senate Minority Leader Mitch McConnell (R-KY) also encouraged Sen. John Cornyn (R-TX) to try to reach a deal with Democrats.

Mental Health

Key committees in both chambers have been working on mental health legislation, but they are at various stages of the policy development process. If, when, and how their bills will coalesce into a single legislative package remains to be seen. House Energy and Commerce Committee (E&C) favorably reported the

Restoring Hope for **Mental Health and Well-Being Act of 2022 (H.R. 7666)** – a bipartisan bill, introduced by Chairman Frank Pallone, Jr. (D-NJ) and Ranking Member Cathy McMorris Rodgers (R-WA), that would reauthorize over 30 programs related to mental health and substance use disorder within the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA) for FY 2023 through 2027 ([WHG Summary](#)). A House floor vote has not yet been scheduled. The House Ways and Means Committee has also [expressed](#) interest in a bipartisan proposal but appear to still be in the early stages of policy development.

Similar to the E&C bill, the **Mental Health Reform Reauthorization Act of 2022 (S. 4170)** recently introduced by Sen. Murphy and Cassidy, members of the Senate Committee on Health, Education, Labor and Pensions (HELP), would reauthorize federal mental health and SUD programs at SAMHSA and HRSA ([WHG summary](#)). Meanwhile, Senate Finance Committee (SFC) Chair Ron Wyden (D-OR) – along with Ranking Member Mike Crapo (R-ID), Sen. Ben Cardin (D-MD), and Sen. John Thune (R-SD) – released the [discussion draft](#) of their **Telemental Health Access to Care Act (WHG summary)**. The bipartisan legislation would advance numerous policies to increase access to telemental health services beyond the COVID-19 pandemic for Medicare, Medicaid, and CHIP beneficiaries. We are still waiting for other bipartisan SFC work groups to release their proposals to address workforce, behavioral health integration, parity, and pediatric mental health access.

COVID-19 and Public Health

The path forward for a [bipartisan \\$10 billion COVID-19 emergency supplemental package](#) remains unclear. 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. Republicans' demand for a vote on an amendment to preserve the Trump-era "Title 42 policy – allowing the U.S. to block entry of migrants, including people seeking asylum, to protect public health – has stalled the package. The Centers for Disease Control and Prevention (CDC) had [determined](#) that the restrictive measure is "no longer necessary to protect the public health," and the termination was set to take effect on May 23, 2022. However, a district court [ordered](#) the Biden Administration to maintain the Title 42 policy. Interestingly, Senate Republicans are still seeking a vote on the amendment.

Of note, the COVID-19 public health emergency (PHE) is currently scheduled to expire on July 15, 2022. However, the Biden Administration is expected to extend the PHE another 90 days to October 13, 2022 since HHS did not notify states by the 60-day deadline on May 16, 2022.

As for legislation addressing broader public health capacity, the Senate HELP Committee advanced the **Prepare for and Response to Existing Viruses, Emerging New Threats, and Pandemics (PREVENT Pandemics Act (S. 3799))**, introduced by Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) in March 2022. However, a floor vote has not yet been scheduled. The bipartisan bill legislation focuses on strengthening and modernizing federal public health and medical preparedness and response systems and programs and includes provisions from over 37 separate bills to strengthen the public health system. It includes initiatives to strengthen the supply chain, bolster the workforce, reform the CDC, support research, combat misinformation, and ensure health equity (see [WHG summary](#)). Chair Murray also introduced the **Public Health Infrastructure Saves Lives Act (S. 674)**, which would provide annual funding to the CDC to strengthen core public health infrastructure at the agency and state, territorial, local, and tribal health departments. This bill has only Democratic support.

Health Care Costs

The looming expiration of enhancements to advance premium tax credits (APTCs), provided by the American Rescue Plan Act of 2021 ([P.L. 117-2](#)), at the end of calendar year is increasing pressure among Democrats to extend the enhancements before the mid-term elections. Last week, Rep. Lauren Underwood (D-IL) and 25 Democrats in swing districts [urged](#) House Speaker Nancy Pelosi (D-CA) and Senate Majority

Leader Chuck Schumer (D-NY) to use budget reconciliation to permanently expand the APTC enhancements.

Sen. Manchin is negotiating a slimmed-down version of the **Build Back Better Act**, focused on climate change and deficit reduction, with other Democrats that could provide a legislative vehicle for APTC enhancements. Whether other health-related provisions, such as allowing Medicare to negotiate drug prices, the budget reconciliation package would be included is questionable. Notably, in his “plan for fighting inflation in an opinion piece [published](#) in the Wall Street Journal yesterday, President Biden reiterated his call to Congress to “reduce the price of prescription drugs by giving Medicare the power to negotiate with pharmaceutical companies and capping the cost of insulin.”

FDA User Fees

The statutory deadline for the reauthorization of FDA user fees is September 30, 2022. Both chambers are working on their own bills. The House E&C Committee favorably reported the bipartisan **Food and Drug Amendments of 2022**, though a House floor vote has not yet been scheduled. In addition to the reauthorization of the user fee programs for prescription drugs, generic drugs, biosimilars, and medical devices, the bill includes several provisions to support patient access to drugs and devices and spur innovation ([WHG summary](#)). Last Friday, Senate HELP Committee Chair Murray and Ranking Member Burr introduced the bipartisan **Food and Drug Administration (FDA) Safety and Landmark Advancements (FDASLA) Act** ([WHG summary](#)). The introduced bill largely mirrors the discussion draft released on May 17. Like the House E&C version, the introduced version includes provisions to increase biosimilar and generic competition and a new provision to modernize the accelerated approval pathway. The Senate HELP Committee is expected to mark-up FDASLA in the coming weeks.

FY 2023 Appropriations

Regarding government funding, the House Appropriations Committee has completed their hearings on the President’s FY 2023 budget request and is expected to begin markups of FY 2023 appropriations bills in June. 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.

THIS WEEK IN HEALTH POLICY

Mon. (5/30)

- **Memorial Day**

Tue. (5/31)

- **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](#).

Thurs. (6/2)

- **10:00am – HRSA Meeting: Childhood Vaccines** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Commission on Childhood Vaccines to discuss program updates. [Details](#).
- **12:00pm – CDC Meeting: Infection Control** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Healthcare Infection Control Practices Advisory Committee to hear workgroup updates. [Details](#).

Additional Multi-Day Events

- **May 31-June 3 – 12:30pm – HRSA Meeting: Agricultural Worker Health** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on Migrant Health to discuss migratory and seasonal agricultural worker health. [Details](#).
- **June 1-June 2 – 1:00pm – CDC Meeting: Preparedness and Response** – The Centers for Disease Control and Prevention (CDC) Center for Preparedness and Response holds a meeting of the Board of Scientific Counselors to discuss program updates. [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](#).

CONGRESSIONAL LOOKBACK

Mon. (5/23)

- **President Biden signed** the Access to Baby Formula Act of 2022, which authorizes the Department of Agriculture (USDA) to address emergencies, disasters, and supply chain disruptions. [Details](#).

Weds. (5/25)

- **Sens. Grassley and Cantwell introduced** the Pharmacy Benefit Manager (PBM) Transparency Act of 2022. [Details](#).

Thurs. (5/26)

- **The Senate Finance Committee released** a discussion draft of their Telemental Health Access to Care Act. [Details](#).

Fri. (5/27)

- **The Senate HELP Committee formally introduced** the FDA Safety and Landmark Advancements (FDASLA) Act. [Details](#).

REGULATORY LOOKBACK

Fri. (5/27)

- **CMS released** a report ([press release](#)) it sent to HHS responding to the Secretary's [request](#) for CMS to reassess the 2022 Medicare Part B premium amount due to the Aduhelm price reduction. [Details](#).
- **The OASH and OMH announced** a NOFO titled, "*Community-Driven Approaches to Address Factors Contributing to Structural Racism in Public Health*." Applications are due July 15. [Details](#).
- **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. Applications June 17. [Details](#).

Thurs. (5/26)

- **CMS approved** SPA in California, Kentucky, and Oregon, and a section 1115 demonstration in Florida to extend Medicaid and CHIP coverage to 12 months postpartum. [Details](#).

Weds. (5/25)

- **The NIH** [announced](#) the establishment of the Advanced Research Projects Agency for Health (ARPA-H). [Details.](#)
- **The FDA** [issued](#) final guidance entitled: Importation of Prescription Drug Final Rule Questions and Answers (Q&A). [Details.](#)
- **CMS** [released](#) a slide deck that details the Agency's strategy for implementation of the Home and Community-Based Settings (HCBS) [final rule](#). [Details.](#)

Mon. (5/23)

- **The U.S. Surgeon General** [issued](#) an Advisory to call attention to the increasing issue of burnout across the health care workforce. [Details.](#)
- **CMS** published the [proposed Basic Health Program \(BHP\) funding methodology](#) for program year 2023. [Details.](#)

COMMENT & APPLICATION DEADLINES

- **May 31:** CMS [released](#) the FY 2023 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule. Comments are due May 31. [Details.](#)
- **May 31:** CMS [released](#) the FY 2023 inpatient psychiatric facility (IPF) prospective payment system (PPS) proposed rule. Comments are due May 31. [Details.](#)
- **May 31:** CMS [released](#) the FY 2023 hospice payment rate update proposed rule. [Details.](#)
- **June 1:** HRSA [released](#) a NOFO to strengthen the public health workforce under the Public Health Scholarship Program. [Details.](#)
- **June 6:** The Treasury Department and the IRS issued a [proposed rule](#) to revise criteria for ACA premium tax credit (PTC) eligibility in the individual market. [Details.](#)
- **June 6:** HHS OCR [issued](#) a RFI to solicit comments on the HITECH Act. [Details.](#)
- **June 7:** The FDA [issued](#) a request for comments on changes to the agency's previously proposed quality metrics (QM) reporting program. [Details.](#)
- **June 10:** CMS [released](#) the FY 2023 SNF PPS proposed rule. [Details.](#)
- **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 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 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 17:** The FDA [issued](#) draft guidance on risk management plans to mitigate the potential for drug shortages. [Details.](#)
- **September 17:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details.](#)

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