

Wynne Health Group Weekly



FRAMING THE WEEK

Congress returns from recess to tackle a slew of priorities. The House will vote on a pair of gun reform bills, that include several of the measures recommended by President Biden in a [speech](#) urging lawmakers to address gun violence. However, the Senate is unlikely to consider them in anticipation of a bipartisan deal under negotiations. The House will also vote on a Food and Drug (FDA) user fee reauthorization package, while the Senate Health, Education, Labor and Pensions (HELP) Committee will mark-up its version of the bill. The House and Senate will also work on the Farm bill and rural health access at the committee level, respectively.

As for budget reconciliation, Senate Majority Leader Chuck Schumer (D-NY) and Sen. Joe Manchin (D-WV) appear to have not yet reached a deal on a slimmed-down version of the **Build Back Better Act**. The legislative vehicle could include an extension to advance premium tax credits enhancements (which expire at the end of 2022) and prescription drug pricing reform.

On the regulatory front, Centers for Medicare & Medicaid Services (CMS) is expected to soon release its proposed calendar year (CY) 2023 annual Medicare payment updates.

Gun Violence

On Wednesday, the House is scheduled to vote on the **Protecting Our Kids Act (H.R. 7910)** – an omnibus bill, advanced by the House Judiciary Committee along party lines (25-19) last week, that would raise the age to purchase semiautomatic rifles from 18 to 21 and stiffen penalties for gun trafficking, among other gun control measures. The House will also vote on the **Federal Extreme Risk Protection Order Act of 2022 (H.R. 2377)**, which would allow family members and law enforcement to petition to temporarily remove firearms from a gun owner who could pose a threat. The House Judiciary Committee approved the “red flag” bill along party lines last October (24-18).

In anticipation of a bipartisan deal led by Sen. Chris Murphy (D-CT), the Senate is expected to hold off on votes on any House-passed bills, including measures pass in March to close loopholes in background checks ([H.R. 1446](#) and [H.R. 8](#)). The bipartisan group appears to be coalescing around “red flag” legislation, limited changes to background checks, and additional funding for mental health services.

FDA User Fee Reauthorization

Tomorrow, the House is scheduled to vote on (and expected to pass) the **Food and Drug Amendments Act of 2022 (H.R. 7667)** – a bipartisan bill unanimously approved by the House Energy and Commerce Committee that would reauthorize FDA user fee programs. The legislation also includes several provisions to support patient access to drugs and devices and spur innovation ([WHG summary](#)). The statutory deadline for the reauthorization of FDA user fees is September 30, 2022.

On Wednesday, the Senate HELP Committee will mark-up its version of an FDA user fee reauthorization bill, **Food and Drug Administration (FDA) Safety and Landmark Advancements (FDASLA) Act**. The

bipartisan 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](#)).

Rural Health Access

The Senate HELP Committee will also consider the Maximizing Outcomes through **Better Investments in Lifesaving Equipment for (MOBILE) Health Care Act (S. 958)** – a bipartisan bill introduced by Sens. Jacky Rosen (D-NV) and Susan Collins (R-ME) aimed at increasing access to primary health care services in rural and underserved communities. Specifically, the bill would expand the allowable use criteria in the [New Access Points \(NAP\) Grant program](#) to include part-time mobile clinics and renovation, acquisition, and new construction of health centers within the program. The Health Resources and Services Administration (HRSA) operates the NAP Grant Program, which last [awarded](#) more than \$50 million to 77 health centers in FY 2019 (up to \$650,000 per awardee).

Nutrition

In preparation for the **2023 Farm Bill**, the House Agriculture Subcommittee on Nutrition, Oversight, and Department Operations will hold another hearing on the Supplemental Nutrition Assistance Program (SNAP). In April, U.S. Department of Agriculture Deputy Under Secretary Stacy Dean and Food and Nutrition Service Administrator Cindy Long fielded questions on the reevaluation of the Thrifty Food Plan, online program administration, and SNAP benefits, among other topics ([WHG summary](#)). On Wednesday, the Subcommittee will hear from stakeholders on ways to reform SNAP.

Regulatory Update

Moving into June, we expect to soon see the Centers for Medicare & Medicaid Services (CMS) release its calendar year (CY) 2023 proposed rules for the annual Medicare payment update cycle. These rules consist of updates to the following payment systems: the Medicare Physician Fee Schedule (MPFS), the Hospital Outpatient Prospective Payment System (HOPPS), the End Stage Renal Disease (ESRD) PPS, and the Home Health PPS. Specific highlights of what issues we may see in this upcoming round of rulemaking include:

- **Health Equity:** In the earlier set of proposed Medicare payment updates for the fiscal year (FY) cycle (e.g., the inpatient prospective payment system, skilled nursing facilities, etc.), CMS included a range of requests for information on better addressing health equity through the various Medicare payment systems. It is likely CMS will continue those proposals and requests in the upcoming CY 2023 rulemaking cycle as well. These could include requests on ways to improve data collection and quality measurement to better capture the effects of social risk factors on beneficiary health.
- **Telehealth:** As in other recent cycles, the 2023 MPFS is likely to contain an array of provisions addressing Medicare telehealth coverage. In addition to implementing the telehealth-related changes included in the recent FY 2023 omnibus (details [here](#)), the proposed rule may include additional discussion of CMS's findings relative to the effects of extended telehealth coverage of certain services on quality, access, costs, and program integrity.
- **Digital Quality Measures:** CMS included a request for information (RFI) on transitioning to digital quality measurement in its proposed rule for the FY 2023 IPPS (details [here](#)). CMS may include similar RFIs in its upcoming proposed rules for the CY 2023 MPFS and HOPPS. This could include specific considerations on how to define digital quality measures, data standardization activities, and approaches to achieving Fast Healthcare Interoperability Resources (FHIR)-based reporting for electronic clinical quality measures.

Other changes could address issues such as 340B payments (via the HOPPS proposed rule), the mandatory kidney care demonstration – the End-Stage Renal Disease Treatment Choices Model (via the ESRD PPS proposed rule), and climate change (via the HOPPS proposed rule or others).

THIS WEEK IN HEALTH POLICY

Mon. (6/6)

- **10:30am – NIH Meeting: Allergy and Infectious Diseases** – The National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases holds a meeting of the National Advisory Allergy and Infectious Diseases Council to hear the Director's report and program updates. [Details.](#)

Tue. (6/7)

- **8:30am – FDA Meeting: Novavax COVID-19 Vaccine** – The Food and Drug Administration (FDA) holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss the Emergency Use Authorization request by Novavax for a vaccine for COVID-19 for individuals ages 18 and older. [Details.](#)
- **9:30am – FDA Meeting: User Fees** – FDA holds a meeting to discuss transparency and efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments. [Details.](#)
- **10:00am – NIH Meeting: Arthritis and Musculoskeletal and Skin Diseases** – The NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases holds a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council to discuss programs and policies. [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.](#)
- **10:30am – NIH Meeting: Mental Health** – The NIH National Institute of Mental Health holds a meeting of the National Advisory Mental Health Council to hear the Director's report and program updates. [Details.](#)
- **2:00pm – HHS Meeting: Pain Research** – The Department of Health and Human Services (HHS) Office of the Secretary holds a meeting of the Interagency Pain Research Coordinating Committee to discuss updates on pain workforce enhancement, pain research, patient engagement, and diversity efforts. [Details.](#)

Wed. (6/8)

- **10:00am – Markup: FDA User Fees** – The Senate Health, Education, Labor, and Pensions (HELP) Committee will convene a markup of the Food and Drug Administration Safety and Landmark Advancements Act and the MOBILE Health Care Act. [Details.](#)
- **10:15am – Hearing: Farm Bill** – The House Agriculture Committee Nutrition, Oversight and Department Operations Subcommittee holds a hearing titled, "A 2022 Review of the Farm Bill: Stakeholder Perspectives on SNAP." [Details.](#)

Thurs. (6/9)

- **9:00am – CDC Meeting: Health Statistics** – The Centers for Disease Control and Prevention (CDC) National Committee on Vital and Health Statistics holds a meeting of the Subcommittee on Standards to discuss actions for near-term improvement of the current standards development and rulemaking process. [Details.](#)

Additional Multi-Day Events

- **June 7-June 10 – CMS Meeting: HCPCS** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting to discuss the Healthcare Common Procedure Coding System (HCPCS) and the preliminary coding, benefit category, and payment determinations for the Level II code set. [Details.](#)

- **June 8-June 9 – CDC Meeting: Community Health Preventive Services** – The CDC Community Preventive Services Task Force holds a meeting 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.](#)

REGULATORY LOOKBACK

Fri. (6/3)

- **CMS [announced](#)** that states will have an additional year to use funding from the ARP to enhance, expand, and strengthen HCBS for Medicaid enrollees who need LTSS. [Details.](#)
- **ONC HITAC [released](#)** a report detailing its recommendations in response to ONC's RFI on the health IT Certification Program. [Details.](#)
- **The FDA [issued](#)** final guidance on electromagnetic compatibility (EMC) of medical devices. [Details.](#)

Thurs. (6/2)

- **The Medicare Trustees [released](#)** their latest report on the status of the Hospital Insurance (HI) and Supplemental Medicare Insurance (SMI) trust funds. [Details.](#)
- **HRSA [issued](#)** a set of new recommendations to improve care for children and youth with special health care needs. [Details.](#)
- **The OASH and OMH [announced](#)** a funding opportunity to promote equitable access to language services in Health and Human Services. Applications are due July 15. [Details.](#)

Weds. (6/1)

- **HHS OIG [released](#)** an audit finding that Medicare improperly paid DME suppliers approximately \$8 million for power mobility device (PMD) repairs. [Details.](#)
- **The CDC [seeks](#)** nominations for the CDC/Health Resources & Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHACHSPT). Nominations are due October 1. [Details.](#)

Tues. (5/31)

- **HHS [announced](#)** it is establishing the Office of Environmental Justice (OEJ). [Details.](#)
- **The USDA [announced](#)** a \$20 million cooperative agreement opportunity to improve participation and retention in the WIC program. Applications are due August 1. [Details.](#)
- **The GAO [released](#)** a new report finding that limited data on short-term health plans hinders understanding of the role they played during the COVID-19 pandemic. [Details.](#)
- **The FDA [announced](#)** an additional delay of the required warnings for cigarette packages and advertisements [final rule](#) until July 8, 2023.

COMMENT & APPLICATION DEADLINES

- **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 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](#).
- **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

