

Wynne Health Group Weekly



FRAMING THE WEEK

Though Democrats and Republicans have not reached a deal on the FY 2023 omnibus appropriations package, “Chairman Leahy feels that sufficient progress in negotiations took place over the weekend to delay the introduction of the omnibus appropriations bill for the time being,” according to a [statement](#) from Leahy’s office. Still, we anticipate lawmakers will need to pass another continuing resolution in order to complete a deal on an end-of-year spending package. Questions remain on which policy provisions will be attached to the must-pass vehicle. At a minimum, we anticipate lawmakers will take steps to reduce the cuts to Medicare physicians in the upcoming spending bill. Whether the deal includes any investments to address mental health or bolster the public health system remain to be seen ([details](#)).

Committee Hearings: Nutrition, Gun Violence

Two Senate committees will hold hearings focused on nutrition as part of the groundwork for reauthorization of the Farm bill in 2023. Tomorrow, the Senate Agriculture Subcommittee on Food and Nutrition, Specialty Crops, Organics, and Research will [discuss](#) current efforts and potential opportunities for “food as medicine.” On Thursday, the Senate Special Committee on Aging will hear from state and local officials and advocates on ways to promote health and affordable food for older Americans. In the [White House National Strategy on Hunger, Nutrition, and Health](#), the Biden-Harris Administration expressed support for legislation to create a pilot to test covering medically tailored meals for individuals in traditional Medicare who are experiencing diet-related health conditions.

On Thursday, the House Judiciary Subcommittee on Crime, Terrorism, and Homeland Security will hold a [hearing](#) intended to discuss bipartisan solutions to gun violence in the aftermath of Uvalde and other mass shootings in the U.S. Given the broad opposition among congressional Republicans for gun control reform, we do not anticipate the Republican-controlled House to prioritize the issue. The hearing appears to be an opportunity for Democrats, while they remain in control, to reiterate their policy priorities. The Bipartisan Safer Communities Act ([P.L. 117-325](#)) had omitted more sweeping gun control reforms, such as the Protecting Our Children Act ([H.R. 7910](#)) and Federal Extreme Risk Protection Order Act ([H.R. 2377](#)) passed by House Democrats.

Regulatory Update

Last week, the Office of Management and Budget (OMB) [concluded](#) its review of the Medicare Advantage (MA) and Part D programmatic changes for contract year (CY) 2024 proposed rule. It is not clear what the Centers for Medicare and Medicaid Services might propose in this rule, though the Administration states it intends to “strengthen and improve” the programs through this rulemaking. We expect its release imminently.

In addition, OMB recently [began reviewing](#) a proposed rule regarding how it counts disproportionate share hospital (DSH) days associated with section 1115 Medicaid demonstrations. As a reminder, CMS previously decided in its recent final rule for the fiscal year 2023 Inpatient Prospective Payment System (IPPS) not to finalize its proposal to revise its regulation pertaining to the calculation of the Medicaid fraction of the DSH

calculation (WHG summary [here](#)). CMS stated it will review the issue of Section 1115 demonstration days for the purposes of DSH adjustment in future rulemaking.

As with previous years, we also expect OMB to release its next update to the Unified Regulatory Agenda, which will detail future rulemaking the Administration intends to undertake. When released, WHG will review the updated agenda and will highlight key upcoming rulemaking efforts the Administration is considering on the health care front.

THIS WEEK IN HEALTH POLICY

Mon. (12/12)

- **10:00am – NQF Meeting: MUC Review** – The Measure Application Partnership (MAP) post-acute care/long-term care (PAC/LTC) Workgroup holds a Measures Under Consideration (MUC) review meeting. [Details.](#)
- **3:00pm – Health Affairs Discussion: COVID-19 Response** – Health Affairs holds a discussion with Ashish Jha, White House coordinator of the COVID-19 Response. [Details.](#)

Tue. (12/13)

- **10:00am – Hearing: Food as Medicine** – The Senate Agriculture, Nutrition, and Forestry Subcommittee on Food and Nutrition, Specialty Crops, Organics, and Research holds a hearing to examine food as medicine, focusing on current efforts and potential opportunities. [Details.](#)
- **12:00pm – KFF Discussion: Future of Contraceptive Care** – The Kaiser Family Foundation (KFF) holds a discussion on the future of contraceptive care in a post-Roe world. [Details.](#)
- **12:30pm – KFF Webinar: Women’s Health** – The Kaiser Family Foundation (KFF) holds a webinar highlighting key findings from KFF’s 2022 Women’s Health Survey on women’s contraceptive access, experiences, and preferences. [Details.](#)

Wed. (12/14)

- **1:00pm – Hearing: Veterans’ Data Privacy** – The House Veterans’ Affairs Technology Modernization Subcommittee holds a hearing on veterans’ data privacy. [Details.](#)
- **3:30pm – Markup: COVID-19** – The House Oversight and Reform Coronavirus Crisis Subcommittee holds a markup of the committee report on COVID-19 and preventing public health emergencies. [Details.](#)

Thurs. (12/15)

- **10:00am – Hearing: Healthy and Affordable Food for Older Adults** – The Senate Special Committee on Aging holds a hearing to examine ways to promote healthy and affordable food for older Americans. [Details.](#)
- **10:00am – Hearing: Bipartisan Solutions to Gun Violence** – The House Committee on the Judiciary Subcommittee on Crime, Terrorism, and Homeland Security holds a hearing to examine bipartisan solutions to gun violence. [Details.](#)

Additional Multi-Day Events

- **December 13-December 14 – 10:00am – NQF Meeting: MUC Review** – The MAP Hospital Workgroup holds a Measures Under Consideration (MUC) review meeting. [Details.](#)
- **December 15-December 16 – 10:00am – NQF Meeting: MUC Review** – The MAP Clinician Workgroup holds a Measures Under Consideration (MUC) review meeting. [Details.](#)

FEATURED WHG ANALYSIS

- **WHG Maternal Health Policy Update: November – December 2022** – In the Policy Hub Insight Bank [here.](#)

- **Blog on Which Issues Warrant Consideration in a Year-End Spending Package** – On Commonwealth Fund’s To the Point [here](#).
- **Blog on What Recent State Elections Mean for Health Care** – On Health Affairs Forefront [here](#).
- **WHG 2022 Midterm Election Recap** – In the Policy Hub Insight Bank [here](#).
- **Blog on Options for CMMI to Make Prescription Drug Affordable** – On Commonwealth Fund’s To the Point [here](#).
- **WHG Roundup of Recent Reproductive Health Developments** – In the Policy Hub Insight Bank [here](#).
- **WHG Tracker of Climate Change Provisions in the IRA** – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Fri. (12/9)

- **MedPAC convened** virtually for Day Two of its December 2022 public meeting and held sessions on payment adequacy for SNFs, home health care, and IRF services. All WHG session summaries are available on Policy Hub [here](#).
- **MACPAC convened** virtually for Day Two of its December 2022 public meeting and held sessions on adults leaving incarceration and response to an RFI on duals. All WHG session summaries are available on Policy Hub [here](#).

Thurs. (12/8)

- **MedPAC convened** virtually for Day One of its December 2022 public meeting and held sessions on payment adequacy for hospitals, ASCs, physicians, outpatient dialysis, and hospice services. All WHG session summaries are available on Policy Hub [here](#).
- **MACPAC convened** virtually for Day One of its December 2022 public meeting and held sessions on race and ethnicity data collection, nursing facility payments, DSH, insurance transitions, section 1115 waivers, managed care rate setting, the MMP demonstration, and Medicaid coverage of drugs with NCDs. All WHG session summaries are available on Policy Hub [here](#).

REGULATORY LOOKBACK

Fri. (12/9)

- **The FDA issued** draft guidance on content of human factors information in medical device marketing submissions. Comments are due March 9. [Details](#).
- **The AHRQ EPC Program** requests information on strategies to address racial/ethnic and related disparities in health and healthcare at the (1) [healthcare system level](#) and (2) [patient and provider level](#). Submissions are due January 11. [Details](#).
- **HHS OIG released** a report finding that the FDA should improve oversight of online tobacco retailers. [Details](#).

Thurs (12/8)

- **HHS OCR and the ONC** jointly [created](#) an updated tool to help health app developers learn about federal regulations that apply to their software. [Details](#).
- **The USPTO announced** the implementation of the Cancer Moonshot Expedited Examination Pilot Program. [Details](#).
- **The FDA issued** a proposed rule to establish a new annual reporting requirement for investigational new drug applications. Comments are due March 9. [Details](#).

Weds. (12/7)

- **FNS announced** \$60.58 million in funding for round two Reach and Resiliency grants in The Emergency Food Assistance Program (TEFAP). Applications are due March 6. [Details](#).

Tues. (12/6)

- **CMS** [released](#) a proposed rule to improve the electronic exchange of health care data and streamline prior authorization. Comments are due March 13. [Details](#).
- **HHS OIG** [released](#) the Semiannual Report to Congress providing an overview of the Agency's activities from March 2022 through September 2022. [Details](#).

Mon. (12/5)

- **HHS OIG** [released](#) a report on telehealth use and program integrity risks across health care programs during the pandemic. [Details](#).
- **HHS** [extended](#) enforcement discretion for the requirement that convening providers and facilities provide good faith estimates (GFEs) for uninsured individuals of expected charges from co-providers and co-facilities. [Details](#).
- **The USDA** [announced](#) a new virtual Agricultural Science Center of Excellence for Nutrition and Diet for Better Health. [Details](#)

COMMENT & APPLICATION DEADLINES

- **December 13:** The FDA [issued](#) a request for public comments on a recently released [discussion paper](#) on areas associated with Distributed Manufacturing (DM) and Point-of-Care (POC) manufacturing. [Details](#).
- **December 20:** The FDA [issued](#) draft guidance on proposed select updates for the Breakthrough Devices Program Guidance. [Details](#).
- **December 29:** The CDC is [seeking](#) nominations for membership on the Advisory Committee on Breast Cancer in Young Women (ACBCYW). [Details](#).
- **December 31:** AHRQ [issued](#) a supplemental solicitation for nominations of members from Populations Underrepresented in Medicine (URIM) to serve on the Initial Review Group (IRG). [Details](#).
- **December 31:** PCORI [released](#) a draft report on their systemic review on postpartum care for women up to one year after birth. [Details](#).
- **January 8:** HHS [issued](#) a proposed rule to adopt updated versions of the retail pharmacy standards for electronic transactions.. [Details](#).
- **January 9:** AHRQ announced a challenge competition to explore the resources and infrastructure needed to integrate real-world data from healthcare systems into systematic review findings. [Details](#).
- **January 11:** The AHRQ EPC Program requests information on strategies to address racial/ethnic and related disparities in health and healthcare at the (1) [healthcare system level](#) and (2) [patient and provider level](#). [Details](#).
- **January 24:** HHS [issued](#) an NRPM to revise the current 340B administrative dispute resolution final rule. [Details](#).
- **January 30:** CMS [issued](#) an RFI seeking feedback on issues related to the Essential Health Benefits. [Details](#).
- **February 9:** The CDC [released](#) a grant opportunity for research programs to assess the effectiveness of programs, policies, or practices that affect SDOH. [Details](#).
- **February 12:** CMS [issued](#) a request for nominations to fill vacancies on the Advisory Panel on Hospital Outpatient Payment. [Details](#).
- **February 13:** HHS [issued](#) a request for public comment on new indicator targets for the National Action Plan to Prevent Health Care-Associated Infections. [Details](#). [Details](#).
- **March 6:** FNS [announced](#) \$60.58 million in funding for round two Reach and Resiliency grants in The Emergency Food Assistance Program (TEFAP). [Details](#).
- **March 9:** The FDA [issued](#) a proposed rule to establish a new annual reporting requirement for investigational new drug applications. [Details](#).
- **March 9:** The FDA [issued](#) draft guidance on content of human factors information in medical device marketing submissions. [Details](#).
- **March 13:** CMS [released](#) a proposed rule to improve the electronic exchange of health care data and streamline prior authorization. [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

