

Wynne Health Group Weekly



FRAMING THE WEEK

On Saturday, President Biden [signed](#) a \$40 billion aid package for Ukraine ([H.R. 7691](#)). Congressional leaders did not include emergency supplemental funding for COVID-19 out of concern that doing so would delay Ukrainian aid. Instead, they plan to advance the COVID funding bill separately, though the timing of the vote is unclear. House votes are not [scheduled](#) until June 7.

In the meantime, House will hold committee hearings this week on top priorities, including the current infant formula shortage and legislation to strengthen communications technologies in the U.S. The Senate will vote to confirm a large number of President Biden's nominees, including the nomination of Samuel Bagenstos to serve as General Counsel of the Department of Health and Human Services. He currently serves as General Counsel to the Office of Management and Budget.

Infant Formula Shortage

On Wednesday, the House Energy and Commerce Subcommittee on Oversight and Investigations will convene a [hearing](#) to examine the current infant formula shortage and supply chain concerns. Senior executives from the three major manufacturers of infant formula (Abbott, Gerber Products Company, and Reckitt) will testify before the Subcommittee, as well as Food and Drug Administration (FDA) Commissioner Robert Califf and other top officials.

The Biden Administration has taken several actions to address the current infant formula shortage. On Saturday, President Biden [signed](#) the Access to Baby Formula Act of 2022 ([H.R. 7791](#)) which authorizes the Department of Agriculture (USDA) to address emergencies, disasters, and supply chain disruptions, especially the current infant formula shortage, that affect participants of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) ([WHG summary](#)).

Last week, FDA and Abbott reached an [agreement](#) for Abbott to restart production of infant formula at the Michigan-based facility. However, it will take six to eight weeks before products are commercially available, [according](#) to Abbott. To support these efforts, President Biden [invoked](#) the Defense Production Act to ensure an adequate supply of infant formula, which will require suppliers to prioritize sending necessary resources to infant formula manufacturers before other customers who may have ordered such resources.

To support the supply chain in the meantime, the FDA recently issued [guidance](#) temporarily exercising enforcement discretion of certain requirements to allow importation of infant formula. The guidance will be in effect until November 14. The Department of Agriculture (USDA) is also [urging](#) states to use and extend flexibilities in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) to address the shortage of infant formula ([WHG summary](#)).

Hearing on "Strengthening Our Communications Networks: Legislation to Connect and Protect"

On Tuesday, the House Energy and Commerce Subcommittee on Communications and Technology will meet to discuss several bills on strengthening communications technologies in the U.S. The bills up for consideration include the following:

- [H.R. 4275](#): the "Ensuring Phone and Internet Access for SNAP Recipients Act of 2021"
- [H.R. 4990](#): the "Institute for Telecommunication Sciences Codification Act" or the "ITS Codification Act"
- [H.R. 5486](#): the Simplifying Management, Reallocation, and Transfer of Spectrum Act" or the "SMART Act"
- [H.R. 7132](#): the "Safe Connections Act of 2022"
- [H.R. 7783](#): the "Extending America's Spectrum Auction Leadership Act of 2022"

While the set of bills address a range of communications technology issues, many would support more individuals in accessing high speed internet connections – an important component to ensuring individuals can participate in telehealth service offerings. For example, H.R. 7783 would reauthorize the federal government's authority to auction wireless spectrum and help connect rural communities to wireless networks. In addition, H.R. 7132 would authorize survivors of domestic violence to temporarily participate in federal programs that subsidize internet connectivity. Last, H.R. 4275 would require the federal government to monitor the number of individuals participating in the supplemental nutrition assistance program (SNAP) who also participate in programs that subsidize internet connectivity.

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THIS WEEK IN HEALTH POLICY

Mon. (5/23)

- **3:00pm – NQF Meeting: Health Equity** – The National Quality Forum (NQF) Core Quality Measures Collaborative (CQMC) holds a meeting of the Health Equity Workgroup to discuss measures to improve health equity. [Details.](#)

Tue. (5/24)

- **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.](#)
- **11:00am – NIH Meeting: Minority Health** – The National Institutes of Health holds a meeting of the National Advisory Council on Minority Health and Health Disparities to hear the director's report and other updates. [Details.](#)
- **11:00am – NIH Meeting: Nursing Research** – The NIH National Institute on Nursing Research holds a meeting of the National Advisory Council for Nursing Research to hear presentations. [Details.](#)
- **12:00pm – Hearing: Climate Change and Food Supply** – The House Select Committee on the Climate Crisis holds a hearing titled, "Climate Smart from Farm to Fork: Building an Affordable and Resilient Food Supply Chain." [Details.](#)
- **1:00pm – The Hill Event: Antibiotic Resistance** – The Hill holds a discussion titled, "Antibiotic Resistance: A Looming Public Health Crisis." [Details.](#)
- **2:00pm – NQF Meeting: EHR** – NQF holds a meeting of the electronic health record (EHR) Care Coordination Committee to discuss ways to leverage EHR-sourced measures. [Details.](#)

Wed. (5/25)

- **11:00am – Hearing: Formula Shortage** – The House Committee on Energy and Commerce Oversight and Investigation Subcommittee holds a hearing titled, "Formula Safety and Supply: Protecting the Health of American's Babies." [Details.](#)
- **12:00pm – CMS Meeting: Continuous Enrollment** – The Centers for Medicare and Medicaid Services (CMS) holds a webinar titled, "Medicaid and CHIP Continuous Enrollment Unwinding: What to Know and How to Prepare." [Details.](#)

Thurs. (5/26)

- **11:00am – CDC Meeting: Health Statistics** – The Centers for Disease Control and Prevention (CDC) Board of Scientific Counselors holds a meeting of the National Center for Health Statistics to hear program updates. [Details](#).

Additional Multi-Day Events

- **May 24-May 25 – 9:45am – NIH Meeting: Aging** – The NIH National Institute on Aging holds a meeting of the Board of Scientific Counselors to hear 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](#).

CONGRESSIONAL LOOKBACK

Tues. (5/17)

- **The Senate HELP Committee** [released](#) a discussion draft of the FDA Safety and Landmark Advancements (FDASLA) Act, which reauthorizes the FDA user fee agreements. [Details](#).

Thurs. (5/19)

- **The House Appropriations Committee Agriculture, Rural Development, FDA and Related Agencies Subcommittee** held a [hearing](#) on the infant formula shortage and the FDA 2023 budget request. [Details](#).

REGULATORY LOOKBACK

Thurs. (5/19)

- **SAMHSA** [announced](#) \$1.5 billion in Fiscal Year (FY) 2022 State Opioid Response (SOR) grant funding to assist states and territories. Applications are due June 18. [Details](#).
- **The USPSTF** posted a final [research plan](#) addressing primary care interventions to prevent child maltreatment. [Details](#).
- **The FDA** [issued](#) draft guidance on risk management plans to mitigate the potential for drug shortages. Comments are due July 17. [Details](#).
- **SAMHSA** [announced](#) \$2 million in funding to establish a National Center of Excellence (CoE) on Social Media and Mental Wellness. [Details](#).

Weds. (5/18)

- **The CDC** [announced](#) an extension on the deadline for accepting nominations for membership on the Advisory Committee to the Director (ACD) Data and Surveillance Workgroup. Nominations are due May 27. [Details](#).
- **MACPAC** [issued](#) a brief that describes financial strategies for addressing the SDOH in Medicaid. [Details](#).
- **The CMS OMH** [published](#) a report with a summary of the activities that OMH has implemented as part of its Rural Maternal Health Initiative. [Details](#).
- **SAMHSA** [announced](#) that \$3.5 million will be made available for a five-year grant to develop an AANHPI Behavioral Health Center of Excellence. [Details](#).

- **CMS** [released](#) a slide deck that describes flexibilities that states can use during Medicaid redetermination at the end of the PHE. [Details](#).
- **HRSA** [announced](#) the final criteria that will be used to identify Maternity Care Target Areas. [Details](#).

Tues. (5/17)

- **The U.S. District Court for the District of Columbia** [granted](#) PhRMA's motion for summary judgement and thereby vacated the accumulator adjustment rule of 2020. [Details](#).
- **SAMHSA** announced that \$15 million will be made available for a three-year grant to establish a program that will strengthen the delivery of behavioral health care to residents in nursing homes. [Details](#).
- **The FDA** [issued](#) final guidance on assessing user fees under the Generic Drug User Fee Amendments of 2017 (GDUFA II). [Details](#).
- **The FDA** released a [white paper](#) on key considerations for measuring and rating a drug manufacturer's quality management maturity (QMM). [Details](#).
- **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." Submissions are due June 16. [Details](#).

Mon. (5/16)

- **The USDA** is [urging](#) states to use and extend flexibilities in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) to address the shortage of infant formula. [Details](#).
- **HHS** released an RFI to help develop the 2022 Environmental Justice Strategy and Implementation Plan. Comments are due June 18. [Details](#).

COMMENT & APPLICATION DEADLINES

- **May 24:** The FDA [issued](#) a proposed rule to amend the device CGMP requirements. [Details](#).
- **May 24:** AHRQ [extended](#) the comment period for its RFI on its proposed strategic framework for the Patient-Centered Outcomes Research Trust Fund (PCORTF) investments. [Details](#)
- **May 27:** The CDC [announced](#) an extension on the deadline for accepting nominations for membership on the Advisory Committee to the Director (ACD) Data and Surveillance Workgroup. [Details](#).
- **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 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 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](#).

WHG Contacts for Inquiries

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