

***Wynne Health Group Weekly***



**FRAMING THE WEEK**

Congress returns this week after a two-week spring recess. At the top of the agenda will be a push to pass the \$10 billion bipartisan COVID-19 supplemental package that was negotiated just prior to leaving town earlier this month. The package was pulled by leadership just prior to recess due to Republicans demanding a vote on reinstating the Title 42 border policy, which the CDC said will end in May. Over the last two weeks several Democrats have also expressed concern about ending the order, saying the Administration has no plan to deal with the migrant surge that is expected once the order is lifted. With COVID rates rising, and states running out of funding for testing and treatment, the White House continues to sound the alarm that additional aid is urgent. Democrats may try to attach the COVID-19 relief package to additional funding for the Ukraine, but the path forward is uncertain.

The bipartisan COVID-19 supplemental appropriations package would provide \$10 billion to Public Health and Social Services Emergency Fund at the Department of Health and Human Services (available until September 30, 2025). Of this amount, \$9.25 billion would be allocated to the Biomedical Advanced Research and Development Authority (BARDA) for research and development, manufacturing, and purchase of vaccines, therapeutics, diagnostics, and supplies. The remaining \$750 million would support research and clinical trials for the development of vaccines against emerging variants. Unspent COVID funds (mostly related to small businesses and aviation) would be used to fully pay for the supplemental bill.

The Congress will also be returning to a focus on the FY 2023 budget this week, as several Administration officials are slated to testify before House and Senate Committees on the Administration's budget proposal. Secretary Becerra will testify before the House Energy and Commerce Committee on Wednesday and the House Ways and Means Committee on Thursday, and FDA Commissioner Robert Califf will appear before the House Appropriations Subcommittee on Agriculture on Wednesday.

Additionally, on the agenda in the Senate this week is a bipartisan effort in the Senate to try to lower the price of insulin, as well as a measure to boost science and technology that includes \$50 billion to help produce more powerful computer chips in the United States.

**THIS WEEK IN HEALTH POLICY**

**Tue. (4/26)**

- **10:00am – Hearing: FDA User Fee Agreements** – The Senate Committee on Health, Education, Labor and Pensions (HELP) holds a hearing on "Food and Drug Administration (FDA)

User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients, FDA Center Directors." [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.](#)
- **3:30pm – CMS Meeting: CMS Strategic Vision** – The Centers for Medicare and Medicaid Services (CMS) Office of Minority Health holds the quarterly national stakeholder call with CMS Administrator Chiquita Brooks-LaSure to provide updates on the Agency's Strategic Vision and key accomplishments. [Details.](#)

#### **Wed. (4/27)**

- **10:00am – Hearing: FY 2023 FDA Budget** – The House Appropriations Committee Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee holds a hearing titled, "Fiscal Year 2023 Budget Request for the Food and Drug Administration." [Details.](#)
- **10:15am – Hearing: FY 2023 HHS Budget** – The House Committee on Energy and Commerce Subcommittee on Health holds a hearing titled, "The Fiscal Year 2023 Health and Human Services (HHS) Budget." [Details.](#)
- **1:00pm – SAMHSA Meeting: Substance Abuse** – The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Center for Substance Abuse Treatment National Advisory Council to discuss the previous meeting and program updates. [Details.](#)

#### **Thurs. (4/28)**

- **10:00am – Hearing: SNAP** – The House Agriculture Committee holds a hearing titled, "A 2022 Review of the Farm Bill: The Supplemental Nutrition Assistance Program (SNAP)." [Details.](#)
- **10:30am – Hearing: FY 2023 HHS Budget** – The House Ways and Means Committee holds a hearing titled, "Proposed Fiscal Year 2023 Budget with Health and Human Services Secretary Becerra." [Details.](#)

#### **Fri. (4/29)**

- **9:00am – NQF Meeting: Rural Health** – The National Quality Forum (NQF) holds a meeting of the Rural Health Advisory Workgroup to discuss how to leverage quality measures to improve rural health. [Details.](#)

#### **Additional Multi-Day Events**

- **April 26-April 28 – 11:00am – CDC and HRSA Meeting: HIV, Viral Hepatitis, and STDs** – The Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) hold a meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and Sexually Transmitted Disease (STD) Prevention and Treatment to discuss program priorities. [Details.](#)

#### **FEATURED WHG ANALYSIS**

- **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.](#)
- **WHG Issue Brief on Health Equity Implications of Potential Telehealth Reform Under Medicare** – In the Policy Hub Insight Bank [here.](#)

## REGULATORY LOOKBACK

### Fri. (4/22)

- **CMS** released a [proposed rule](#) to implement CAA provisions to extend Medicare Part B coverage of immunosuppressive drugs beyond 36 months after transplant and simplify Medicare enrollment rules. [Details.](#)

### Thurs. (4/21)

- **HRSA** [announced](#) that it is providing \$88.4 million in ARP funding to support data-driven efforts to address disparities among HRSA-funded health centers and look-alikes. Applications are due May 23. [Details.](#)

### Weds. (4/20)

- **CMS** [released](#) its action plan to drive health equity and address systemic inequities. [Details.](#)
- **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. Comments are due June 20. [Details.](#)
- **HHS** [released](#) new data and a report on hospital and nursing home ownership. [Details.](#)
- **White House** [announced](#) that it is awarding nearly \$105 million to states and territories to strengthen crisis call center services in advance of the transition to the 988 crisis line. [Details.](#)

### Tues (4/19)

- **HHS, DOL, and the Treasury** [issued](#) FAQs regarding enforcement of the Transparency in Coverage (TiC) Final Rules with regard to alternative reimbursement arrangements. [Details.](#)
- **MACPAC** [released](#) its response to the CMS [request for information](#) on access and coverage in Medicaid and CHIP. [Details.](#)

### Mon. (4/18)

- **CMS** [released](#) the FY 2023 IPPS/LTCH proposed rule. Comments are due June 17. [Details.](#)
- **SAMHSA** [released](#) a notice of funding opportunity (NOFO) for Rural Opioid Technical Assistance Regional Centers. Applications are due June 14. [Details.](#)
- **CMS** launched the [Federal Independent Dispute Resolution \(IDR\) portal](#) for health care providers, facilities, and health plans and issuers to resolve payment disputes. [Details.](#)

## COMMENT & APPLICATION DEADLINES

- **April 22:** The NIH [announced](#) a \$1 million prize competition for innovative diagnostics technologies to help improve maternal health. [Details.](#)
- **April 25:** The FTC [issued](#) a request for public comments on the ways that [pharmacy](#) benefit managers (PBMs) affect drug affordability and access. [Details.](#)
- **April 28:** AHRQ posted a request for supplemental data and evidence on postpartum home blood pressure monitoring and postpartum treatment of hypertensive disorders. [Details.](#)
- **May 2:** The HHS Office of the Surgeon General is [seeking](#) input on the impact and prevalence of health misinformation in the digital information environment during the COVID-19 pandemic. [Details.](#)
- **May 9:** The USPSTF issued draft recommendation statements in favor of screening for [major depressive disorder \(MDD\)](#) and [anxiety](#) among children and adolescents. [Details.](#)
- **May 9:** HRSA [released](#) a RFI on ways to strengthen and improve the Organ Procurement and Transplantation Network (OPTN). [Details.](#)
- **May 9:** The NIH [released](#) a notice of proposed rulemaking to update the NIH Loan Repayment Programs (LRP) to reflect changes made by the 21<sup>st</sup> Century Cures Act. [Details.](#)
- **May 12:** The FNS [released](#) proposed scientific questions to inform the development of the *Dietary Guidelines for Americans 2025-2030*. [Details.](#)

- **May 17:** SAMHSA [posted](#) three grant opportunities related to mental health. [Details.](#)
- **May 17:** SAMHSA [posted](#) a notice of funding opportunity for the Infant and Early Childhood Mental Health Grant Program. [Details.](#)
- **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 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 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.](#)
- **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.](#)
- **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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