

Wynne Health Group Weekly



FRAMING THE WEEK

The deadline to fund the government for fiscal year (FY) 2022 is this Friday, March 11. Democrats are pushing to include COVID-19 supplemental funding in the FY 2022 appropriations omnibus, along with Ukraine assistance. “Democrats have made a reasonable global offer to Republicans and it is my hope that we will reach an agreement very soon so that we can meet the March 11 government funding deadline,” wrote Senate Majority Leader Chuck Schumer (D-NY) in a [Dear Colleague letter](#) released this morning. If Democrats and Republicans are unable to reach deal on COVID-19 supplemental funding, another continuing resolution may need to be passed.

The Office of Management and Budget (OMB) [requested](#) Congress provide \$22.5 billion to “initiate action on the National COVID-19 Preparedness Plan,” unveiled last week ([WHG summary](#)). “Additional funding will be needed” for the COVID-19 response, [noted](#) OMB Acting Director Shalanda Young. The \$22.5 billion request includes \$18.25 billion for the Department of Health and Human Services (HHS) and \$4.25 for the Department of State and USAID.

More than half of the funding request is dedicated to ensuring “sufficient and timely supply” of medical countermeasures in the United States in the near-term, a major component of the President’s latest preparedness plan. OMB requests the following for the domestic response:

- \$12.2 billion to procure and distribute medical countermeasures (i.e., vaccines, oral antiviral, and monoclonal antibodies);
- \$2 billion to support testing and supplies, including the Increasing Community Access to Testing ([ICATT](#)) program at the Centers for Disease Control and Prevention (CDC), which is slated to run out of funding this May;
- \$1.5 billion to develop medical countermeasures to protect against future variants;
- \$1.5 billion for (1) [COVID-19 claims reimbursement](#) for testing, treatment, and vaccine administration for the uninsured; and (2) the [COVID-19 Coverage Assistance Fund](#), which covers vaccine administration for the underinsured; and
- \$300 million for surveillance and laboratory capacity at CDC to detect emerging variants.

The House may vote as soon as Wednesday on the FY 2022 appropriations omnibus before adjourning for recess on Wednesday. House Democrats will hold their annual retreat this Wednesday through Friday. Senate Democrats will also convene for their caucus retreat this week, where they “will spend a great deal of time going over the numerous proposals that Democrats have to lower costs for working families,” [wrote](#) Senate Majority Leader Schumer. Notably, the Senate Finance Committee will hold a hearing on lowering the cost of prescription drugs next week, said Schumer.

[Regulatory Update](#)

Of note, a proposed rule regarding the Center for Medicare and Medicaid Innovation (CMMI)'s [Radiation Oncology model](#) has [appeared](#) at the Office of Management and Budget (OMB) for review. It is unclear what will be included in this proposed rule, though the Administration may use it to implement additional refinements to the model parameters.

The mandatory model to improve radiotherapy for cancer patients was originally proposed in 2019 and has since been delayed multiple times through legislative action. Stakeholders have repeatedly expressed concerns with the payment methodology of the model and warned that such changes could lead to reductions in access and quality of care. The most recent delay of the model – via the Protecting Medicare and American Farmers from the Sequester Cuts ([P.L. 117-71](#)) – punted the demonstration's start date to January 1, 2023.

THIS WEEK IN HEALTH POLICY

Mon. (3/7)

- **10:00am – ONC Meeting: Prior Authorization RFI** – The ONC Health Information Technology Advisory Committee (HITAC) holds a meeting of the e-Prior Authorization Request for Information (RFI) Task Force 2022 to discuss the recent RFI and next steps. [Details](#).

Tue. (3/8)

- **8:30am – NIH Meeting: Diabetes** – The National Institutes of Health (NIH) holds a meeting of the Diabetes Mellitus Interagency Coordinating Committee titled, "Opportunities for Research Supported by the Special Statutory Funding Program for Type 1 Diabetes Research." [Details](#).
- **10:30am – ONC Meeting: Interoperability** – ONC holds a meeting of the Interoperability Standards Workgroup to discuss how to improve interoperability. [Details](#).

Wed. (3/9)

- **12:00pm – NIH Meeting: Cancer** – The NIH National Cancer Institute holds a meeting of the National Cancer Institute Council of Research Advocates to hear program updates. [Details](#).

Thurs. (3/10)

- **10:00am – ONC Meeting: HITAC** – ONC holds a meeting of the Health IT Advisory Committee (HITAC) to discuss ongoing work. [Details](#).
- **10:00am – FDA Meeting: Cellular, Tissues, and Gene Therapy** – The Food and Drug Administration (FDA) holds a meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee to provide advice and recommendations on regulatory issues. [Details](#).

Additional Multi-Day Events

- **March 7-March 8 – 10:00am – HHS Meeting: Physician-Focused Payment Models** – The Department of Health and Human Services (HHS) holds a meeting of the Physician-Focused Payment Model Technical Advisory Committee to hear presentations on proposed models. [Details](#).
- **March 8-March 9 – 9:00am – CDC Meeting: ICD-10** – The Centers for Disease Control and Prevention (CDC) National Center for Health Statistics holds a meeting of the ICD-10 Coordination and Maintenance Committee to discuss proposed modifications to the International Classification of Diseases (ICD). [Details](#).
- **March 10-March 11 – 11:00am – HHS Meeting: Human Research** – The HHS Office of the Assistant Secretary for Health holds a meeting of the Secretary's Advisory Committee on Human Research Protections to discuss draft recommendations. [Details](#).

FEATURED WHG ANALYSIS

- **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](#).

CONGRESSIONAL LOOKBACK

Fri. (3/4)

- **MedPAC convened** virtually for Day Two of its March 2022 public meeting and held sessions on integrating episode-based payments and improving MA risk adjustment. All WHG session summaries are available on Policy Hub [here](#).
- **MACPAC convened** virtually for Day Two of its March 2022 public meeting and held sessions on redesigning HCBS and access to vaccines for adults in Medicaid. All WHG session summaries are available on Policy Hub [here](#).

Thurs. (3/3)

- **MedPAC convened** virtually for Day One of its March 2022 public meeting and held sessions on findings from focus groups, safety-net provider payments, and opportunities to support the geriatric workforce. All WHG session summaries are available on Policy Hub [here](#).
- **MACPAC convened** virtually for Day One of its March 2022 public meeting and held sessions on directed payments in managed care, improving EHR uptake, leveraging Medicaid to promote health equity, an integrated care strategy for duals, and risk mitigation and rate setting. All WHG session summaries are available on Policy Hub [here](#).

Tues. (3/1)

- **President Biden addressed** Congress in his first State of the Union, which included several health care priorities including lingering provisions from the BBBA, COVID-19, and mental health. [Details](#).

REGULATORY LOOKBACK

Fri. (3/4)

- **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. Comments are due May 2. [Details](#).
- **CMS released** a toolkit to help states inform Medicaid and CHIP beneficiaries about how to renew their coverage. [Details](#).
- **CMS released** a state health official (SHO) letter to provide guidance on promoting continuity of coverage after the end of the COVID-19 PHE. [Details](#).

Thurs. (3/3)

- **MACPAC published** an issue brief examining state policy levers to address nursing facility staffing issues. [Details](#).
- **ASPE published** an issue brief examining trends and characteristics of Medicare beneficiary enrollment in 2019. [Details](#).

Weds. (3/2)

- **The White House released** President Biden's National COVID-19 Preparedness Plan. [Details](#).
- **The White House released** a fact sheet on the President's strategy for addressing the "national mental health crisis." [Details](#).
- **HHS Office of Infectious Disease and HIV/AIDS Policy announced** that it seeks public comment on the draft Vaccines Federal Implementation Plan 2021-2025. Comments are due April 1. [Details](#).

Tues. (3/1)

- **CMS** issued a [memo](#) announcing actions that HHS will take in response to the court ruling that invalidated portions of the Surprise Billing interim final rule. [Details](#).
- **The White House** [announced](#) a series of actions the Administration is taking to improve the quality and safety of nursing homes. [Details](#).
- **The FDA** [issued](#) three final guidance documents regarding cancer clinical trials. [Details](#).
- **AHRQ** [released](#) an announcement detailing research showing reduced antibiotic use at long-term care facilities. [Details](#).

Monday (2/28)

- **CMS** [released](#) a request for nominations for membership on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). Nominations are due March 28. [Details](#).
- **The FTC** [issued](#) a request for public comments on the ways that [pharmacy](#) benefit managers (PBMs) affect drug affordability and access. [Details](#).
- **The FDA** [announced](#) the delay of the required warnings for cigarette packages and advertisements [final rule](#) until April 9. [Details](#).

COMMENT & APPLICATION DEADLINES

- **March 7:** CMS [released](#) the Contract Year (CY) 2023 Policy and Technical Changes to Medicare Advantage (MA) and Part D proposed rule. [Details](#).
- **March 10:** The ACL released two Innovations in Nutrition Programs and Services funding opportunities ([here](#) and [here](#)) to support research and programs improving nutrition services programs for aging adults. [Details](#).
- **March 11:** The FDA [issued](#) draft guidance on notifying the agency of a permanent discontinuance or interruption in manufacturing of a device. [Details](#).
- **March 11:** ASPR [issued](#) a request for comments to help inform the development of the 2023-2026 National Health Security Strategy. [Details](#).
- **March 14:** The FDA [issued](#) a request for nominations for voting and nonvoting consumer representatives to serve on advisory committees and panels. [Details](#).
- **March 14:** The USDA FNS [released](#) a notice of funding opportunity for Team Nutrition Training Grants. [Details](#)
- **March 15:** AHRQ [released](#) a solicitation for nominations for members of the U.S. Preventive Services Task Force (USPSTF). [Details](#).
- **March 18:** HRSA [released](#) a notice of funding opportunity (NOFO) for the Rural Public Health Workforce Training Network (RPHWTN) Program. [Details](#).
- **March 21:** The USPSTF [issued](#) a draft recommendation statement in favor of statin use for the primary prevention of cardiovascular disease (CVD) in adults. [Details](#).
- **March 23:** The ONC [issued](#) an RFI seeking stakeholder input on whether to adopt additional standards, implementation specifications, and certification criteria regarding electronic prior authorization. [Details](#).
- **March 28:** CMS [released](#) a request for nominations for membership on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). [Details](#).
- **March 31:** HRSA [announced](#) the availability of \$19.2 million in ARP funding to support primary care and dental resident training in rural and underserved communities. [Details](#).
- **April 1:** HHS Office of Infectious Disease and HIV/AIDS Policy [announced](#) that it seeks public comment on the draft Vaccines Federal Implementation Plan 2021-2025.. [Details](#).
- **April 4:** SAMHSA released a NOFO that will make \$10 million available for the Services Grant Program for Residential Treatment for Pregnant and Postpartum Women. [Details](#)
- **April 11:** The CDC [announced](#) it is requesting comments on the proposed clinical practice guideline, "CDC Clinical Practice Guideline for Prescribing Opioids." [Details](#).
- **April 12:** The NIH [issued](#) an RFI to gather public input on developing the NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA). Comments are due April 12. [Details](#).

- **April 16:** HRSA released a NOFO to support long term improvements in early developmental health through the Transforming Pediatrics for Early Childhood program. [Details](#).
- **April 18:** CMS [released](#) an RFI on access to care and coverage for Medicaid and CHIP enrollees. Comments are due April 18. [Details](#).
- **April 19:** HHS [announced](#) the availability of \$13 million to support increased access to behavioral health care services, including treatment for substance use disorder, in rural communities. [Details](#).
- **April 19:** AHRQ [released](#) an RFI from the public on its proposed strategic framework for its Patient-Centered Outcomes Research Trust Fund ([PCORTE](#)) investments. [Details](#).
- **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](#).
- **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 24:** The FDA [issued](#) a proposed rule to amend the device CGMP requirements. [Details](#).

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