

Wynne Health Group Weekly



FRAMING THE WEEK

This week, House leaders plan to vote on a standalone \$15.6 billion COVID supplemental package (H.R. 7007) that was pulled from the fiscal year (FY) 2022 appropriations omnibus due to pushback from some Democrats over the offsets. Nearly identical to the original version, this new bill includes \$9.85 billion to procure therapeutics and vaccines, \$750 million to develop vaccines against future variants, and \$5 billion for global health and humanitarian efforts. The major difference is that the new COVID bill is not completely offset, because it does not rescind \$7 billion in unspent Coronavirus State and Local Fiscal Recovery Funds. Even with this change, it is unclear if the House and Senate have the votes to pass the package.

In addition, committees in both chambers will work on health-related legislative priorities, including pandemic preparedness, prescription drugs, and public health. Tomorrow, the Senate Health, Education, Labor, and Pensions Committee will [mark up](#) the **Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act, S. 3799) – bipartisan legislation focused on strengthening and modernizing federal public health and medical preparedness and response systems and programs introduced by Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) ([WHG summary](#)).** The introduced bill incorporates feedback on the discussion draft unveiled in January and includes new provisions to:

- Improve biosafety and biosecurity, focusing on laboratories and research.
- Address undue foreign influence in biomedical research by requiring National Institutes of Health (NIH) extramural researchers to disclose participation in foreign talent programs, as well as requiring the Health and Human Services (HHS) Secretary to develop a risk framework for assessing and managing national security risks for biomedical research involving human genomic information.
- Bolster the public health and allied health workforces by increasing educational opportunities in physical therapy, occupational therapy, respiratory therapy, audiology, and speech-language pathology professions.
- Direct HHS to ensure coordination and collaboration between relevant Federal departments and agencies related to the safety and availability of the blood supply.
- Authorize the Centers for Disease Control and Prevention (CDC) Director to appoint directors of individual centers at CDC and regularly review leadership within the agency; and
- Establish the Office of Pandemic Preparedness and Response Policy (OPPRP) in the White House to advise on pandemic preparedness and response policy and support coordination and communication within the federal government.

On Wednesday, the Senate Finance Committee will hold a [hearing](#) on lowering prescription drug prices in Medicare. The hearing appears to be an attempt to advance prescription drug pricing reform through regular order. We anticipate lawmakers will discuss drug pricing provisions contained in the Build Back Better Act, such as negotiations, inflation rebates, and Part D redesign. Of note, former Senate Finance Chairman Sen. Charles Grassley (R-IA) issued a [letter](#) last week urging the Biden Administrator to

support passage of the Prescription Drug Pricing Reduction Act – bipartisan legislation from the 116th Congress that included some of the policies likely up for discussion in this week’s hearing.

On Thursday, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) to discuss an array of bills “intended to encourage the development of new cures and treatments, strengthen regulatory oversight at FDA, including the Accelerated Approval Program, and ensure clinical trials reflect the diversity of all American patients,” said E&C Chairman Frank Pallone, Jr. (D-NJ) and Health Subcommittee Chairwoman Anna Eshoo (D-CA).

Key bills to be discussed include authorizing bills to establish Advanced Research Projects Agency for Health (ARPA-H), which was funded at \$1 billion in the appropriations omnibus:

- **Cures 2.0 Act (H.R. 6000)**, introduced by Reps. Diana DeGette (D-CO) and Fred Upton (R-MI), would authorize the creation of ARPA-H within the National Institutes of Health (NIH), permanently expand a number of telehealth flexibilities enacted during the ongoing COVID-19 public health emergency, expand public health capacity and improve pandemic preparedness, increase the use of real-world evidence and novel trial designs in the medical device and drug product development process, and improve the experience of patients and caregivers ([WHG summary](#)).
- **Advanced Research Project Agency-Health Act (H.R. 5585)**, introduced by Health Subcommittee Chairwoman Eshoo, would authorize the creation of ARPA-H within HHS.

The Health Committee will also discuss the **Accelerated Approval Integrity Act of 2022 (H.R. 6963)**, introduced by Chairman Pallone, which would direct FDA to impose stricter requirements for its Accelerated Approval Program (AAP) ([WHG summary](#)). Overall, the bill requires the Secretary of the Department of Health and Human Services (HHS) and sponsors of AAP products to enter into agreements prior to approval that describe the how to conduct the required post-approval studies, as well as requiring these studies to be underway prior to approval. Pursuant to the agreement, sponsors must also report on their progress to study completion every 90 days. Finally, the bill outlines the instances in which the Secretary can withdraw accelerated approval or approval automatically expires, including failing to confirm clinical benefit.

THIS WEEK IN HEALTH POLICY

Mon. (3/14)

- **2:00pm – BPC Discussion: Nursing Shortage** – The Bipartisan Policy Center (BPC) holds a discussion titled, “Help Wanted: Alleviating the Nursing Shortage.” [Details](#).

Tue. (3/15)

- **10:00am – Markup: PREVENT Pandemics Act** – The Senate Committee on Health, Education, Labor and Pensions holds a meeting to markup the PREVENT Pandemics Act. [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](#).
- **1:00pm – SAMHSA: Substance Abuse** – The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Prevention National Advisory Council to discuss activities of the council. [Details](#).

Wed. (3/16)

- **10:00am – Hearing: Home Visiting** – The House Ways and Means Committee Worker and Family Support Subcommittee holds a hearing titled, “Improving Family Outcomes Through Home Visiting.” [Details](#).
- **10:00am – Hearing: Drug Price Inflation** – The Senate Committee on Finance holds a hearing titled, “Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare.” [Details](#).

- **12:00pm – NIH Meeting: Cancer** – The National Institutes of Health (NIH) National Cancer Institute holds a meeting of the Clinical Trials and Translational Research Advisory Committee to hold strategic discussions. [Details.](#)
- **1:00pm – CMMI Roundtable: Provider Participation** – The Centers for Medicare and Medicaid Services Innovation Center (CMMI) holds a roundtable to discuss provider participation in CMMI models. [Details.](#)

Thurs. (3/17)

- **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 – BPC Discussion: Public Health Emergency** – BPC holds a discussion titled, “Transitioning Out of the COVID-19 Emergency Phase.” [Details.](#)

Fri. (3/18)

- **2:00pm – NQF Meeting: Opioids and Behavioral Health** – The National Quality Forum (NQF) holds a meeting of the Opioids and Behavioral Health Committee to discuss measures related to opioids and behavioral health. [Details.](#)

Additional Multi-Day Events

- **March 14-March 15 – HHS Meeting: HIV/AIDS** – The Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health holds a meeting of the Presidential Advisory Council on HIV/AIDS to discuss the national HIV/AIDS strategy. [Details.](#)
- **March 15-March 16 – HRSA Meeting: Infant and Maternal Mortality** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Infant and Maternal Mortality to hear updates on COVID-19, race-concordant care, indigenous mothers and babies, and the impact of violence on maternal mortality. [Details.](#)

FEATURED WHG ANALYSIS

- ***NEW* 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.](#)

CONGRESSIONAL LOOKBACK

Weds. (3/9)

- **Congressional appropriators** released the text of a \$1.5 trillion Fiscal Year (FY) 2022 Omnibus Appropriations bill ([H.R. 2471](#)). [Details.](#)
- **The FY 2022 spending package** [features](#) several provisions to fund nutrition programs. [Details.](#)
- **The Senate HELP Committee** [introduced](#) the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act). [Details.](#)

Tues. (3/8)

- **E&C Committee Chairman Pallone (D-NJ)** [introduced](#) legislation that would direct the FDA to impose stricter requirements for its Accelerated Approval Program (AAP). [Details.](#)

REGULATORY LOOKBACK

Fri. (3/11)

Thurs. (3/10)

- **MACPAC** [published](#) an issue brief examining Medicaid managed care capitation rate setting. [Details.](#)
- **AHRQ** [issued](#) a request for supplemental evidence and data to inform a review on *Postpartum Care for Women Up to One Year After Pregnancy*. Submissions are due April 11. [Details.](#)

Tues. (3/8)

- **MACPAC** [released](#) their comment letter regarding the CMS CY 2023 Policy and Technical Changes to MA and Part D proposed rule. [Details.](#)
- **The FDA** [issued](#) a request for comments on changes to the agency's previously proposed quality metrics (QM) reporting program. Comments are due June 7. [Details.](#)
- **CMS** [approved](#) two California SPAs to respond to the COVID-19 national emergency. [Details.](#)
- **PCORI** [adopted](#) a new [Research Agenda](#) to inform the development of a broad portfolio of patient-centered clinical effectiveness research. [Details.](#)

Monday (3/7)

- **CMS** [released](#) an updated data snapshot of Medicaid and CHIP during the COVID-19 PHE. [Details.](#)
- **CDC** is [seeking nominations](#) for the Advisory Committee to the Director (ACD) Health Equity Workgroup (HEW). Nominations are due March 17. [Details.](#)
- **The NIH** [released](#) a notice of proposed rulemaking to update the NIH Loan Repayment Programs (LRP) to reflect changes made by the 21st Century Cures Act. Comments are due May 9. [Details.](#)
- **The USDA FNS** [released](#) the results of the School Food Authority (SFA) Survey on Supply Chain Disruption. [Details.](#)

COMMENT & APPLICATION DEADLINES

- **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 17:** CDC is [seeking nominations](#) for the Advisory Committee to the Director (ACD) Health Equity Workgroup (HEW). Nominations are due March 17. [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 9:** The NIH [released](#) a notice of proposed rulemaking to update the NIH Loan Repayment Programs (LRP) to reflect changes made by the 21st Century Cures Act. [Details.](#)
- **May 24:** The FDA [issued](#) a proposed rule to amend the device CGMP requirements. [Details.](#)
- **June 7:** The FDA [issued](#) a request for comments on changes to the agency's previously proposed quality metrics (QM) reporting program. [Details.](#)

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