# <u>This Week in Health Policy</u>, <u>Congressional Lookback</u>, <u>Regulatory Lookback</u>, <u>Comment & Application</u> Deadlines

# Wynne Health Group Weekly



#### FRAMING THE WEEK

Without an agreement on a fiscal year (FY) 2022 spending, and with the February 18 deadline of the <u>second continuing resolution</u> (CR) approaching, top appropriators are considering a third CR with a March 11 expiration. The protracted bipartisan talks over topline spending numbers have stalled the finalization of all 12 appropriations bills. The House is expected to vote on a clean CR (with no policy riders) this week before adjourning for a two-week recess, and the Senate would take it up next week.

Still, we are optimistic that with additional time for negotiations Congress will eventually reach a spending deal for FY 2022 (i.e., no full-year continuing resolution). A major incentive for collaboration and cooperation is the return of earmarks (up to one percent of discretionary spending, which amounts to billions) and their positive impact in an election year for both parties. We imagine that appropriations leaders who are retiring (including Senate Appropriations Chairman Patrick Leahy (D-VT) and Ranking Member Richard Shelby (R-AL), as well as Labor-HHS Subcommittee Ranking Member Roy Blunt (R-MO)), are highly motivated to pass an FY 2022 omnibus spending package with millions in earmarks for their constituents. Committee staff have made progress on working through conference items, although they are stifled somewhat by not knowing their final subcommittee allocation levels.

Whether COVID-19 supplemental funding will be attached to the FY 2022 appropriations omnibus is uncertain, especially since the White House has not yet appeared to have made a formal request for additional funding. Any supplemental funding would be relatively small and narrow in scope, given current pushback from Republicans to provide additional federal resources and the need for 60 votes in the Senate.

As for other legislative priorities, congressional committee will hold hearings this week on mental health, the health care workforce shortage, and the Advanced Research Projects Agency for Health (ARPA-H).

#### Mental Health

Tomorrow, the Senate Finance Committee (SFC) will hold its first <a href="hearing">hearing</a> on youth mental health with Surgeon General Dr. Vivek Murthy. A second hearing featuring policy experts and providers will be convened in several weeks. In December, the Surgeon issued an <a href="advisory">advisory</a> outlining recommendations to improve youth mental health, including federal actions that can be taken. Chairman Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID) are expected to provide an update on their <a href="bipartisan legislation">bipartisan legislation</a> in the works since last September. The duo seeks to enhance behavioral health care in the following areas: (1) strengthening the workforce; (2) increasing integration, coordination, and access to care; (3) ensuring parity between behavioral and physical health care; (4) expanding telehealth; and (5) improving access for children and young people. Addressing youth mental health is among the top legislative priorities discussed by the Senate Committee on Health, Education, Labor and Pensions (HELP) last week (WHG summary).

## Health Care Workforce

On Thursday, the Senate HELP Subcommittee on Employment and Workplace Safety will convene a hearing examining the health care workforce shortage. Subcommittee members will hear policy recommendations from witnesses, including those representing nurse practitioners and medical assistants, about ways to improve recruitment, retention, and diversity. The PREVENT Pandemics Act discussion draft unveiled by Senate HELP Committee Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) does not provide federal resources to grow the health care workforce, and is instead focused on "revitalizing the public health workforce." The hearing could shed light on whether Sen. Murray and others are interested in incorporating provisions bolstering the health care workforce in the pandemic preparedness legislation (WHG summary).

#### ARPA-H

On Tuesday, the House Energy and Commerce Subcommittee on Health will hold a <a href="hearing">hearing</a> on <a href="hearing">ARPA-H</a>, which would be critical to the success of President Biden's relaunched <a href="Cancer Moonshot">Cancer Moonshot</a>. The Cancer Moonshot aims to reduce the cancer death rate by at least 50 percent over the next 25 years and improve the experience of living with and surviving cancer. Multiple bills have been introduced to establish ARPA-H, and they contain key differences regarding funding level and where ARPA-H would be located. In the <a href="FY 2022 budget">FY 2022 budget</a>, President Biden requested \$6.5 billion to establish ARPA-H within the National Institutes of Health (NIH). See **Table 1** below for a comparison of these different bills.

Table 1. Comparison of Legislation to Establish and Fund ARPA-H

	House	Senate
Authorizations	H.R. 5585, E&C Health Subcommittee Chair Anna Eshoo's ARPA-H Act: \$3 billion for FY 2022; ARPA-H within HHS  H.R. 6000, bipartisan Cures 2.0 Act introduced by Reps. Diana DeGette (D-CO) and Fred Upton (R-MI): \$6.5 billion for FY 2022; ARPA-H within NIH	Sens. Murray and Burr are considering including provisions authorizing ARPA-H in their bipartisan PREVENT Pandemics Act. Whether their bill would place ARPA-H within NIH or HHS is an open question.
Appropriations	H.R. 4502, House-passed FY 2022 appropriations measures: \$3 billion through September 30, 2024	S. 3062, Sen. Murray's Labor, HHS, Education FY 2022 appropriations bill: \$2.4 billion through September 30, 2024

# THIS WEEK IN HEALTH POLICY

#### Mon. (2/7)

- 11:30am NIH Meeting: Human Genome The National Institutes of Health (NIH) National Human Genome Research Institute holds a meeting of the National Advisory Council for Human Genome Research to hear presentations. Details.
- **2:00pm BPC Discussion: Child Nutrition Programs** The Bipartisan Policy Center (BPC) holds a discussion titled, "Strengthening the Child Nutrition Programs." Details.
- 2:00pm HHS Meeting: HIV/AIDS The Department of Health and Human Services (HHS)
   Office of Infectious Disease and HIV/AIDS Policy holds a discussion titled, "A Conversation
   Commemorating National Black HIV/AIDS Awareness Day." Details.

## Tue. (2/8)

- 10:00am Hearing: Youth Mental Health The Senate Finance Committee holds a hearing titled, "Protecting Youth Mental Health: Part I An Advisory and Call to Action." <u>Details</u>.
- 10:00am Hearing: COVID-19 The Senate Committee on Health, Education, Labor & Pensions (HELP) holds a hearing titled, "Lessons Learned from COVID-19: Highlighting Innovations, Maximizing Inclusive Practices and Overcoming Barriers to Employment for People with Disabilities." <u>Details</u>.
- 10:30am Hearing: ARPA-H The House Committee on Energy & Commerce Subcommittee on Health holds a hearing titled, "ARPA-H: The Next Frontier of Biomedical Research." 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. <a href="Details.">Details</a>.
- 12:45 NIH Meeting: Drug Abuse The NIH National Institute on Drug Abuse holds a meeting
  of the National Advisory Council on Drug Abuse to hear presentations and other business of the
  council. Details.
- 2:00pm NQF Meeting: EHR The National Quality Forum (NQF) holds a meeting of the Electronic Health Record (EHR) Care Coordination Committee to discuss how to leverage EHRsourced measures to improve care coordination. <u>Details</u>.

# Wed. (2/9)

- 12:15pm FDA Town Hall: COVID-19 Tests The Food and Drug Administration (FDA) holds a virtual town hall on COVID-19 test development and validation. Details.
- 2:00pm CMMI Listening Session: Beneficiary Perspectives The Centers for Medicare and Medicaid Services (CMS) Innovation Center (CMMI) holds a listening session to discuss ways to incorporate beneficiary perspectives into model testing, implementation, and evaluation. Details.

## Thurs. (2/10)

- 9:30am Hearing: Medicare and Medicaid Experience The Senate Special Committee on Aging holds a hearing titled, "Improving Care Experiences for People with Both Medicare and Medicaid." Details.
- **10:00am Hearing: Health Care Workforce** The Senate HELP Subcommittee on Employment and Workplace Safety holds a hearing titled, "Recruiting, Revitalizing and Diversifying: Examining the Health Care Workforce Shortage." Details.
- 10:00am HITAC Meeting: e-Prior Authorization The Health Information Technology Advisory Committee holds a meeting to discuss the electronic prior authorization request for information. Details.
- 10:00am FDA Meeting: Oncologic Drugs The Food and Drug Administration (FDA) holds a
  meeting of the Oncologic Drugs Advisory committee to provide recommendations to the FDA on
  regulatory issues. Details.
- 11:00am CDC Meeting: Health Statistics The Centers for Disease Control and Prevention (CDC) holds a meeting of the Board of Scientific Counselors of the National Center for Health Statistics to discuss program updates. <a href="Details">Details</a>.
- 12:45 NIH Meeting: Alcohol Abuse The NIH National Institute on Alcohol Abuse and Alcoholism holds a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism to hear program updates. Details.

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

- February 10-February 11 10:00am HRSA Meeting: Heritable Disorders The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Heritable Disorders in Newborns and Children to discuss newborn screening for Mucopolysaccharidosis Type II (MPS II). Details.
- February 10-February 11 1:00pm HHS Meeting: Vaccines The Department of Health and Human Services (HHS) National Vaccine Advisory Committee holds a meeting to discuss issues and policies related to vaccines. Details.

#### **FEATURED WHG ANALYSIS**

- WHG Issue Brief on Health Equity Implications of Potential Telehealth Reform Under Medicare – In the Policy Hub Insight Bank here.
- WHG Side-by-Side of Live Drug Pricing Proposals Under Consideration for Reconciliation In the Policy Hub Insight Bank here.
- WHG Side-by-Side of Medicaid Expansion Gap Bills In the Policy Hub Insight Bank here.
- WHG Side-by-Side of Health Technology Assessment Models In the Policy Hub Insight Bank here.
- WHG Updated 2021 Legislative and Regulatory Outlook In the Policy Hub Insight Bank here.
- WHG Chart Key Federal Public Option Bills in the 117<sup>th</sup> Congress; Side-by-Side Comparison – In the Policy Hub Insight Bank <u>here</u>.

#### **CONGRESSIONAL LOOKBACK**

## Thurs. (2/3)

• The E&C Subcommittee on Health <u>convened</u> a hearing on the reauthorization of three FDA user fee programs. Details.

## Wed. (2/2)

 The SFC <u>convened</u> a hearing to examine the Hospital Insurance (HI) trust fund and the future of Medicare financing. <u>Details</u>.

#### Tues. (2/1)

• The Senate HELP Committee convened a <a href="hearing">hearing</a> to discuss priorities and proposals for bipartisan legislation addressing mental health and substance use disorders (SUD). Details.

## **REGULATORY LOOKBACK**

#### Fri. (2/4)

- ASPE <u>published</u> a report on sociodemographic factors of parental hesitancy to vaccinate children. Details.
- The FDA issued <u>final guidance on population pharmacokinetics</u> and <u>draft guidance on the assessment of pressor effects of drugs</u>. <u>Details</u>.
- ASPE published reports containing findings from <u>research</u> to understand how states are addressing FASD, as well as <u>reports</u> reviewing care delivery approaches for integrating SUD and OB/GYN care. <u>Details</u>.

# Thurs. (2/3)

- The ONC <u>hosted</u> virtual office hours to talk about information sharing and the e-prior authorization RFIs. Details.
- **HHS** <u>released</u> an RFI regarding a proposed revision to the 2020 PHS Guideline on organ donors and transplant recipients for HIV, HBV, and HCV infection. Comments are due March 6. <u>Details</u>.
- **CMS** <u>announced</u> it is hosting a set of public meetings to discuss alternative coverage pathways for new emerging technologies. <u>Details</u>.
- The FDA <u>issued</u> a proposed rule to establish national standards for the licensing of prescription drug wholesale distributors. Comments are due March 6. Details.

# Wed. (2/2)

 CMS <u>announced</u> the Calendar Year 2023 Advance Notice for Medicare Advantage and Part D. Comments are due March 4. Details.

- ASPE released a report on health coverage changes from 2020-2021. <u>Details</u>.
- ASPE <u>released</u> a report on national survey trends in <u>telehealth</u> use in 2021, including disparities in utilization. Details.

#### Tues. (2/1)

The CDC Advisory Committee to the Director held a <u>meeting</u> to review CDC's work. <u>Details</u>.

# Mon. (1/31)

- The USDA FNS <u>released</u> a notice of funding opportunity for Team Nutrition Training Grants. Applications are due March 14. <u>Details</u>.
- MACPAC published an issue brief on beneficiary preferences for communications. Details.

### **COMMENT & APPLICATION DEADLINES**

- February 10: CMS <u>proposed</u> a NCD to cover FDA approved monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease through coverage with evidence development.

  Details
- February 11: The GAO released a request for nominations for appointments to MedPAC. Details.
- **February 15:** The FDA <u>issued</u> a request for nominations for voting members to serve on the Medical Devices Advisory Committee device panels. <u>Details</u>.
- **February 18:** CMS is seeking <u>nominations</u> for a TEP and Clinician Committee related to the development of a Patient-Reported Outcome Performance Measure (PRO-PM) to assess preventive screenings for cancers. <u>Details</u>.
- **February 22:** The USDA <u>announced</u> \$1.15 billion in grant funding for rural broadband access. Details.
- **February 28:** The CDC <u>announced</u> it is seeking nominations for individuals to serve as members of the Advisory Committee on Breast Cancer in Young Women. <u>Details</u>.
- March 4: CMS <u>announced</u> the Calendar Year 2023 Advance Notice for Medicare Advantage and Part D. <u>Details</u>.
- March 6: The FDA <u>issued</u> a proposed rule to establish national standards for the licensing of prescription drug wholesale distributors. <u>Details</u>.
- March 6: HHS <u>released</u> an RFI regarding a proposed revision to the 2020 PHS Guideline on organ donors and transplant recipients for HIV, HBV, and HCV infection. <u>Details</u>.
- March 7: CMS <u>released</u> the Contract Year (CY) 2023 Policy and Technical Changes to Medicare Advantage (MA) and Part D proposed rule. <u>Details</u>.
- March 10: The ACL released two Innovations in Nutrition Programs and Services funding
  opportunities (<u>here</u> and <u>here</u>) to support research and programs improving nutrition services
  programs for aging adults. <u>Details</u>.
- **March 11:** The FDA <u>issued</u> draft guidance on notifying the agency of a permanent discontinuance or interruption in manufacturing of a device. <u>Details</u>.
- March 14: The FDA <u>issued</u> a request for nominations for voting and nonvoting consumer representatives to serve on advisory committees and panels. <u>Details</u>.
- March 14: The USDA FNS <u>released</u> a notice of funding opportunity for Team Nutrition Training Grants. Details
- March 15: AHRQ <u>released</u> a solicitation for nominations for members of the U.S. Preventive Services Task Force (USPSTF). <u>Details</u>.
- March 18: HRSA <u>released</u> a notice of funding opportunity (NOFO) for the Rural Public Health Workforce Training Network (RPHWTN) Program. <u>Details</u>.
- March 23: The ONC <u>issued</u> an RFI seeking stakeholder input on whether to adopt additional standards, implementation specifications, and certification criteria regarding electronic prior authorization. <u>Details</u>.
- April 19: HHS <u>announced</u> the availability of \$13 million to support increased access to behavioral health care services, including treatment for substance use disorder, in rural communities. <u>Details</u>.

• April 22: The NIH <u>announced</u> a \$1 million prize competition for innovative diagnostics technologies to help improve maternal health. <u>Details</u>.

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