# This Week in Health Policy, Congressional Lookback, Regulatory Lookback, Comment & Application Deadlines

# Wynne Health Group Weekly



# FRAMING THE WEEK

# Senate Votes

A third continuing resolution (CR) appears to be the charm for fiscal year (FY) 2022 appropriations. On the heels of an <u>agreed-to</u> "bipartisan appropriations framework," the Senate is expected to pass the House-approved (272-162) <u>stopgap funding extension</u> before the <u>current CR</u> expires on February 18. Lawmakers will then have until March 11 to negotiate and finalize all 12 appropriations bills.

The FY 2022 omnibus appropriations bill could serve as a legislative vehicle for health policy priorities – possibly mental health provisions with strong bipartisan support that lawmakers are prepared to pass (as opposed to advancing them in the forthcoming bipartisan Senate mental health bills). Whether COVID-19 supplemental funding will be attached to the FY 2022 omnibus appropriations bill remains an open question. The White House appears to not yet have made a formal request for additional funding.

The Senate is also expected to vote on the confirmation of Dr. Robert Califf, President Biden's pick to lead the Food and Drug Administration (FDA). Dr. Califf previously served as FDA Commissioner from 2016-2017, for which he was confirmed by the Senate with broad bipartisan support (89-4). We anticipate that the Senate will confirm Dr. Califf, though likely by a narrower margin. A simple majority is needed to confirm executive branch nominations.

## COVID-19 Public Health Emergency

Early in the Biden Administration, the Department of Health and Human Services (HHS) <u>vowed</u> to give states a 60-day notice prior to the end of the <u>COVID-19 public health emergency</u> (PHE) – i.e., terminating the PHE or allowing the PHE to expire. February 15 marks 60 days until the end of the PHE on April 16. If HHS does not give such notice tomorrow, we can expect HHS Secretary Xavier Becerra to extend the PHE another 90 days to July 15. If the PHE is renewed, the next 60-day mark would be May 16.

The end of the PHE will initiate the winding down of key health policy measures:

- Medicaid: States will resume Medicaid eligibility redeterminations at the end of the PHE. As a condition of receiving enhanced federal funding for Medicaid 6.2 percentage point bump to the state's Federal Medical Assistance Percentage (FMAP) states must keep individuals enrolled in Medicaid throughout the PHE. States will have up to 12 months after the month in which the PHE ends to complete verifications, redeterminations, and renewals. However, the enhanced FMAP for the continuous enrollment requirement, as well as other maintenance of eligibility requirements, would expire at the end of the quarter in which the PHE ends (i.e., before the 12 months are up).
- Telehealth: The COVID-19 telehealth flexibilities under Medicare will cease at the end of the PHE
  absent congressional action (through the Administration may allow any flexibilities to persist for up
  to an additional 60 days following the end of the PHE). While there is bipartisan interest to act on
  telehealth reform, Congress still appears to be divided on the extent to which it will extend these

flexibilities. The timing of reform is also uncertain and may depend on the Administration's timing for ending the PHE. Additional details are available in WHG's latest roundup of telehealth policy.

Under the scenario that the PHE expires on April 16, key dates below:

- February 15, 2022: 60-day mark until the end of the current PHE
- April 16, 2022: End of current PHE
- **June 15, 2022:** End of certain telehealth flexibilities, assuming the Administration uses the additional 60-day period
- June 30, 2022: Expiration of 6.2 percent FMAP bump for Medicaid for continuous enrollment
- April 16, 2023: Deadline for state Medicaid programs to complete verifications, redeterminations, and renewals

## Mental Health

Lawmakers will continue to ramp up their legislative efforts on mental health with two additional hearings this week.

Tomorrow, the Senate Finance Committee's (SFC) second <u>hearing</u> on youth mental health will feature a panel of providers and policy experts. "The goal is to produce a bipartisan bill this summer that brings all that work together," said Chairman Ron Wyden (D-OR) at the first hearing (<u>WHG summary</u>). So far, areas of most consensus appear to be strengthening workforce, expanding telehealth, and improving access to mental health care for children through school-based programs.

Opening remarks from Ranking Member Mike Crapo (R-ID) at the first hearing signal where we could see disagreements arise between Democrats and Republicans over the mental health bill. Ranking Member Crapo's call for "fiscal integrity, fully paying for any and all provisions we look to enact," and warning that "unrestrained government spending risks pushing inflation even higher" will likely complicate consensus building between the two parties. These sticking points could ultimately limit the size and scope of the mental health bill.

On Thursday, the House Energy and Commerce Subcommittee on Oversight and Investigations will hold a <u>hearing</u> focused on "mental health challenges facing Americans, particularly those affecting children and young people, people of color, and LGBTQI+ individuals."

# Regulatory Update

The fiscal year (FY) 2023 Medicare payment update proposed rules have begun to arrive at the Office of Management and Budget (OMB) for review. Specifically, OMB is reviewing the FY 2023 Inpatient Prospective Payment System proposed rule as well as the 2023 Hospice Wage Index proposed rule. These, as well as the other FY 2023 Medicare payment update proposed rules, are expected for release later this April.

# THIS WEEK IN HEALTH POLICY

## Tue. (2/15)

- 8:30am FDA Meeting: Vaccines The Food and Drug Administration (FDA) holds a meeting
  of the Vaccines and Related Biological Products Advisory Committee to discuss a request to
  amend the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 vaccine for
  administration to children six months through four years of age. <u>Details</u>.
- 10:00am Hearing: Youth Mental Health The Senate Finance Committee holds a hearing titled, "Protecting Youth Mental Health: Part II Identifying and Addressing Barriers to Care." 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.
- **2:00pm Hearing: Immigrant Physicians** The House Committee on the Judiciary Subcommittee on Immigration and Citizenship holds a hearing titled, "Is There a Doctor in the House? The Role of Immigrant Physicians in the US Healthcare System." Details.
- **2:00pm NQF Meeting: Surgery** The National Quality Forum (NQF) holds a meeting of the Surgery Committee to evaluate surgery-related measures. <u>Details</u>.

# Wed. (2/16)

- 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. <a href="Details">Details</a>.
- 10:00am NQF Meeting: Patient Safety NQF holds a meeting of the Patient Safety Standing Committee to evaluate measures related to patient safety. <u>Details</u>

# Thurs. (2/17)

- **10:00am ONC Meeting: Health IT** The Office of the National Coordinator for Health Information Technology (ONC) convenes a meeting of the Health IT Advisory Committee. <u>Details</u>.
- 10:15am Hearing: Biosecurity The Senate Committee on Homeland Security and Government Affairs holds a hearing titled, "Addressing the Gaps in America's Biosecurity Preparedness." Details.
- 11:00am ASPR Meeting: Children The Assistant Secretary for Preparedness and Response (ASPR) holds the inaugural meeting of the National Advisory Committee on Children to discuss challenges, opportunities, and priorities for public health and medical preparedness specific to the needs of children and their families. Details.
- 11:00am BPC Discussion: PACE The Bipartisan Policy Center (BPC) holds a discussion titled, "Kickoff Event: Improving Access to Programs of All-Inclusive Care for the Elderly (PACE). Details.
- 11:30am Hearing: Mental Health The House Energy & Commerce Committee Oversight and Investigations Subcommittee holds a hearing titled, "Americans in Need: Responding to the National Mental Health Crisis." Details.
- **1:00pm BPC Discussion: Housing** BPC holds a discussion titled, "Getting Serious About Housing Supply: Aligning Housing Subsidies." Details.
- 3:00pm CMS Listening Session: Transitional Coverage for Emerging Technologies The Centers for Medicare & Medicaid Services (CMS) holds a listening session to help inform CMS' development of an alternative coverage pathway to provide transitional coverage for emerging technologies. Details.

## Fri. (2/18)

10:00am – NQF Meeting: Geriatrics and Palliative Care – The NQF Geriatrics and Palliative
Care Standing Committee holds a meeting to evaluate measures related to geriatrics and
palliative care. <u>Details</u>.

# **Additional Multi-Day Events**

• February 17-February 18 – HRSA Meeting: Training, Primary Care, and Dentistry – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Training and Primary Care Medicine and Dentistry to discuss to provide recommendations on policies and program development concerning training programs for primary care and dentistry. 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 here.

## **CONGRESSIONAL LOOKBACK**

# Wed. (2/9)

• **Sens. Sanders and Klobuchar** <u>introduced</u> new legislation that would tie Medicare Part B and Part D drug prices to those prices paid by the Department of Veterans Affairs. <u>Details</u>.

## Tues. (2/8)

- The SFC convened a hearing to discuss policy solutions to address the nation's youth mental health crisis. Details.
- The E&C Subcommittee on Health <u>convened</u> a hearing to examine the proposed Advanced Research Projects Agency for Health (ARPA-H). <u>Details</u>.

#### REGULATORY LOOKBACK

## Fri. (2/11)

- CMS published a report to Congress on Medicaid managed care regulation. Details.
- **ASPR** <u>issued</u> a request for comments to help inform the development of the 2023-2026 National Health Security Strategy. Comments are due March 11. Details.
- HRSA <u>announced</u> the winners of a national competition to increase pediatric vaccination rates and well-child visits. <u>Details</u>.
- CMMI <u>hosted</u> a listening session to discuss its strategic objective of better engaging beneficiaries in model development and implementation. <u>Details</u>.
- MACPAC <u>published</u> an issue brief comparing beneficiary experiences in accessing medical care by race and ethnicity. <u>Details</u>.

# Thurs. (2/10)

- The CDC <u>announced</u> it is requesting comments on the proposed clinical practice guideline, "CDC Clinical Practice Guideline for Prescribing Opioids." Comments are due April 11. <u>Details</u>.
- The NIH <u>issued</u> 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.
- **HITAC** <u>held</u> a meeting of the Electronic Prior Authorization Request for Information (RFI) Task Force 2022. Details.

#### Wed. (2/9)

- **The FDA** issued draft guidance on the development of non-opioid analgesics for acute pain. Details.
- **HRSA** <u>announced</u> the availability of \$66.5 million in ARP funding to support community-based efforts to increase COVID-19 vaccine confidence and vaccination rate. <u>Details</u>.

# Tues. (2/8)

 CMS <u>released</u> a report to Congress on state challenges and best practices implementing PRMP requirements pursuant to the SUPPORT Act. <u>Details</u>.

- The GAO <u>released</u> a CARES Act-mandated report on the federal effort to provide vaccines to racial and ethnic groups. <u>Details</u>
- **CMS** <u>released</u> a high-level overview of states' planned activities under Section 9817 of the American Rescue Plan Act of 2021. Details.
- **CMS** released two Medicaid Drug Rebate Program (MDRP) Notices for <u>participating drug</u> <u>manufacturers</u> and for <u>state technical contacts</u>. <u>Details</u>.

## Mon. (2/7)

- **HRSA** <u>announced</u> the availability of \$19.2 million in ARP funding to support primary care and dental resident training in rural and underserved communities. Applications are due March 31. Details.
- HRSA released a NOFO to support long term improvements in early developmental health through the Transforming Pediatrics for Early Childhood program. Applications are due April 19. Details.
- FNS <u>issued</u> a final rule with request for comments detailing transitional standards for milk, whole grains, and sodium for the NSLP, SBP, SMP, and CACFP. Comments are due March 24. Details.
- SAMHSA <u>released</u> a NOFO that will make \$10 million available for the Services Grant Program for Residential Treatment for Pregnant and Postpartum Women. Applications are due April 4.
   Details.
- The BPC <u>hosted</u> a virtual discussion with members of the Food and Nutrition Security Task Force to discuss recommendations for strengthening child nutrition programs. <u>Details</u>.

## **COMMENT & APPLICATION DEADLINES**

- **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. Details.
- **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 11: ASPR <u>issued</u> a request for comments to help inform the development of the 2023-2026 National Health Security Strategy. <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. <u>Details</u>
- 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. Details.
- 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>.
- March 31: HRSA <u>announced</u> the availability of \$19.2 million in ARP funding to support primary care and dental resident training in rural and underserved communities. <u>Details</u>.
- **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 <u>announced</u> it is requesting comments on the proposed clinical practice guideline, "CDC Clinical Practice Guideline for Prescribing Opioids." <u>Details</u>.
- April 12: The NIH <u>issued</u> 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 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. Details.
- 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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