

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

With the COVID-19 public health emergency (PHE) declaration currently set to end on July 15, today is the deadline for the Department of Health and Human Services (HHS) to provide states at least 60 days' notice that the PHE will expire or terminate. On the congressional front, several committees will convene hearings on various topics, including mental health, fiscal year 2023 appropriations, abortion, and cybersecurity.

As discussed in our latest [WynneSights blog](#), the general consensus is that it seems more likely that the PHE will not be renewed. There has been some discussion about continuing the PHE to maintain temporary flexibilities another 90 days given the increase in cases due to Omicron and its subvariants, as well as the administrative ease of continuing COVID-19 flexibilities through the fiscal year (a renewal of the PHE declaration would extend it to October 13, 2022). However, the Biden administration is likely interested in moving on from the PHE ahead of the midterm elections in November so it can focus voters on what has been accomplished to date and its vision for the future. To aid in a post-PHE transition, WHG has compiled a chart that delineates a comprehensive set of temporary flexibilities pursuant to the COVID-19 PHE, available [here](#).

This week, the House Energy and Commerce Committee is expected to mark-up a slate of six bipartisan bills related to Food and Drug Administration (FDA) user fees, mental health, cardiovascular health, and health research. All of the bills were favorably reported out of the Health Subcommittee last week ([WHG Summary](#)). Committee leaders are pushing to pass the Food and Drug Amendments of 2022 ([H.R. 7667](#)) coupled with the Restoring Hope for Mental Health and Well-Being Act of 2022 ([H.R. 7666](#)) by July. The FDA user fee amendments will need to be passed by the end of the end of the fiscal year on September 30, 2022.

- Food and Drug Amendments of 2022 ([H.R. 7667](#)) ([WHG Summary](#))
- Restoring Hope for Mental Health and Well-Being Act of 2022 ([H.R. 7666](#)) ([WHG Summary](#))
- Keeping Incarceration Discharges Streamlined for Children and Accommodating Resources in Education Act or "KIDS CARES Act" ([H.R. 7233](#))
- Gabriella Miller Kids First Research Act 2.0 ([H.R. 623](#))
- South Asian Heart Health Awareness Act of 2021 ([H.R. 3771](#))
- Advanced Research Projects Agency-Health Act or the "ARPA-H Act" ([H.R. 5585](#))

Tomorrow, the Senate Appropriations Committee hearings will continue with [directors from the National Institute of Health](#) testifying on the FY 2023 budget proposal. On Thursday, FDA Commissioner Robert Califf will field questions on the FY 2023 budget request for [FDA](#) before the House Appropriations Committee.

On Wednesday, the House Judiciary Committee will hold a [hearing](#) on abortion care access, which has become a top priority for congressional Democrats ahead of the anticipated Supreme Court decision overturning *Roe v. Wade*. Congress is currently unable to codify abortion rights given its political makeup, as demonstrated by the failed Senate vote (49-51) on abortion rights legislation last week. The House hearing is likely intended to provide fodder for the midterm elections.

Also on Wednesday, the Senate Committee on Health, Education, Labor and Pensions (HELP) will convene a [hearing](#) on cybersecurity in the health and education sectors. The PREVENT Pandemics Act ([S. 3799](#)), introduced by Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) includes two provisions mentioning cybersecurity: (1) requires the HHS Secretary to include privacy and cybersecurity protections in interagency data use agreements with HHS for public health emergencies; and (2) requires the HHS Secretary to include recommendations for protection of clinical trial participants data against cybersecurity threats in guidance clarifying the use of digital health technologies in clinical trials.

## THIS WEEK IN HEALTH POLICY

### Mon. (5/16)

- **1:30pm – NQF Meeting: PRO/PM** – The National Quality Forum (NQF) holds a Technical Expert Panel titled, “Building a Roadmap from Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures.” [Details.](#)

### Tue. (5/17)

- **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.](#)
- **12:00pm – NIH Meeting: Biomedical Imaging** – The National Institutes of Health (NIH) National Institute of Biomedical Imaging and Bioengineering holds a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering to hear the Director’s report. [Details.](#)

### Wed. (5/18)

- **10:00am – Hearing: Cybersecurity** – The Senate Committee on Health, Education, Labor and Pensions holds a hearing titled, “Cybersecurity in the Health and Education Sectors.” [Details.](#)
- **10:00am – Hearing: Abortion** – The House Judiciary Committee holds a hearing titled, “Revoking Your Rights: The Ongoing Crisis in Abortion Care Access.” [Details.](#)
- **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 to develop and submit recommendations to the National Coordinator. [Details.](#)

### Thurs. (5/19)

**10:00am – Hearing: FDA FY 2023 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 (FDA).” [Details.](#)

## FEATURED WHG ANALYSIS

- **\*NEW\* WHG Round-up of Recent Actions Related to the PHE Declaration** – In the Policy Hub Insight Bank [here.](#)
- **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.](#)

## CONGRESSIONAL LOOKBACK

### Tues. (5/10)

- **Sens. Cassidy and Murphy** [introduced](#) legislation to reauthorize federal mental health and substance use disorder programs. [Details](#).

## REGULATORY LOOKBACK

### Fri. (5/13)

- **ASPE** [released](#) the fifth annual report from the Interagency Task Force for Combating Antibiotic-Resistant Bacteria. [Details](#).
- **The GAO** [released](#) a report on the Food and Drug Administration's (FDA) oversight of COVID-19 tests. [Details](#).

### Thurs. (5/12)

- **HHS OIG** released a [report](#) finding that one quarter of Medicare patients experience adverse events in hospitals. [Details](#).
- **CMS** [issued](#) a final rule that authorizes states to make payment to third parties to facilitate access to employee benefits. [Details](#).

### Weds. (5/11)

- **The FDA** [announced](#) the launch of the Accelerating Rare Disease Cures (ARC) Program. [Details](#).

### Tues. (5/10)

- **The HCP LAN** [convened](#) its virtual spring event on equity in alternative payment models and social risk adjustment. [Details](#)

### Mon. (5/9)

- **CMS** [approved](#) a Texas SPA allowing the option to receive [telehealth](#) services using an audio-only platform. [Details](#).
- **HRSA** launched the new [Maternal Mental Health Hotline](#). [Details](#).

## COMMENT & APPLICATION DEADLINES

- **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.](#)
- **June 24:** HHS is [seeking nominations](#) for members on the [National Vaccine Advisory Committee](#). Nominations are due June 24. [Details.](#)
- **June 24:** The CDC released a solicitation of nominations for appointment of individuals to serve as members of the Community Preventive Services Task Force (CPSTF). [Details.](#)
- **June 27:** FNS [announced](#) \$5 million in grant funding for Process and Technology Improvement Grants in SNAP. [Details.](#)
- **June 27:** SAMHSA [announced](#) \$55 million in grant funding for Tribal Opioid Response Grants. [Details.](#)
- **July 3:** The FDA [released](#) proposed rules to prohibit menthol in cigarettes and characterizing flavors in cigars. [Details.](#)
- **July 5:** AHRQ [released](#) a notice of request for nominations for members of the National Advisory Council for Healthcare Research and Quality. [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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