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

Wynne Health Group Weekly



FRAMING THE WEEK

This week, both chambers are working through their priority to-do list before leaving for the summer recess. The House adjourns on August 1, and the Senate adjourns a week later. Beginning tomorrow, the House will vote on a <u>slew of legislation</u>, including bills on telehealth flexibilities, long COVID research (<u>H.R. 7180</u>), and heart health initiatives in the South Asian community (H.R. 3771).

Meanwhile, Senate Democrats are awaiting guidance from the Senate Parliamentarian on whether their slimmed down budget reconciliation package, expected to only include drug pricing provisions (<u>WHG summary</u>) and a two-year extension to ACA premium subsidy enhancements, complies with the Byrd Rule. Senate Majority Leader Chuck Schumer (D-NY) is pushing to hold a final vote on the package next week.

In addition, Senate Appropriations Committee Chairman Patrick Leahy (D-VT) <u>plans</u> to release Senate Democrats' long-awaited 2023 appropriations bills this week, which we view as a starting point for bipartisan negotiations on FY 2023 government funding later this year. Due in part to time constraints and political factors, we anticipate Congress will pass a continuing resolution for FY 2023, level funding the government until at least after the midterm elections and possibly through early December.

Telehealth

The House plans to vote on a <u>modified version</u> of the **Advancing Telehealth Beyond COVID-19 Act of 2021 (H.R. 4040)**, introduced by Reps. Liz Cheney (R-WY) and Debbie Dingell (D-MI), that would further extend several temporary Medicare telehealth flexibilities. The bill would provide a clear end date for flexibilities. Currently, the end date is contingent upon the expiration of the COVID-19 Public Health Emergency (PHE), which was last renewed through October 13, 2022.

The Cheney-Dingell bill addresses the following flexibilities:

- Eliminating the statutory geographic and originating site requirements for all telehealth services;
- Expanding the list of practitioners eligible to furnish telehealth services;
- Extending telehealth services for federally qualified health centers and rural health clinics;
- Delaying the in-person requirements under Medicare for mental health services furnished through telehealth;
- Allowing the furnishing of audio-only telehealth services; and
- Allowing a hospice physician or nurse practitioner to continue conducting face-to-face encounters required for recertification,

In the FY 2022 omnibus appropriations package (P.L. 117-103) enacted in March, Congress permitted these flexibilities to continue for a 151-day period following the end of the COVID PHE. The modified Cheney-Dingell bill would allow the flexibilities through December 31, 2024. The introduced version of their bill would have made these flexibilities permanent.

	Current Federal Law	Modified Cheney-Dingell Bill
Extension Policy	Permits flexibilities for a 151-day	Extends flexibilities through
	period following the end of the PHE	December 31, 2024
Effective Expiration Date	March 13, 2023	December 31, 2024

Medicaid

On Wednesday, the Medicaid and CHIP Payment and Access Commission (MACPAC) will convene a <u>special meeting</u> to discuss the challenges that state Medicaid programs may face when COVID-19 PHE ends and Medicaid eligibility redeterminations resume.

Earlier this month, Department of Health and Human Services (HHS) Secretary Xavier Becerra officially renewed the COVID-19 PHE, extending it through October 13, 2022. The deadline for HHS to give states a 60-day notice that the PHE will end is August 14, 2022. States are permitted to begin the unwinding period up to two months prior to the end of the month in which the PHE ends, according to guidance from the Centers for Medicare and Medicaid Services (CMS). This means that the 60-day notice from HHS could mark the start of redeterminations.

THIS WEEK IN HEALTH POLICY

Mon. (7/25)

• 9:30am-4:00pm ASPE Meeting: Alzheimer's – The Office of the Assistant Secretary for Planning and Evaluation (ASPE) holds a meeting of the Advisory Council on Alzheimer's Research, Care, and Services to hear updates from federal workgroups. Details.

Tue. (7/26)

- 10:00am Hearing: Fentanyl The Senate Health, Education, Labor, and Pensions (HELP)
 Committee holds a hearing titled, "Fighting Fentanyl: The Federal Response to a Growing Crisis."

 Details.
- 10:30am ONC Meeting: Adopted Standards The Office of the National Coordinator of Health Information Technology (ONC) holds a meeting of the Health Information Technology Advisory Committee (HITAC) Adopted Standards Taskforce to make recommendations on ONCadopted standards and implementation specifications. <u>Details</u>.

Wed. (7/27)

 1:30pm – MACPAC Meeting: End of the PHE – The Medicaid and CHIP Payment and Access Commission (MACPAC) holds a special meeting to discuss Medicaid redetermination after the end of the COVID-19 public health emergency (PHE). Details.

Thurs. (7/28)

- 12:00pm ACL Meeting; Intellectual Disabilities The Administration for Community Living (ACL) holds a meeting of the President's Committee for People with Intellectual Disabilities to identify topics for the Report to the President. Details.
- **2:00pm ONC Meeting: Annual Report** HITAC holds a meeting of the Annual Report Workgroup to develop recommendations for improving health IT. <u>Details</u>.

FEATURED WHG ANALYSIS

- WHG Regulatory Outlook Summer 2022 Update In the Policy Hub Insight Bank here
- WHG Issue Brief on the Nutrition Policy Landscape In the Policy Hub Insight Bank here.
- WHG A Suite Of Potential Executive Actions For A Post-Roe World In the Policy Hub Insight Bank here.
- 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.

CONGRESSIONAL LOOKBACK

Wed. (7/20)

The legislative text of the Healthy Meals, Health Kids Act of 2022 was released. <u>Details</u>.

Tues. (7/19)

• The E&C Subcommittee on Oversight and Investigations <u>held</u> a hearing on the consequences of the Supreme Court's decision in *Dobbs vs. Jackson Women's Health Organization* that overturned *Roe vs. Wade.* <u>Details</u>.

REGULATORY LOOKBACK

Fri. (7/22)

• **CMS** <u>released</u> the first-ever quality measure set for Medicaid home and community-based services. Details.

Thurs. (7/21)

- The CDC is <u>seeking nominations</u> for the Clinical Laboratory Improvement Advisory Committee (CLIAC). Nominations are due September 30. Details.
- **The CBO** <u>released</u> a letter explaining the effects of making the enhanced premium tax credits provided under the American Rescue Plan permanent. <u>Details</u>.
- CMS <u>announced</u> that \$49 million in grant funding was awarded to organizations working to increase health care coverage for children, and families. <u>Details</u>.

Wed. (7/20)

• The FDA <u>issued</u> draft guidance on the evaluation of therapeutic equivalence. Comments are due September 19. <u>Details</u>.

Mon. (7/18)

- The USDA FNS <u>announced</u> several new actions that the Biden Administration is taking to strengthen access to infant formula in the WIC program. <u>Details</u>.
- **CMS** is seeking <u>nominations</u> for a Technical Expert Panel (TEP) related to the development of a HQRP and HHQRP health equity structural composite measure. Nominations are due August 12. Details.
- **HHS OIG** <u>released</u> an audit of nursing home life safety and emergency preparedness that found issues with noncompliance. <u>Details</u>.

COMMENT & APPLICATION DEADLINES

- **August 1:** The USDA <u>announced</u> a \$20 million cooperative agreement opportunity to improve participation and retention in the WIC program. <u>Details</u>.
- August 1: HHS <u>issued</u> a request for information on ways to strengthen primary care in the U.S. Responses are due August 1. Details.
- August 5: The FDA <u>issued</u> a request for industry organizations to serve as nonvoting representatives on certain panels of the Medical Device Advisory Committee. <u>Details</u>.
- August 12: CMS is seeking <u>nominations</u> for a Technical Expert Panel (TEP) related to the development of a HQRP and HHQRP health equity structural composite measure. <u>Details</u>.
- August 15: 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>.

- August 16: CMS <u>issued</u> the cycle year (CY) 2023 home health prospective payment system and rate update proposed rule. <u>Details</u>.
- **August 23:** The FDA <u>issued</u> draft guidance on considerations for rescinding breakthrough therapy designation (BTD). <u>Details</u>.
- August 27: CMS <u>released</u> its CY 2023 ESRD prospective payment system (PPS) proposed rule.
 Details.
- August 29: CMS <u>issued</u> a proposed rule that would establish conditions of participation (CoPs) for rural emergency hospitals (REHs) and make updates to the CoPs for critical access hospitals (CAHs). Details.
- **August 31:** The FDA <u>announced</u> the extension of the comment period for the draft guidance on risk management plans to mitigate the potential for drug shortages. <u>Details</u>.
- **September 1:** The CDC_<u>seeks</u> nominations for the National Center for Injury Prevention and Control (NCIP) <u>Board of Scientific Counselors (BSC)</u>. <u>Details</u>.
- **September 6:** The CDC <u>released</u> a notice of grant funding to establish and fund regional Tuberculosis (TB) Centers of Excellence (COE). <u>Details</u>.
- September 13: CMS <u>released</u> the CY 2023 Hospital OPPS and ASC Payment System Proposed Rule. Comments are due September 13. <u>Details</u>.
- **September 17:** The CDC <u>issued</u> a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). <u>Details</u>.
- **September 19:** The FDA <u>issued</u> draft guidance on the evaluation of therapeutic equivalence. Comments are due September 19. Details.
- September 29: The FDA <u>issued</u> draft guidance entitled: Patient Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments (COAs). Details.
- **September 30:** The CDC is <u>seeking nominations</u> for the Clinical Laboratory Improvement Advisory Committee (CLIAC). <u>Details</u>.
- **September 30:** CMMI <u>announced</u> a new demonstration model aimed at improving oncology care. Details.
- October 1: The CDC <u>seeks</u> nominations for the CDC/Health Resources & Services
 Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and
 Treatment (CHACHSPT). Details.
- October 26: The FDA <u>issued</u> a proposed rule to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). <u>Details</u>.

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