

Wynne Health Group Weekly



FRAMING THE WEEK

The timing of a Senate vote on a continuing resolution (CR) for fiscal year (FY) 2023, level-funding the federal government through December 16, remains uncertain. Senate Majority Leader Chuck Schumer's (D-NY) deal with Sen. Joe Manchin (D-WV) to include reforms to energy permitting, the process for obtaining federal approval for energy projects (e.g., oil and gas pipelines), has complicated the process. Still, we do not anticipate a government shutdown.

CRs are relatively clean and typically only include provisions with broad bipartisan support. Whether the CR will include the reauthorization of the Food and Drug Administration (FDA) user fee programs, which also expires on September 30, is questionable. The CR may also include additional assistance for Ukraine as well as emergency funding to address the clean drinking water crisis in Jackson, Mississippi. Congress is not expected to provide the Biden Administration with funding [requested](#) for COVID-19 and monkeypox (\$22.4 billion and \$3.9 billion, respectively). Congressional Republicans have shown no appetite for appropriating additional funding, as evidenced at the recent hearing on the monkeypox response ([WHG summary](#)).

FDA User Fees

Congress has until September 30 to reauthorize the Food and Drug Administration (FDA) user fee programs for the next five years. Lawmakers are looking to attach the reauthorization of the user fee programs on to the CR. While many members are pressing for a timely and clean reauthorization of the user fee package, debate continues on which, if any, policy riders to include. Reform of the agency's Accelerated Approval Pathway is a bipartisan provision that could be included in the final package. Other policy riders, such as oversight of diagnostic tests, cosmetics, and dietary supplements, could be included in a year-end omnibus.

If Congress fails to pass reauthorization before September 30, FDA Commissioner Robert Califf has [indicated](#) that carryover funding for the prescription drug user fee program (the program that would run out of funding first) would last approximately 5 weeks into the new fiscal year. At that point, the agency would have to prepare to issue furlough notice to employees funded by the user fees. Notably, the reauthorization of the FDA user fee programs has only been delayed once in the past 25 years.

Regulatory Update

The [proposed rule](#) to fix the "family glitch" [arrived](#) at the Office of Management and Budget (OMB) for review on Thursday. In April, the Treasury Department and Internal Revenue Service (IRS) issued a proposed rule to revise criteria for Affordable Care Act (ACA) premium tax credit (PTC) eligibility in the individual market. In short, the proposed rule would fix the "family glitch," which prevents family members from accessing

PTCs if an employee's self-only coverage meets the affordability threshold. As a result, family members could qualify for a PTC and purchase subsidized individual coverage on the ACA Marketplace for the 2023 coverage period and beyond. The final rule is forecasted for December 2022.

THIS WEEK IN HEALTH POLICY

Tue. (9/20)

- **10:00am – Hearing: Clean Water Act** – The House Committee on Transportation Subcommittee on Water Resources and Environment holds a hearing titled, “The Clean Water Act at Fifty: Highlights and Lessons Learned from a Half Century of Transformative Legislation.” [Details.](#)
- **12:00pm NIH Meeting: Mental Health** – The National Institutes of Health (NIH) National Institute of Mental Health holds a meeting of the National Advisory Mental Health Council to hear the director's report. [Details.](#)
- **1:00pm – CHCS Webinar: Medicaid Managed Care** – The Center for Health Care Strategies (CHCS) holds a webinar titled, “Implementing Tech-Enabled Innovation in Medicaid Managed Care: Opportunities to Advance Health Equity and Quality.” [Details.](#)

Wed. (9/21)

- **10:00am – Hearing: VA EHR Modernization** – The House Committee on Appropriations Subcommittee on Military Construction, Veterans Affairs (VA), and Related Agencies holds a hearing titled, “VA's Electronic Health Record (EHR) Modernization: An Updated on Rollout, Cost, and Schedule.” [Details.](#)
- **10:00am – Hearing: Water Infrastructure** – The House Committee on Homeland Security holds a hearing titled, “Critical Infrastructure Preparedness and Resilience: A Focus on Water.” [Details.](#)
- **10:30am – ONC Meeting: Public Health Data Systems** – ONC holds a meeting of the Public Health Data Systems Task Force 2022 to identify and prioritize policy and technical gaps associated with information systems relevant to public health and identify improvements that can be made. [Details.](#)
- **3:00pm – Hearing: Veterans Access to Care** – The Senate Committee in Veterans' Affairs holds a hearing titled, “Ensuring Veterans' Timely Access to Care in VA and the Community.” [Details.](#)

Thurs. (9/22)

- **12:30pm – HHS Webinar: Decarbonization** – The Department of Health and Human Services (HHS) holds a webinar titled, “Introduction to the Agency for Healthcare Research and Quality's (AHRQ's) Decarbonization Primer.” [Details.](#)
- **2:00pm – DOL Webcast: No Surprises Act** – The Department of Labor holds a webcast to discuss No Surprises Act compliance. [Details.](#)
- **3:00pm – USDA Webinar: SNAP-Ed** – The Department of Agriculture (USDA) Food and Nutrition Service (FNS) holds a webinar on equity considerations for conducting needs assessments in Supplemental Nutrition Assistance Program Education (SNAP-Ed). [Details.](#)

Additional Multi-Day Events

- **September 22-September 23 – 9:00am – FDA Meeting: Oncology** – The Food and Drug Administration (FDA) holds a meeting of the Oncologic Drugs Advisory Committee to discuss new drug applications. [Details.](#)

FEATURED WHG ANALYSIS

- **WHG Roundup of CMS information releases on long-term services and supports and children's health** – In the Policy Hub Insight Bank [here.](#)

- **Blog on President Biden’s Executive Order Protecting Access to Reproductive Health Services** – On the Commonwealth Fund’s To the Point [here](#).
- **WHG Roundup of Recent Telehealth Policy** – In the Policy Hub Insight Bank [here](#).
- **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](#).

CONGRESSIONAL LOOKBACK

Fri. (9/16)

- **MACPAC convened** virtually for Day Two of its September 2022 public meeting and held a sessions on LTSS and integrated care for duals. All WHG session summaries are available on Policy Hub [here](#).

Thurs. (9/15)

- **MACPAC convened** virtually for Day One of its September 2022 public meeting and held sessions on race and ethnicity data collection, unwinding continuous coverage, rate setting, nursing facility payments, DSH, and Alzheimer’s Disease treatments. All WHG session summaries are available on Policy Hub [here](#).
- **The House W&M Committee held** a hearing on preparing America’s health care infrastructure for climate change. [Details](#).
- **The Senate Judiciary Subcommittee on Immigration, Citizenship, and Border Safety held** a hearing entitled, “Flatlining Care: Why Immigrants Are Crucial to Bolstering Out Health Care Workforce.” [Details](#).

Weds. (9/14)

- **The House of Representatives passed** an updated version of the Improving Seniors’ Timely Access to Care Act by voice vote. [Details](#).
- **The Senate HELP Committee convened** a [hearing](#) to discuss the federal government’s response to the monkeypox outbreak. [Details](#).
- **The House E&C Committee favorably reported five bills**, including a bill that would reform Medicare Advantage (MA) prior authorization. [Details](#).

Mon. (9/12)

- **Sens. Bennet (D-CO) and Cornyn (R-TX) released** a white paper detailing the bipartisan pair’s vision for a reformed mental health system in the U.S. [Details](#).

REGULATORY LOOKBACK

Fri. (9/16)

- **The FDA issued** a request for applications from patient advocates interested in participating on the Patient Engagement Collaborative (PEC). Applications are due October 19. [Details](#).

Thurs. (9/15)

- **The Departments of Labor, HHS, and Treasury issued** a RFI to inform future rulemaking for advanced explanation of benefits (AEOB) and good faith estimate (GFE) requirements. Comments are due November 15. [Details](#).
- **CMS released** a Telehealth Trends Report drawing on Medicare FFS claims data from January 1, 2020 to March 31, 2022. [Details](#).
- **The AHRQ issued** a RFI on the current state of comprehensive, longitudinal, person-centered care planning for people with Multiple Chronic Conditions. Submissions are due November 15. [Details](#).
- **The FNS announced** that it will provide \$2 billion in additional funding to food banks and school meal programs to purchase American-grown foods. [Details](#).

Tues. (9/13)

- **SAMHSA** [announced](#) a new \$35 million grant opportunity to further support the 988 Suicide and Crisis Lifeline. Applications are due October 25. [Details](#).
- **The HHS OWH** [invites](#) public and private sector organizations to apply to become a Women's Health Champion. [Details](#).
- **The USPSTF** [released](#) a final recommendation statement concluding that current evidence is insufficient to assess screening for type 2 diabetes in asymptomatic children and adolescents. [Details](#).

Mon. (9/12)

- **CMS** [released](#) a slide deck detailing strategies to support COVID-19 PHE unwinding for states. [Details](#).
- **President Biden** [issued](#) an executive order entitled "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy." [Details](#).
- **The FDA** [issued](#) draft guidance on computer software assurance for production and quality system assurance. Comments are due November 14. [Details](#).
- **The AHRQ** [released](#) an analysis of the existing requirements for coverage with evidence development (CED). Comments are due September 28. [Details](#).

COMMENT & APPLICATION DEADLINES

- **September 19:** The FDA [issued](#) draft guidance on the evaluation of therapeutic equivalence. Comments are due September 19. [Details](#).
- **September 19:** HHS [announced](#) it is seeking nominations for individuals to participate as either a voting or non-voting member on the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. [Details](#).
- **September 28:** The AHRQ [released](#) an analysis of the existing requirements for coverage with evidence development (CED). [Details](#).
- **September 29:** The FDA [issued](#) draft guidance entitled: Patient Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments (COAs). [Details](#).
- **September 30:** The CDC is [seeking nominations](#) for the Clinical Laboratory Improvement Advisory Committee (CLIAC). [Details](#).
- **September 30:** CMMI [announced](#) a new demonstration model aimed at improving oncology care. [Details](#).
- **October 1:** The CDC [seeks](#) nominations for the CDC/Health Resources & Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHACHSPT). [Details](#).
- **October 19:** The FDA [issued](#) a request for applications from patient advocates interested in participating on the Patient Engagement Collaborative (PEC). [Details](#).
- **October 25:** SAMHSA [announced](#) a new \$35 million grant opportunity to further support the 988 Suicide and Crisis Lifeline. [Details](#).
- **October 26:** The FDA [issued](#) a proposed rule to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). [Details](#).
- **October 31:** A group of eight House representatives are [seeking](#) input on how to improve upon the Medicare Access and CHIP Reauthorization Act (MACRA). [Details](#).
- **November 4:** CMS issued a [Request for Information](#) seeking public input and feedback on issues related to health equity. [Details](#).
- **November 6:** CMS [released](#) a proposed rule entitled, "Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment and Renewal Processes". [Details](#).
- **November 14:** FDA [issued](#) draft guidance on computer software assurance for production and quality system assurance. [Details](#).

- **November 15:** The Departments of Labor, HHS, and Treasury [issued](#) a RFI to inform future rulemaking for advanced explanation of benefits (AEOB) and good faith estimate (GFE) requirements. [Details](#).
- **November 15:** The AHRQ [issued](#) a RFI on the current state of comprehensive, longitudinal, person-centered care planning for people with Multiple Chronic Conditions. [Details](#).
- **December 7:** The FDA [issued](#) revised draft guidance on general clinical pharmacology considerations for pediatric studies of drugs. [Details](#).

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