

Wynne Health Group Weekly



FRAMING THE WEEK

Congress returns this week to a full plate with about three weeks before lawmakers are scheduled to adjourn for the holiday recess.

- **Fiscal Year 2023 funding:** The current continuing resolution expires on December 16. Lawmakers are eyeing a one-week extension to allow for more time to figure out the omnibus spending package. The inclusion of other measures in the must-pass legislative vehicle are in flux.
- **COVID-19 Response:** The Biden Administration is [requesting](#) the omnibus spending package include emergency supplemental funding for the COVID-19 response and other public health needs. Specifically, the administration requests \$9 billion “to address on-going and emerging COVID-19 needs, restore smallpox vaccine supply used during the monkeypox response, and begin the procurement and distribution of treatments for hepatitis C and pre-exposure prophylaxis to help prevent HIV.” The Biden Administration also requests \$1 billion to support the global COVID-19 response. Congressional Republicans have previously blocked the inclusion of additional COVID-19 funding.
- **Annual defense policy bill:** The Senate will resume consideration [National Defense Authorization Act \(NDAA\)](#), which includes provisions to strengthen environmental health and security. For example, the bill reauthorizes the Centers for Disease Control and Prevention’s ongoing study and assessment on human health impacts of PFAS chemicals in drinking water.
- **Same-sex marriage:** Today, the Senate will continue to move the Respect for Marriage Act ([HR 8404](#)) forward. The bill, which would codify protections for same-sex and interracial marriage, cleared a key procedural vote earlier this month. The House will need to pass the Senate-version of the bill before sending it to Biden’s desk for signature.
- **Debt limit:** Democrats also plan to pursue legislation to raise the debt limit. Incoming House Speaker Kevin McCarthy [signaled](#) House Republicans would use raising the debt limit as leverage to force spending cuts on Medicare and Social Security.

In addition, the House is scheduled to vote on a [slate of legislation](#) this week, including a pair of maternal health bills:

- **Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022 ([H.R. 8876](#)):** The bill would reauthorize the MIECHV program for FY 2023 and FY 2027 and provide a \$10 million increase in base funding starting in FY 2023. The bill would also make changes to the program. For example, the Department of Health and Human Services (HHS) would be required to create and annually update an “outcomes dashboard” to help Congress and the public track MIECHV’s success in improving family outcomes in every state or territory. The House Ways and Means Committee passed the bill with overwhelming bipartisan support.

- **Pregnant Women in Custody Act (H.R. 6878):** The bill includes several provisions to strengthen and promote the safety of pregnant inmates. The bill would provide a national standard of care to address pregnancy-related needs of incarcerated women during pregnancy, labor, delivery and post-partum periods. The House Judiciary Committee advanced the bill by a voice vote.

Regulatory Update

A number of regulations remain unpublished in the *Federal Register* despite their recent approval by the Office of Management and Budget (OMB). We detail these items below, which could be released before the year's end:

- **Request for Information on the Essential Health Benefits:** The Centers for Medicare & Medicaid Services (CMS) is planning to request feedback on the essential health benefits, possibly in response to the recent court decision that partially struck down the Affordable Care Act's (ACA's) requirement that insurers cover certain types of preventive care without cost sharing ([details](#)).
- **Final Rule for Basic Health Program:** CMS is planning to release its final rule for the funding methodology for the program year 2023 basic health program.
- **Proposed Rule for the 340B Drug Pricing Program:** The Health Resources and Services Administration (HRSA) is planning to issue a proposed rule to replace the Administrative Dispute Resolution (ADR) rule currently in place with new requirements and procedures for the 340B Program's ADR process.
- **Proposed Rule on Substance Use Disorder Patient Records:** The HHS Office of Civil Rights (OCR) is planning to issue a proposed rule to better harmonize the 42 CFR part 2 (part 2) confidentiality requirements with certain permissions and requirements of the HIPAA Rules and the HITECH Act.
- **Proposed Rule on Opioid Use Disorder:** The Substance Abuse and Mental Health Services Administration (SAMHSA) is set to issue a proposed rule that would permanently extend the current COVID-19 flexibility that permits health care providers to prescribe buprenorphine for opioid use disorder via telehealth.

THIS WEEK IN HEALTH POLICY

Wed. (11/30)

- **10:00am – Hearing: Children's Mental Health** – The Senate Committee on Health, Education, Labor, and Pensions (HELP) Subcommittee on Children and Families holds a hearing titled, "Caring for Our Kids: Supporting Mental Health in the Transition from High School to College." [Details](#).
- **10:00am – Hearing: Native American Veteran Health** –The Senate Committee on Veterans' Affairs holds a hearing titled, "Native American Veterans: Ensuring Access to VA Health Care and Benefits." [Details](#).
- **3:30pm – WH Stakeholder Call: Nutrition, Hunger, and Health** – The White House (WH) holds a monthly stakeholder call to provide updates on the National Strategy on Hunger, Nutrition, and Health and proposed updates to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). [Details](#).

Thurs. (12/1)

- **12:00pm – NIH Meeting: Sleep Disorders** – The National Institutes of Health (NIH) National Heart, Lung, and Blood Institute holds a meeting of the Sleep Disorders Research Advisory Board to discuss program updates. [Details](#).

- **3:00pm – ONC Meeting: HITAC Annual Report** – The Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to discuss the recommendations for the annual report. [Details](#).

Fri. (12/2)

- **1:00pm – HRSA Meeting: Childhood Vaccines** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Commission on Childhood Vaccines to discuss program updates. [Details](#).

Additional Multi-Day Events

- **November 29-December 1 – 9:00am – CMS Meeting: HCPCS** – The Centers for Medicare and Medicare Services (CMS) holds a meeting to discuss preliminary coding, benefit category, and payment determinations for revisions to the Healthcare Common Procedure Coding System (HCPCS). [Details](#).

FEATURED WHG ANALYSIS

- ***NEW* Blog on Which Issues Warrant Consideration in a Year-End Spending Package** – On Commonwealth Fund's To the Point [here](#).
- ***NEW* Blog on What Recent State Elections Mean for Health Care** – On Health Affairs Forefront [here](#).
- **WHG 2022 Midterm Election Recap** – In the Policy Hub Insight Bank [here](#).
- **Blog on Options for CMMI to Make Prescription Drug Affordable** – On Commonwealth Fund's To the Point [here](#).
- **WHG Roundup of Recent Reproductive Health Developments** – In the Policy Hub Insight Bank [here](#).
- **WHG Tracker of Climate Change Provisions in the IRA** – 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](#).

CONGRESSIONAL LOOKBACK

Tues. (11/15)

- **The Senate** voted 72 to 37 to advance the Respect for Marriage Act ([HR 8404](#)). [Details](#).

REGULATORY LOOKBACK

Fri. (11/18)

- **The CDC** [issued](#) clinical practice guideline for prescribing opioid for pain. [Details](#).

Thus (11/17)

- **The FNS** [released](#) a proposed rule with changes to the food packages in WIC. [Details](#).
- **The USPSTF** [released](#) its annual Report to Congress on high-priority evidence gaps for clinical preventive services. [Details](#).

Tues. (11/15)

- **The KFF** released an [issue brief](#) on racial and ethnic disparities across selected measures of maternal and infant health. [Details](#).
- **CMS** [released](#) a CMCS Informational Bulletin describing the 2023 and 2024 updates to the Core Set of children's health care quality measures for Medicaid and CHIP. [Details](#).

Mon. (11/14)

- **SAMHSA released** new report titled, “National Guidelines for Child and Youth Behavioral Health Crisis Care.” [Details](#).
- **CMS issued** a request for nominations to fill vacancies on the Advisory Panel on Hospital Outpatient Payment. Nominations are due February 12. [Details](#).
- **HHS issued** a request for public comment on new indicator targets for the National Action Plan to Prevent Health Care-Associated Infections. Details. Comments are due February 13. [Details](#).
- **HHS OIG released** a report on the decline in the number of beneficiaries who received Part B clinical laboratory tests during the COVID-19 pandemic. [Details](#).

COMMENT & APPLICATION DEADLINES

- **December 2:** HHS [issued](#) a request for written comments on proposed Healthy People 2030 objectives. [Details](#).
- **December 2:** HRSA [issued](#) an RFI on a proposed update to the Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care. [Details](#).
- **December 3:** HRSA [issued](#) a request for public comment on two draft recommendations to update the HRSA-Supported Women’s Preventive Services Guidelines relating to Screening for Diabetes. [Details](#).
- **December 6:** CMS [issued](#) an RFI on the current state of health care provider directories. [Details](#).
- **December 7:** The FDA [issued](#) revised draft guidance on general clinical pharmacology considerations for pediatric studies of drugs. [Details](#).
- **December 8:** AHRQ is [seeking](#) scientific information submissions from the public to inform AHRQ’s review on *Respectful Maternity Care*. [Details](#).
- **December 13:** The FDA [issued](#) a request for public comments on a recently released [discussion paper](#) on areas associated with Distributed Manufacturing (DM) and Point-of-Care (POC) manufacturing. [Details](#).
- **December 20:** The FDA [issued](#) draft guidance on proposed select updates for the Breakthrough Devices Program Guidance. [Details](#).
- **December 29:** The CDC is [seeking](#) nominations for membership on the Advisory Committee on Breast Cancer in Young Women (ACBCYW). [Details](#).
- **December 31:** AHRQ [issued](#) a supplemental solicitation for nominations of members from Populations Underrepresented in Medicine (URIM) to serve on the Initial Review Group (IRG). [Details](#).
- **January 8:** HHS [issued](#) a proposed rule to adopt updated versions of the retail pharmacy standards for electronic transactions.. [Details](#).
- **January 9:** AHRQ announced a challenge competition to explore the resources and infrastructure needed to integrate real-world data from healthcare systems into systematic review findings. [Details](#).
- **February 12:** CMS [issued](#) a request for nominations to fill vacancies on the Advisory Panel on Hospital Outpatient Payment. [Details](#).
- **February 13:** HHS [issued](#) a request for public comment on new indicator targets for the National Action Plan to Prevent Health Care-Associated Infections. Details. [Details](#).

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