

Wynne Health Group Weekly



FRAMING THE WEEK

Congress enters its busiest season with less than 10 scheduled working days before lawmakers adjourn on December 13.

- **Fiscal Year 2021 funding** – With the current [continuing resolution](#) set to expire on December 3, lawmakers are expected to vote on a new CR to fund the government at least until mid-December, though it could be extended through late January.
- **Debt ceiling** – Treasury Secretary Janet Yellen estimates that the U.S. could reach its debt limit on December 15. How exactly Congress will address the looming cliff remains to be seen, but Senate Majority Leader Chuck Schumer and Senate Minority Leader Mitch McConnell (R-KY) are trying to negotiate a deal.
- **Build Back Better Act (H.R. 5376)** – The House passed President Biden's \$1.75 trillion social spending and climate framework on November 19 ([WHG summary](#)). Senate Democrats want to pass the budget reconciliation package in December, though it could spill into the new year. We could see the President's first State of the Union address in late January or early February as congressional Democrats' self-imposed deadline to finalize BBBA and deliver President Biden a legislative victory to tout before the American people.

Some of the more contentious provisions (due to policy or process) around paid leave, immigration and so forth may be subject to change, especially in an attempt to secure the support of all 50 Democrats, including key moderates Joe Manchin (D-WV) and Kyrsten Sinema (D-AZ). For health care, the broad contours of the provisions are not expected to change drastically, though we could see tweaks to the components addressing Medicare benefit expansion, the Medicaid coverage gap, and expansions for home- and community-based services. Changes to other key health care policies – namely, drug pricing reform – would alter the savings currently expected from such changes, currently expected to save approximately \$300 billion according to estimates from the Congressional Budget Office (CBO) and nearly cover the health care provisions of the bill that would increase federal spending.

- **National Defense Authorization Act (H.R. 4350)** – Today, the Senate will hold a procedural vote on an [amendment](#) to NDAA submitted by Sen. Jack Reed (D-RI), Chairman of the U.S. Senate Committee on Armed Services. The amendment includes the Maternal Health Quality Improvement Act ([S. 1675](#) / [press release](#)) introduced by Sens. Raphael Warnock (D-GA) and Marco Rubio (R-FL).

Tomorrow, the House will vote on a slate of relatively uncontroversial health-related bills. They include:

- **Opioid crisis**

- Opioid Prescription Verification Act of 2021 ([H.R. 2355](#))
- Synthetic Opioid Danger Awareness Act ([H.R. 2364](#))
- **Social determinants of health**
 - CARING for Social Determinants Act of 2021 ([H.R. 3894](#))
 - Social Determinants of Health Data Analysis Act of 2021 ([H.R. 4026](#))
- **Immunization data and vaccination rates**
 - Immunization Infrastructure Modernization Act of 2021 ([H.R. 550](#))
 - Maternal Vaccination Act ([H.R. 951](#))
 - PREVENT HPV Cancers Act of 2021 ([H.R. 1550](#))
- **Medical product development**
 - Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act ([H.R. 3743](#))

Regulatory Update

A number of notable developments occurred on the regulatory front last week. These include the following:

Federal Register

- The Food and Drug Administration (FDA) issued a [proposed rule](#) to reclassify HIV viral load monitoring tests as a means to reasonably assure the safety and effectiveness of this device type.

Office of Management and Budget (OMB)

- A final rule regarding the currently paused Most Favored Nation (MFN) model [arrived](#) for review at OMB. The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule in August 2021 to rescind the model ([details](#)).
- A proposed rule for policy and technical changes to Medicare Advantage and Part D for Contract Year 2023 [arrived](#) at OMB for review.
- A request for information for modernizing the organ transplant system [cleared](#) OMB review, meaning we may see its release in the *Federal Register* shortly.

THIS WEEK IN HEALTH POLICY

Tue. (11/30)

- **12:00pm – AHP Briefing: Native American Health** – The Alliance for Health Policy (AHP) holds a briefing titled, “Policymaking to Support the Health of Native American People.” [Details](#).

Thurs. (12/2)

- **9:00am – FDA Meeting: Oncologic Drugs** – The Food and Drug Administration (FDA) holds a meeting of the Oncologic Drugs Advisory Committee to hear updates on new drug applications. [Details](#).
- **10:00am – HRSA Meeting: Childhood Vaccination** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Childhood Vaccines to provide program updates. [Details](#).
- **11:00am – CDC Webinar: Biological Agent Importation** – The Center for Disease Control and Prevention (CDC) Division of Select Agents and Toxins holds a webinar to provide information about import permit regulations for infectious biological agents, infectious substances, and vectors. [Details](#).
- **1:00pm – BPC Discussion: Health System Modernization** – The Bipartisan Policy Center (BPC) holds a panel discussion titled, “Public Health Forward: Modernizing the US Public Health System.” [Details](#)

Additional Multi-Day Events

- **November 30-December 1 – 10:00am – HHS Meeting: Antimicrobial Resistance** – The Department of Health and Human Services (HHS) holds a meeting of the Presidential Advisory Council on combatting Antibiotic-Resistant Bacteria to discuss a report titled, “Examining the Long-term Health and Economic Effects of Antimicrobial Resistance in the United States.” [Details](#).
- **December 1-December 2 – 9:00am – CMS Meeting: HCPCS** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting to discuss coding recommendations for revisions to the Healthcare Common Procedure Coding System (HCPCS) Level II Code Set. [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 117th Congress; Side-by-Side Comparison** – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Fri (11/19)

- **The House** passed along party lines the Build Back Better Act (BBBA) ([H.R. 5376](#)) ([text](#); [section-by-section](#)) reconciliation legislation. [Details](#).

Tues. (11/16)

- **Reps. DeGette and Upton** [introduced](#) Cures 2.0 – a bipartisan bill that would authorize the creation of the Advanced Research Projects Agency for Health. [Details](#).
- **MACPAC** released their final [response](#) to the Senate Finance Committee’s (SFC) RFI on advancing behavioral health services. [Details](#).

REGULATORY LOOKBACK

Fri (11/19)

- **SAMHSA** [announced](#) that the take-home flexibility for methadone will be extended for one year upon the expiration of the COVID-19 public health emergency. [Details](#).

Thurs. (11/18)

- **The ONC** [published](#) a blog post discussing new survey data showing that patient facing application programming interfaces (API) are increasingly available and utilized by patients. [Details](#).
- **NIOSH** published a [notice](#) extending the public comment period for the previously announced request for information (RFI) on interventions to support health worker mental health. Comments are now due January 25. [Details](#).

Wed. (11/17)

- **HHS, DOL, the Treasury, and OPM** [issued](#) an IFC to implement the health insurance plan reporting requirements on prescription drug and health care spending. Comments are due January 24. [Details](#).

- **The ONC** [released](#) information on the future of interoperability and changes in electronic health information sharing. [Details](#).
- **CMS** [announced](#) that they estimate that improper payments under Medicare fee-for-service (FFS) have been reduced by over \$20 billion since 2014. [Details](#).
- **The GAO** released a [report](#) on the transition to Advanced Alternative Payment Models (APMs) in rural, health professional shortage, or underserved areas. [Details](#).
- **The NIH** [released](#) a report that found an association between persistent, distressing psychotic-like experiences (PLEs) and impairment in youth. [Details](#).

Tues. (11/16)

- **CMS** [published](#) their strategic vision for Medicaid and CHIP. [Details](#).
- **The USPSTF** [released](#) the 11th Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services. [Details](#).
- **The DEA** [issued](#) an ANPRM to obtain information about the practice of telepharmacy in order to inform the agency in developing regulations. [Details](#).

Mon. (11/15)

- **HHS** [announced](#) the availability of \$143.5 million in American Rescue Plan Act of 2021 (ARP) funding to expand community-based efforts to address barriers to COVID-19 vaccination. [Details](#).
- **CMS** issued [final guidance](#) for hospitals co-locating with other hospitals or health care facilities. [Details](#).

COMMENT & APPLICATION DEADLINES

- **November 29:** The FDA issued draft guidance on [assessing electronic health records \(EHRs\) and medical claims data to support regulatory decision-making; interpreting sameness of gene therapy products under orphan drug regulations; and benefit-risk assessment for new drug and biological products.](#) [Details](#).
- **November 29:** The HHS OMH is [seeking](#) nominations for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee. [Details](#).
- **November 29:** The FDA OMHHE [released](#) a funding opportunity announcement (FOA) to fund innovative research that will strengthen and advance COVID-19 health equity research. [Details](#)
- **December 6:** HHS, DOL, and Treasury issued an [interim final rule with comment period](#) (IFC) on Part II of its implementation of the No Surprises Act's surprise billing policies. [Details](#).
- **December 6:** The USDA FNS [issued](#) an RFI to support state and local Special Nutrition Program for Women, Infants, and Children (WIC) agencies in improving the WIC application and certification process. [Details](#).
- **December 7:** The FDA announced the launch of the [Novel Excipient Review Pilot Program](#) as a new pathway for manufacturers to obtain agency review of certain novel excipients. [Details](#).
- **December 8:** HHS [seeks](#) public comment and nominations to inform the development of the Physical Activity Guidelines (PAG) Midcourse Report on older adults. [Details](#).
- **December 13:** AHRQ released a request for information (RFI) on [climate change](#). [Details](#).
- **January 11:** HHS [announced](#) it is making available up to \$256 million in grant funding to support equitable, affordable, and high-quality access to family planning services through the Title X family planning program. [Details](#).
- **December 28:** HHS issued a [proposed rule](#) to withdraw or repeal the "Securing Updated and Necessary Statutory Evaluations Timely" SUNSET final rule. [Details](#).
- **January 18:** The FDA issued a [proposed rule](#) and [draft guidance](#) to improve access to hearing aids through the establishment of an over-the-counter (OTC) hearing aid category. [Details](#).
- **January 21:** The FDA [issued](#) draft guidance on data standards for drug and biological product submissions containing real-world data (RWD). [Details](#).
- **January 24:** HHS, DOL, the Treasury, and OPM [issued](#) an IFC to implement the health insurance plan reporting requirements on prescription drug and health care spending. [Details](#).

- **January 25:** NIOSH published a [notice](#) extending the public comment period for the previously announced request for information (RFI) on interventions to support health worker mental health. [Details.](#)
- **February 2:** The FDA [issued](#) draft guidance on content of premarket submissions for device software functions. [Details.](#)
- **February 22:** The USDA [announced](#) \$1.15 billion in grant funding for rural broadband access. [Details.](#)

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