

Wynne Health Group Weekly



FRAMING THE WEEK

Please note that Wynne Health Group will be closed for the winter holidays beginning Mon., Dec. 20 through Fri., Dec. 31, reopening Mon., Jan. 3, 2022. We are grateful for your continued partnership and look forward to our work together in the new year. Happy Holidays!

Reconciliation

Over the weekend, the Senate Finance (SFC) and Health, Education, Labor and Pensions (HELP) Committees released updated legislative text ([SFC](#); [HELP](#)) of the House-passed reconciliation bill, the Build Back Better Act (BBBA) ([H.R. 5376](#); [WHG summary of House-passed BBBA](#)). The updated Senate measure includes both technical and policy changes denoted below.

Senate Democrats hope to advance President Biden's \$1.9 trillion social spending and climate framework by Christmas, leaving only two short weeks to meet the upper chamber's ambitious self-imposed deadline. Meanwhile, significant hurdles to reconciliation passage persist. Chiefly, securing the vote of centrist Sen. Joe Manchin's (D-WV), who has not yet indicated his support, especially amid its significant cost which could add more than \$3 trillion to the deficit if the programs included in the package are made permanent ([updated CBO score](#)). Sen. Manchin also opposes key coverage provisions on which Congressional Democrats are united, including the addition of Medicare coverage of hearing services, a provision that the SFC retained in its updated legislative text. Senate deliberations on the updated reconciliation text are expected to continue this week, with additional changes to the bill, especially amid conversations with Sen. Manchin and the Senate parliamentarian.

On the former, President Biden spoke with Sen. Manchin late last week and [plans](#) to speak with the hold-out senator again, as early as today. If the Senate fails to secure the 50 necessary votes over the next two weeks, the chances for the legislation's passage wane as we head into a contentious election year. Congressional Democrats hope to deliver President Biden a legislative victory to tout before the President's State of the Union address in late January or early February of next year.

Highlights of the updated Senate BBBA text follow. Note that our comprehensive summary of the bill is forthcoming.

- **Coverage Provisions:**
 - **Hearing:** Coverage for hearing services under Medicare would go into effect on Jan. 1, 2023.

- **Medicaid and CHIP:** The Senate bill retains the House-backed phase-down of the enhanced federal medical assistance percentage (FMAP) provided to states during COVID-19, as well as key maternal and child health improvements, such as the requirement of 12 months continuous eligibility (CE) to postpartum women and children under Medicaid and CHIP.

Notably, the Senate legislation omits the contentious House language that would have reduced Medicaid disproportionate share hospital (DSH) payments to facilities in non-expansion states. However, the Senate bill does include a new provision that adjusts uncompensated care (UC) pools by excluding from Medicaid federal matching funds services provided under section 1115 waiver authority to the newly eligible group in states that have not expanded Medicaid pursuant to the Affordable Care Act (ACA). The updated Senate language also enhances the federal medical assistance percentage (FMAP) for individuals in the newly eligible group.

- **ACA Marketplace:** The Senate bill largely follows the House with the retention of provisions that aim to expand access to ACA Marketplace coverage and lower costs.
- **Capital and Public Health Infrastructure –** The updated Senate language retains several House provisions aimed at bolstering the health care workforce, including critical investments in Medicare graduate medical education (GME) residency training programs, as well as the one-time \$200 million funding bump for the Children’s Hospital Graduate Medical Education (CHGME) program. Consistent with the House measure, the updated Senate text does not include the \$10 billion in Hill-Burton program funding for hospital and other infrastructure projects included in an earlier iteration of the House bill.
- **Drug Pricing:** Overall, the drug price negotiations section remains largely unchanged in the updated Senate text from the House passed version. The Senate bill still features a drug price negotiations program, Medicare Part D redesign, and inflation rebates, but features minor policy changes including modifying the maximum ceiling price for negotiated drugs; establishing a premium stabilization for Part D; and exempting generics from inflation rebates.
- **Long-term Care and HCBS:** The Senate bill retains investments in Medicaid home and community-based services (HCBS) via state planning grants and a six percentage point FMAP increase, as well as most of the skilled nursing facility (SNF)-focused provisions incorporated in the House bill, such as the provisions on SNF data, cost report audits, survey and enforcement process improvements, and nurse staffing requirements (though no longer enforces the minimum ratio requirements).
- **Other Issues, Tax Reforms:** Regarding climate change, the bill provides \$85 million for establishing a program to award grant to medical schools or other schools or programs for the purpose of identifying and addresses health risk associated with climate change. The Senate Finance Committee released separate [draft legislation](#) that addresses tax reform ([section-by-section](#), [summary](#)) and features closing tax loopholes for pass-through entities, primarily partnerships.

Medicare Sequester Cuts Extended + Debt Limit and NDAA Votes

Late last week, the Senate cleared a major procedural hurdle to fast-track the legislative vehicle (House amendment to [S.610](#)) to raise the debt limit prior to the December 15 debt ceiling deadline estimated by Treasury Secretary Janet Yellen. A final vote on the measure is anticipated this week. As part of the legislative package teeing-up expedited debt limit deliberations that are still unfolding, last week Congress passed, and the President [signed](#), legislation staving off automatic statutory cuts to Medicare through March 31, 2022 ([WHG summary](#)). Finally, the Senate is expected to vote on the fiscal year (FY) 2022 National Defense Authorization Act (NDAA) legislation (House amendment to [S.1605](#)), following House passage last week.

FDA Commissioner Nominee

In addition to the key events ahead this week, we call your attention to the Senate HELP Committee's [consideration](#) of President Biden's nominee to lead the Food and Drug Administration (FDA), Dr. Robert Califf, who previously led the FDA from 2016-2017 under the Obama Administration.

THIS WEEK IN HEALTH POLICY

Tue. (12/14)

- **9:00am – CMS Meeting: New Medical Services and Technologies** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting to discuss FY 2023 applications for New Medical Services and Technologies Add-On Payments. [Details](#).
- **10:00am – NQF Meeting: Clinicians** – The National Quality Forum (NQF) holds a meeting of the Measure Application Partnership (MAP) Clinician workgroup to review submitted measures for clinicians. [Details](#).

Wed. (12/15)

- **10:00am – NQF Meeting: Hospitals** – NQF holds a meeting of the MAP Hospital Workgroup to review submitted measures for hospitals. [Details](#).

Thurs. (12/16)

- **10:00am – NQF Meeting: Long Term Care** – NQF holds a meeting of the MAP Post-Acute Care/Long-Term Care Workgroup to review submitted measures for long-term care hospitals, skilled nursing facilities, and home health care. [Details](#).
- **1:00pm – HHS Meeting: Biodefense** – The Department of Health and Human Services (HHS) holds a meeting of the National Biodefense Science Board to discuss issues related to national public health emergency preparedness and response and review recommendations for the National Health Security Strategy. [Details](#).
- **1:00pm – SAMHSA Meeting: Serious Mental Illness** – The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee to discuss issues related to serious mental illness. [Details](#).
- **2:00pm – FEMA Meeting: Pandemic Response** – The Federal Emergency Management Agency (FEMA) holds a meeting to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic. [Details](#).

Fri. (12/17)

- **2:00pm – HITAC Meeting: Annual Report** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to develop the annual report for fiscal year 2021. [Details](#).

Additional Multi-Day Events

- **December 14-December 15 – 10:00am – CDC Meeting: Tuberculosis** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Advisory Council for the Elimination of Tuberculosis to discuss project updates. [Details](#).

- **December 14-December 15 – 12:00pm – HRSA Meeting: Maternal and Infant Mortality** – The health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Infant and Maternal Mortality to discuss recommendations to reduce infant and maternal mortality. [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. (12/10)

- **The House Committee on O&R** [released](#) the final report of its three-year investigation on drug prices. [Details](#).
- **The House O&R Ranking Member James Comer** also [released](#) a report on how pharmacy benefit manager (PBM) practices contribute to the rising drug costs. [Details](#).
- **MedPAC** [convened](#) virtually for Day Two of its December 2021 public meeting and held sessions on payment adequacy, and a mandated report on BBA changes to home health payment system. All WHG session summaries are available on Policy Hub [here](#).
- **MACPAC** [convened](#) virtually for Day Two of its December 2021 public meeting and held sessions on applying a health equity lens to Medicaid, nursing facility staffing issues, and next steps on access monitoring. All WHG session summaries are available on Policy Hub [here](#).

Thurs. (12/9)

- **MedPAC** [convened](#) virtually for Day One of its December 2021 public meeting and held sessions on payment adequacy, and a mandated report on BBA changes to low-volume hospital payment adjustment. All WHG session summaries are available on Policy Hub [here](#).
- **MACPAC** [convened](#) virtually for Day One of its December 2021 public meeting and held sessions on transparency of directed payments, an approach for monitoring access to care, and options to strengthen behavioral health integration. All WHG session summaries are available on Policy Hub [here](#).

Tues. (12/7)

- **The House Rules Committee** released the [legislative text](#) of the Protecting Medicare and American Farmers from Sequester Cuts Act. [Details](#).

REGULATORY LOOKBACK

Fri (12/10)

- **OMB** [released](#) the Fall 2021 Unified Regulatory Agenda. This resource serves to outline the planned rulemaking the Administration intends to undertake and offers a base case on timing. [Details](#).
- **CMMI** [hosted](#) a listening session to discuss its strategic objective of advancing health equity. [Details](#).

- **SAMHSA** [announced](#) a notice of funding opportunity for the first SAMHSA Harm Reduction grant program. [Details](#).

Thurs. (12/9)

- **HRSA** released a [request for comments](#) on the revised updated recommendations to the [Women's Preventive Services Guidelines](#). Comments are due December 20. [Details](#).
- **ASPE** released an [issue brief](#) on state-level implications of extending postpartum Medicaid coverage. [Details](#).
- **The FDA** [issued](#) draft guidance on considerations for the use of RWD and RWE to support regulatory decision-making for drug and biological products. Comments are due January 8. [Details](#).
- **The FDA** [issued](#) final guidance on the development of anti-infective drug products for the pediatric population. [Details](#).

Wed. (12/8)

- **CMS** released [updates](#) to the State Medicaid & CHIP Telehealth [Toolkit](#): Policy Considerations for States Expanding Use of Telehealth, COVID-19 Version and the [Supplement](#) to the toolkit. [Details](#).
- **CMS** [issued](#) a notification of enforcement discretion to announce that the Agency will not take action to enforce compliance with payer-to-payer data exchange provisions until certain implementation challenges can be met. [Details](#).
- **CMS** published a [State Medicaid Director Letter](#) on mandatory coverage of routine patient costs related to participation in qualifying clinical trials. [Details](#).

Tues. (12/7)

- **The Biden-Harris Administration** [issued](#) a Call to Action to reduce maternal mortality and morbidity. [Details](#).
- **The NIH** [announced](#) a \$1 million prize competition for innovative diagnostics technologies to help improve maternal health. Submissions are due April 22. [Details](#).
- **CMS** released a [letter](#) providing guidance on the implementation of the option introduced by the ARP to extend Medicaid and CHIP coverage for pregnant individuals to up to 12 months postpartum. [Details](#).

Mon. (12/6)

- **ASPE** published a [report](#) examining Medicare fee-for-service (FFS) beneficiaries' use of telehealth in 2020. [Details](#).

COMMENT & APPLICATION DEADLINES

- **December 13:** AHRQ released a request for information (RFI) on [climate change](#). [Details](#).
- **December 13:** CMS [seeks](#) nominations for appointees to the Advisory Committee on Ground Ambulance and Patient Billing (GAPB Advisory Committee), which is newly established as required by the No Surprises Act. [Details](#).
- **December 20:** HRSA released a [request for comments](#) on the revised updated recommendations to the [Women's Preventive Services Guidelines](#). [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 8:** The FDA [issued](#) draft guidance on considerations for the use of RWD and RWE to support regulatory decision-making for drug and biological products. [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.](#)
- **April 22:** The NIH [announced](#) a \$1 million prize competition for innovative diagnostics technologies to help improve maternal health. [Details.](#)

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