

Wynne Health Group Weekly



FRAMING THE WEEK

Infrastructure and Budget Reconciliation

Lawmakers are back home on recess this week. The Senate will be in session on September 13 and the House will return next week to vote on the \$3.5 trillion budget resolution for fiscal year (FY) 2022, unlocking the partisan path for President Biden and congressional Democrats to advance their legislative agenda. Whether the House will also vote on the Senate-approved infrastructure bill next week remains to be seen. The ongoing standoff between House Democratic leaders and nine moderate House Democrats over which legislation to advance first – budget reconciliation or bipartisan infrastructure – has raised questions about the exact vote sequence.

In an attempt to appease the nine moderate House Democrats who warned they will not vote for the budget resolution until the House first passes the Senate-approved infrastructure bill, House Speaker Nancy Pelosi (D-CA) is pushing to move forward simultaneously with the bipartisan infrastructure bill and the \$3.5 trillion budget resolution unlocking reconciliation. She has [directed](#) the House Rules Committee to “explore the possibility of a rule that advances both the budget resolution and the bipartisan infrastructure package.” However, the nine Democrats are not budging. “It’s very important that we don’t back off of this path which is voting first on infrastructure and then consider the budget resolution. There’s enough of us who really feel strongly that we’re going to hold to our guns here and find a solution,” [said](#) Rep. Gottheimer, who is leading the group. Ultimately, we do not anticipate the intraparty skirmish in the House will derail Democrats’ plans for budget reconciliation since it is essential to advancing their legislative agenda.

In addition to major health coverage reforms – such as addressing the Medicaid expansion coverage gap; extending the temporary to Affordable Care Act (ACA) premium subsidies; and expanding Medicare to include dental, vision, and hearing benefits – the budget reconciliation package is expected to address health issues amplified by the COVID-19 pandemic. We could see some of the ongoing legislative work (notably bipartisan and detailed below) make its way into the partisan budget reconciliation package. Committees have until September 15 to draft their respective bills that meeting the spending targets outlined in the \$3.5 trillion budget resolution – at least \$1 billion in deficit reduction for the Senate Finance Committee (SFC) and \$726 billion in spending for the Senate Health, Education, Labor and Pensions Committee (HELP).

Ongoing bipartisan legislative work includes:

- **Access to Mental Health Care:** SFC Chairman Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID) are developing bipartisan legislation to address barriers to mental health care. They recently invited SFC members to submit policy recommendations to address the behavioral health workforce shortage, improve care integration and coordination, expand access to telehealth

services, and address gaps in care for children (more details [here](#)). The deadline for committee-level input is August 31. SFC leaders also indicated that a separate request for public- and private sector stakeholder input would be announced later this month.

- **Pandemic Preparedness** – Senate HELP Committee Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) are crafting bipartisan legislation on public health infrastructure and medical preparedness and response. The bill intends to reflect lessons learned from the COVID-19 pandemic and include strategies for bolster federal public health and medical preparedness and response systems and programs and strengthening the pipeline of medical countermeasures (more details [here](#)).
- **Workforce Development** – Senate HELP Committee leaders are also working on bipartisan legislation to update and expand workforce training programs, including in the health care and public health sectors, and improve programs authorized under the Workforce Innovation and Opportunity Act (WIOA) (more details [here](#)). House Education and Labor Committee Chairman Bobby Scott (D-VA) and Ranking Member Virginia Foxx (R-NC) are also [working](#) on a bipartisan package to reauthorize WIOA.

Prescription Drug Pricing

Prescription drug pricing reforms are imperative to generating savings – “hundreds of billions”, according to Democrats’ [blueprint](#) – for major health care reforms in budget reconciliation. Last week, President Biden [called](#) on Congress to allow Medicare to negotiate prices, impose inflation rebates, cap out-of-pocket (OOP) costs, and import drugs from Canada. We could see the Biden Administration unveil additional details this week on its plan to lower prescription drug prices through regulation, which will likely depend in part on how Congress acts on this issue.

Biden’s recent [executive order](#) on competition mandates the Department of Health and Human Services (HHS) to submit to the White House “a plan to continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the Federal Government for such drugs, and to address the recurrent problem of price gouging” by August 23. In the [proposed rule](#) rescinding the Most Favored Nations model, the Administration referenced the executive order and the ensuing HHS plan and detailed that the agency is currently exploring opportunities to:

- Promote value-based care for beneficiaries;
- Address the high cost of Part B drugs, manufacturers’ pricing, and the resulting growth in Part B spending; and
- Modernize the Medicare program to improve the quality and cost of care for beneficiaries.

THIS WEEK IN HEALTH POLICY

Tue. (8/17)

- **1:00pm – SAMHSA Meeting: Mental Health** –The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Center for Mental Health Services National Advisory Council to discuss the Mental Health Block Grant, Certified Community Behavioral Health Clinics, Children Services, and updates from the Office of the Assistant Secretary for Mental Health and Substance Abuse. [Details](#).

Thurs. (8/19)

- **12:00pm – AHP Discussion: Mental Health** – The Alliance for Health Policy (AHP) holds a virtual discussion titled, “Investing in Mental Health to Support Our Workforce.” [Details](#).
- **12:00pm – CDC Meeting: Healthcare Infection Control** – The Centers for Disease Control and Prevention (CDC) holds a meeting by teleconference of the Healthcare Infection Control Practices Advisory Committee to discuss updates from the Healthcare Personnel Guideline Workgroup, the Isolation Precautions Guideline Workgroup, and the Neonatal Intensive Care Unit Workgroup. [Details](#).

Additional Multi-Day Events

- **August 17-August 18 – 10:00am – HHS Meeting: Blood Supply** – The Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability holds a meeting by teleconference to discuss recommendations for the supply chain and data infrastructure that supports the blood industry. [Details](#).

FEATURED WHG ANALYSIS

- **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](#).
- **WHG Overview of Recent Development on Federal Telehealth Policy** – In the Policy Hub Insight Bank [here](#).
- **WHG Chart of the Major Drug Pricing Proposals in the 117th Congress** – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Thurs. (8/12)

- **President Biden** released a [fact sheet](#) detailing the Administration’s priorities for lowering prescription drug costs. [Details](#).

REGULATORY LOOKBACK

Fri. (8/13)

- **The FDA** [amended](#) the EUAs for the Pfizer-BioTech and Moderna COVID-19 vaccines to allow for an additional dose for certain immunocompromised individuals. [Details](#).
- **The NIH** [released](#) findings from a study that demonstrate larger racial disparities in maternal mortality than previously reported. [Details](#).
- **CMS** released a State Health Official (SHO) [letter](#) to assist states in planning for the large volume of actions they will need to take after the end of the COVID-19 PHE. [Details](#).

Thurs. (8/12)

- **The FDA** [issued](#) a request for comments on issues related to the post-approval regulation of PANDAs. Comments are due December 11. [Details](#).

Wed. (8/11)

- **The Department of Agriculture RUS** [announced](#) available grant funding for the establishment of the Emergency Rural Health Care Grant Program. Applications are due October 11. [Details](#).

Tues. (8/10)

- **The FDA [announced](#)** a request for nominees to serve as voting or nonvoting consumer representatives on several agency advisory committees. Nominations are due September 25. [Details.](#)
- **The USPSTF [issued](#)** a final recommendation statement in favor of screening for gestational diabetes mellitus (GDM) in asymptomatic pregnant persons at 24 weeks of gestation or after. [Details.](#)
- **CMS [released](#)** a new report describing enrollment in the health insurance marketplaces during the 2021 Special Enrollment Period (SEP). [Details.](#)

Mon. (8/9)

- **The GAO [released](#)** a report on staffing in Skilled Nursing Facilities. [Details.](#)

COMMENT & APPLICATION DEADLINES

- **August 22:** The FDA [issued](#) a request for applications of patient advocates interested in participating on the Patient Engagement Collaborative. [Details.](#)
- **August 27:** CMS [issued](#) the cycle year (CY) 2022 home health prospective payment system and rate update proposed rule. Comments are due August 27. [Details.](#)
- **August 27:** PCORI [issued](#) a request for comment on its five national priorities for health that will serve as the foundation for developing PCORI's Research Agenda. [Details.](#)
- **August 27:** The FDA [issued](#) draft guidance entitled "Cancer Clinical Trial Eligibility Criteria: Approach to Available Therapy in Non-Curative Settings." [Details.](#)
- **August 30:** HRSA [announced](#) three funding opportunities totaling \$103 million from the American Rescue Plan Act to address mental health needs. [Details.](#)
- **August 30:** HRSA [announced](#) a funding opportunity for the Teaching Health Center Planning and Development Program. [Details.](#)
- **August 30:** HRSA [announced](#) a funding opportunity for Teaching Health Center Planning and Development Technical Assistance. [Details.](#)
- **August 31:** 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.](#)
- **September 13:** CMS [released](#) its calendar year (CY) 2022 Medicare Physician Fee Schedule (MPFS) proposed rule. [Details.](#)
- **September 15:** The NIH Office of Research on Women's Health [requests](#) comments to inform planning of the Women's Health Consensus Conference. [Details.](#)
- **September 17:** The CDC [announced](#) it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee. [Details.](#)
- **September 17:** CMS [released](#) the CY 2022 Hospital Outpatient Prospective Payment System and ASC Payment System Proposed Rule. [Details.](#)
- **September 21:** HRSA [announced](#) a funding opportunity for the teaching Health Center Graduate Medical Education (THCGME) New and Expanded Residency Program. [Details.](#)
- **September 25:** The FDA [announced](#) a request for nominees to serve as voting or nonvoting consumer representatives on several agency advisory committees. [Details](#)
- **September 28:** CMS [issued](#) a proposed rule that would authorize states to make payment to third parties, to facilitate easier access to employee benefits. [Details.](#)
- **October 9:** CMS [issued](#) a proposed rule with rescind the Most Favored Nation (MFN) Model interim final rule. [Details.](#)
- **October 11:** The Department of Agriculture RHS [announced](#) available grant funding for the establishment of the Emergency Rural Health Care Grant Program. [Details.](#)
- **December 11:** The FDA [issued](#) a request for comments on issues related to the post-approval regulation of PANDAs. [Details.](#)

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