

Wynne Health Group Weekly



FRAMING THE WEEK

The House returns for a two-day session to adopt the Senate-approved \$3.5 trillion budget resolution ([S. Con. Res. 14](#)) needed to begin the reconciliation process for enacting many of President Biden and congressional Democrats' legislative priorities. However, with the group of nine moderate Democrats still opposed to the planned sequence of votes (budget resolution first, bipartisan infrastructure package second), House Speaker Nancy Pelosi (D-CA) does not have the votes. Reps. Josh Gottheimer (D-NJ), Carolyn Bourdeaux (D-GA), Ed Case (D-HI), Jim Costa (CA), Henry Cuellar (D-TX), Jared Golden (D-ME), Vicente Gonzalez (D-TX), Kurt Schrader (D-OR) and Filemon Vela (D-TX) reiterated their opposition in an [op-ed](#) yesterday.

Still, the House is likely to move quickly on the budget resolution, especially since progressives (who outnumber moderates) strongly support passing the budget resolution before the infrastructure package. We could see House Democratic leadership provide moderates with some assurances that the House will vote on the bipartisan infrastructure package sooner than planned but after passage of the budget resolution. In her latest [Dear Colleague letter](#) (August 21), Pelosi stated her plan to "enact both the Build Back Better Plan and the bipartisan infrastructure bill before October 1st, when the BIF would go into effect." After this brief session, the House is not scheduled for floor votes until September 20. House Democratic leadership could add another voting day earlier in September.

The House Rules Committee is [meeting](#) this morning to set up floor debate for the continuing resolution, which will likely take place tomorrow, and the bipartisan infrastructure package for later this year (possibly the week of September 20, the earliest date that floor votes are scheduled, if the House sticks to Pelosi's plan). Committees have until September 15 to draft their respective bills that meeting the spending targets outlined in the \$3.5 trillion budget resolution.

Regulatory Update

A number of rules arrived at the Office of Management and Budget (OMB) last week, signaling what the Administration is currently aiming to move forward through its regulatory authorities. First, pursuant to President Biden's recent Executive Order (EO) on promoting competition in the U.S. economy (WHG summary [here](#)), a [proposed rule](#) and [draft guidance](#) from the Food and Drug Administration (FDA) regarding over the counter (OTC) hearing aids appeared at OMB for review. Per the EO, the intent of these actions will be to authorize the sale of hearing aids OTC, bypassing the need for costly specialist evaluations that the Administration says drives the cost of hearing aids currently to an average of \$5,000 per pair.

In addition, the final rule for the Administration's updates to the Affordable Care Act (ACA)'s payment parameters for 2022 and beyond also arrived at OMB for review. In the proposed rule (WHG summary [here](#)), the Centers for Medicare & Medicaid Services (CMS) proposed a number of changes to improve affordability in the individual market. Such proposals include:

- allowing Exchanges to offer a new special enrollment period each month for consumers with low incomes;
- lengthening the current annual open enrollment period for an additional 30 days; and

- reinstating the duties of Exchange Navigators to aid consumers seeking support for purchasing insurance on the Exchanges.

Of final note, the proposed rule included changes to rescind and replace the regulatory text that codified the Trump Administrations 2018 guidance for section 1332 waiver guardrails, which loosened the “statutory guardrails” originally designed to prevent states from using 1332 waivers to weaken individual market coverage options.

Each of these above developments will have to clear OMB review before their release and publication in the *Federal Register*. Their target dates for publication are listed as June 2021, suggesting their release could be in the very near term. We note, however, that the FDA has until approximately November 6 per the EO before it must promulgate regulations concerning OTC hearing aids.

THIS WEEK IN HEALTH POLICY

Mon. (8/23)

- **9:30am – CMS Meeting: Hospital Outpatient Payment** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting by teleconference of the Advisory Panel on Hospital Outpatient Payment to discuss Ambulatory Payment Classifications (APCs). [Details.](#)

Wed. (8/25)

- **10:00am – HHS Meeting: Health Data** – The Department of Health and Human Services (HHS) holds a meeting by teleconference of the National Committee on Vital and Health Statistics Standards Subcommittee to discuss data standards, new Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs), and readiness for administrative and clinical standards. [Details.](#)
- **12:00pm – AHP Briefing: COVID-19 Vaccine** – The Alliance for Health Policy (AHP) holds a virtual briefing titled, “COVID-19 Vaccine Confidence in Geographic Areas of Need.” [Details.](#)
- **2:30pm – BPC Discussion: Paid Leave** – The Bipartisan Policy Center (BPC) holds a virtual discussion titled, “A Paid Leave Conversation with Top Philanthropic, Business, and Advocacy Leaders.” [Details.](#)

Thurs. (8/26)

- **12:00pm – NIH Workshop: Sexual and Gender Minority Health** – The National Institutes of Health holds a Scientific Workshop on Violence and Related Health Outcomes in Sexual and Gender Minority Communities.” [Details.](#)
- **1:00pm – SAMHSA Meeting: Substance Use Disorder** – The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting by teleconference of the Interdepartmental Substance Use Disorders Coordinating Committee to discuss advances to address challenges in substance use disorder. [Details.](#)

Fri. (8/27)

- **1:00pm – SAMHSA Meeting: Serious Mental Illness** – SAMHSA holds a meeting by teleconference of the Interdepartmental Serious Mental Illness Coordinating Committee to review federal efforts related to serious mental illness (SMI) and serious emotional disturbance (SED). [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](#).

REGULATORY LOOKBACK

Fri. (8/20)

- **MACPAC** released an [issue brief](#) examining behavioral health conditions among youth in foster care and access to treatment services. [Details](#).
- **The White House** issued a [memorandum](#) on maximizing assistance to respond to COVID-19 that extends 100% federal funding for eligible emergency costs through the end of the year. [Details](#).
- **The FDA** [issued](#) a safety communication for robotically-assisted surgical (RAS) devices used in mastectomy procedures or in the prevention or treatment of breast cancer. [Details](#).

Thurs. (8/19)

- **HRSA** [seeks comments](#) on draft updates to the [Women's Preventive Services Guidelines](#). Comments are due September 19. [Details](#).
- **HHS OIG** issued a [report](#) detailing an audit of 112 hospitals. [Details](#).

Wed. (8/18)

- **CMS** [announced](#) that it is developing an emergency regulation requiring staff of nursing homes participating in Medicare or Medicaid to be vaccinated against COVID-19. [Details](#).
- **The CDC** [seeks comments](#) on two contraception guidance documents, which provide evidence-based recommendations to assist health care providers when counseling patients on contraceptive choice and use. Comments are due October 18. [Details](#).
- **HHS** [announced](#) it has concluded a booster shot will be needed for individuals to maximize vaccine-induced protection from COVID-19. [Details](#).

Mon. (8/16)

- **The USDA** [released](#) a re-evaluation of the Thrifty Food Plan and outlined the increases in the Supplemental Nutrition Assistance Program (SNAP) that will occur as a result. [Details](#).

COMMENT & APPLICATION DEADLINES

- **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 19:** HRSA [seeks comments](#) on draft updates to the [Women's Preventive Services Guidelines.](#) [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.](#)
- **October 18:** The CDC [seeks comments](#) on two contraception guidance documents, which provide evidence-based recommendations to assist health care providers when counseling patients on contraceptive choice and use. [Details.](#)

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