

Wynne Health Group Weekly



FRAMING THE WEEK

While congressional Democrats continue to negotiate a scaled down version of the Build Back Better Act (BBBA), lawmakers are homing in on other key legislative priorities. This week, committees in both chambers will hold hearings on an array of health policy issues – including mental health, Medicare financing, Food and Drug Administration’s (FDA) user fee programs, public health, and broadband.

Mental Health

Lawmakers from both parties have announced their intent to advance major policy reforms to address the nation’s mental health and substance use crisis. Except for provisions expanding access to mental health care through telehealth for Medicare beneficiaries (e.g., permanently removing geographic and originating site restrictions for mental health [\[P.L. 116-260\]](#), and allowing federally qualified health centers and rural health clinics to furnish mental health care through telehealth [\[P.L. 116-136\]](#)), federal support for mental and behavioral health has mostly been in the form of additional grant funding. For example, the American Rescue Plan Act (ARPA, [P.L. 117-2](#)) provided nearly \$4 billion in funding for programs that support prevention and treatment for mental health and substance use disorders.

Over the last year, many lawmakers have been working on a bipartisan basis on various policy measures to address the ongoing mental health and substance use crisis. These efforts include:

- [Forthcoming bipartisan legislation](#) from the Senate Finance Committee (SFC), spearheaded by Chairman Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID), to enhance behavioral health care in the following areas: (1) strengthening the workforce; (2) increasing integration, coordination, and access to care; (3) ensuring parity between behavioral and physical health care; (4) expanding telehealth; and improving access for children and young people. Sens. Michael Bennet (D-CO) and John Cornyn have also been active on the behavioral health front, having [issued](#) their own white paper and request for information last year to generate ideas for improving mental health care in the U.S.
- Bipartisan Addiction and Mental Health Task Force led by Reps. Annie Kuster (D-NH), Brian Fitzpatrick (R-PA), David Trone (D-MD), and Jaime Herrera Beutler (R-WA). Last September, the Task Force unveiled its [2021 legislative agenda](#) – a compilation of House bills that tackle issues similar to those prioritized by SFC and more.

Three scheduled congressional hearings focused on mental health in February, including two this week, signal that lawmakers are ramping up legislative efforts on this issue. On Wednesday, the [Senate Health, Education, Labor and Pensions \(HELP\) Committee](#) and [House Ways and Means \(W&M\) Committee](#) will hold hearings on mental health and substance use disorders. Both committees will hear policy recommendations from mental health professionals and advocates, including those centered on youth mental health – which will be the focus of the upcoming [SFC hearing](#) with the Surgeon General on February 8.

Medicare Financing

On Wednesday, the Senate Finance Subcommittee on Fiscal Responsibility and Economic Growth will hold a [hearing](#) on the Hospital Insurance (HI) Trust Fund and the future of Medicare financing. According to the [latest Medicare Trustees report](#), the HI Trust Fund (for Medicare Part A), absent congressional action, will become insolvent in 2026.

In the 2021 report, Trustees issued a “Medicare Funding warning” – the fourth consecutive year in which they have done so. This means the President is required to submit proposed legislation to respond to this warning within 15 days after submission of the fiscal year 2023 Budget and that Congress will have to consider the proposed legislation on an expedited basis. However, previous administrations have not followed through on this request. For example, the Obama Administration [viewed](#) the “requirement to submit legislation in response to the Medicare funding warning to be advisory and not binding.” The President’s FY 2023 budget is expected to be released sometime in March, after the President’s State of the Union address on March 1.

The witness panel for the HI Trust Fund hearing includes Michael Chernew, Chair of the Medicare Payment Advisory Commission (MedPAC). The financial future of the Medicare program is among the factors considered by MedPAC in its annual Medicare payment recommendations released every March. Earlier this month, MedPAC voted on 2023 payment recommendations ([WHG summary](#)).

FDA User Fee Programs

On Thursday, the House Energy and Commerce (E&C) Subcommittee on Health will hold a [hearing](#) to discuss draft legislation reauthorizing FDA’s user fee programs for [prescription drugs](#), [generic drugs](#), and [biosimilars](#) with top FDA officials and stakeholders. Given that user fees paid by the pharmaceutical industry make up [46 percent](#) (or \$2.8 billion) of FDA’s budget, the user fee reauthorization bill is considered must-pass legislation. The current user fee authorization is set to expire on September 30, 2022. Legislation reauthorizing user fees for medical devices will not be discussed, because the FDA has not yet submitted its final commitment letter, which was due January 15, 2022. E&C and HELP leaders recently [requested](#) a briefing with FDA and industry representatives on their discussions and expected timeline for a deal.

The hearing may shed light on whether lawmakers plan to attach other legislation to the must-pass legislative vehicle, such as changes to FDA regulation of medical products and pandemic preparedness measures included in Cures 2.0 ([H.R. 6000](#)) to shore up the nation’s public health system. The bipartisan bill – led by E&C Committee members Reps. Diana DeGette (D-CO) and Fred Upton (R-MI), who sit on the Health Subcommittee – includes several provisions that align with goals outlined in the FDA’s [PDUFA VII commitment letter](#). They include increasing the use of real-world evidence in evaluating the safety and effectiveness of breakthrough devices, drugs, and biologicals and providing guidance on the use of digital health technologies in clinical trials.

Public Health

On Wednesday, the House E&C Subcommittee on Consumer Protection and Commerce will hold a [hearing](#) to discuss the COVID-19 Price Gouging Prevention Act ([H.R. 675](#)) – a bill introduced by Rep. Jan Schakowsky (D-IL) that prohibits the sale of “consumer goods and services” during the COVID-19 public health emergency that is “unconscionably excessive.” The definition for covered goods and services is broad and includes food and beverages, personal hygiene products, personal protective equipment, and healthcare services. Cosponsors include E&C Chairman Frank Pallone, Jr. (D-NJ); House Judiciary Committee Chairman Jerry Nadler (D-NY); and Rep. Pramila Jayapal, Chair of the Congressional Progressive Caucus. No House Republicans support the bill.

On Thursday, the House W&M Committee will holding a [hearing](#) on addressing health equity gaps for people with disabilities and chronic conditions. We anticipate lawmakers will discuss home and community-based services (HCBS) benefits under Medicaid. The 10-percentage point Federal Medical Assistance Percentage (FMAP) increase for Medicaid home and community-based services (HCBS) authorized by ARPA expires March 31. BBBA would provide \$130 million in HCBS improving planning grants to states

and provide a six-percentage point increase to the FMAP for states implementing a HCBS improvement program through 2030.

Broadband and Telehealth

Congress will also convene on broadband expansion this week. In a Tuesday hearing, Secretary of Commerce Gina Raimondo will sit as a witness for the Senate Appropriation Committee's inquiry into the Department's [broadband programs](#) included in the Infrastructure Investment and Jobs Act ([P.L. 117-58](#)). Broadband expansion has been seen as an important component for increasing access to telehealth in a more equitable way, as these broadband programs aim to enhance broadband coverage for those in low-income and rural areas, who would then be better able to access care via telehealth platforms.

For many Medicare beneficiaries, however, such changes would have little effect without congressional action to remove existing statutory barriers to telehealth access (i.e., the originating and geographic site restrictions). Most recently on this front, Sens. Brian Schatz (D-HI) and Roger Wicker (R-MS) [led a bipartisan and bicameral group](#) of 45 legislators calling for the inclusion of telehealth expansion language in the forthcoming February must-pass legislation. The letter points to the CONNECT for Health Act ([S. 1512](#)) as the most comprehensive telehealth legislation in Congress. However, language in the latest version of [Cures 2.0](#) would also make a number of telehealth flexibilities during the public health emergency permanent, including waiver of the geographic and originating site restrictions.

THIS WEEK IN HEALTH POLICY

Mon. (1/31)

- **10:30am – NIH Meeting: Infectious Diseases** – The National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases holds a meeting of the National Advisory Allergy and Infectious Diseases Council to hear the Director's report and other updates. [Details](#).
- **3:30pm – HITAC Meeting: Health IT** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to develop the annual report. [Details](#).

Tue. (2/1)

- **9:30am – NIH Meeting: Arthritis, Musculoskeletal and Skin Diseases** – The NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases holds a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council to discuss program policies and issues. [Details](#).
- **11:00am – CDC Meeting: Health Equity** – The Centers for Disease Control and Prevention (CDC) Advisory Committee to the Director holds a meeting to discuss the CDC's current work on health equity and public health system infrastructure. [Details](#).
- **12:00pm – NIH Meeting: Mental Health** – The NIH National Institute of Mental Health holds a meeting of the National Advisory Mental Health Council to hear the Director's report and other updates. [Details](#).
- **2:30pm – Hearing: Broadband Access** – The Senate Committee on Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies holds a hearing titled, "Expanding Broadband Access: Department of Commerce Broadband Programs in the Infrastructure Investment and Jobs Act." [Details](#).

Wed. (2/2)

- **10:00am – Hearing: Mental Health** – The House Ways & Means Committee holds a hearing titled, "American's Mental Health Crisis." [Details](#).
- **10:00am – Hearing: Mental Health** – The Senate Committee on Health, Education, Labor & Pensions (HELP) holds a hearing titled, "Mental Health and Substance Use Disorders: Responding to the Growing Crisis." [Details](#).
- **10:00am – HRSA Meeting: Nursing** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on Nurse Education and Practice to

discuss issues related to the nursing workforce, nursing practice improvement, and nursing education. [Details.](#)

- **10:30am – Hearing: Price Gouging** – The House Committee on Energy & Commerce Subcommittee on Consumer Protection and Commerce holds a hearing titled, “Pandemic Profiteers: Legislation to Stop Corporate Price Gouging.” [Details.](#)
- **1:00pm – NIH Meeting: Neurological Disorders and Stroke** – The NIH National Institute of Neurological Disorders and Stroke holds a meeting of the National Advisory Neurological Disorders and Stroke Advisory Committee to hear the Director’s report and other updates. [Details.](#)
- **2:30pm – Hearing: Medicare Financing** – The Senate Committee on Finance Subcommittee on Fiscal Responsibility and Economic Growth holds a hearing titled, “The Hospital Insurance Trust Fund and the Future of Medicare Financing.” [Details.](#)

Thurs. (2/3)

- **9:30am – NIH Meeting: General Medicine** – The NIH National Institute of General Medicine holds a meeting of the National Advisory General Medicine Council to hear the Director’s report and other updates. [Details.](#)
- **10:30am – Hearing: FDA User Fee Reauthorization** – The House Committee on Energy & Commerce Subcommittee on Health holds a hearing titled, “FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics.” [Details.](#)
- **12:00pm – CMS Meeting: Outreach and Education** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting of the Advisory Panel on Outreach and Education to discuss program priorities. [Details.](#)
- **2:00pm – Hearing: Disabilities and Chronic Conditions** – The House Ways & Means Committee Health Subcommittee holds a hearing titled, “Bridging Health Equity Gaps for People With Disabilities and Chronic Conditions.” [Details.](#)

Fri. (2/4)

- **11:00am – NIH Meeting: Minority Health** – The NIH National Institute on Minority Health and Health Disparities holds a meeting of the National Advisory on Minority Health and Health Disparities to hear the Director’s report and other updates. [Details.](#)
- **12:00pm – AHP Panel Discussion: FDA User Fees** – The Alliance for Health Policy (AHP) holds a panel discussion titled, “Health Policy Roundup: Background on FDA User Fee Programs.” [Details.](#)

Additional Multi-Day Events

- **February 2-February 3 – 12:00pm – ONC Meeting: Annual Meeting** – The Office of the National Coordinator for Health Information Technology (ONC) holds the 2022 Annual Meeting to present on the Trusted Exchange Framework and Common Agreement, information sharing, and other topics. [Details.](#)
- **February 3-February 4: HHS Meeting: AA and NHPI Issues** – The Department of Health and Human Services (HHS) holds the first meeting of the President’s Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders (AA NHPI) to hear briefing on immediate systemic challenges facing AA and NHPI communities. [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

Tues. (1/25)

- **The Senate HELP Committee** [released](#) a discussion draft of the highly anticipated PREVENT Pandemics Act. [Details](#).

REGULATORY LOOKBACK

Fri. (1/28)

- **CMS** [announced](#) that they will commit a total of \$49.4 million in funding to connect more eligible children, parents, and pregnant individuals to health care coverage through Medicaid and CHIP. [Details](#).
- **CMS** [announced](#) new occurrence span and revenue codes for Hospital-at-Home services to identify and track inpatient claims submitted for the Acute Hospital Care At Home program. [Details](#).
- **The FDA** [issued](#) final guidance on principles for premarket review of combination products. [Details](#).
- **The GAO** [released](#) the ninth in a series of reports on the government response to the COVID-19 pandemic with five new recommendations. [Details](#).
- **CMS** [published](#) a [home infusion therapy](#) (HIT) monitoring report. [Details](#).
- **CMS** is seeking [nominations](#) for a TEP and Clinician Committee related to the development of a Patient-Reported Outcome Performance Measure (PRO-PM) to assess preventive screenings for cancers. Nominations are due February 18. [Details](#).
- **CMS** [announced](#) that 14.5 million people have signed up for 2022 health care coverage through Federal or State-Based Marketplaces during the Marketplace Open Enrollment Period. [Details](#).

Thurs. (1/27)

- **The FDA** [issued](#) a request for nominations for voting and nonvoting consumer representatives to serve on advisory committees and panels. Nominations are due March 14. [Details](#).

Wed. (1/26)

- **The Advisory Council on Alzheimer's Research, Care, and Services** [discussed](#) programs impacting people with Alzheimer's disease and related dementias. [Details](#).

Tues. (1/25)

- **The FDA** [issued](#) final guidance on incorporating patient engagement data in medical device development and clinical investigations. [Details](#).
- **The FDA** [issued](#) integrating patient-reported outcome instruments for medical device evaluation. [Details](#).

Mon. (1/24)

- **HHS** [launched](#) an HHS-wide Task Force on Reproductive Healthcare Access to address sexual and reproductive health. [Details](#).
- **The USPSTF** [announced](#) it is seeking nominations for new members to begin a four-year term in January 2023. [Details](#).

COMMENT & APPLICATION DEADLINES

- **February 2:** The FDA [issued](#) draft guidance on content of premarket submissions for device software functions. [Details.](#)
- **February 10:** CMS [proposed](#) a NCD to cover FDA approved monoclonal antibodies that target amyloid for the treatment of Alzheimer’s disease through coverage with evidence development. [Details.](#)
- **February 11:** The GAO [released](#) a request for nominations for appointments to MedPAC. [Details.](#)
- **February 15:** The FDA [issued](#) a request for nominations for voting members to serve on the Medical Devices Advisory Committee device panels. [Details.](#)
- **February 18:** CMS is seeking [nominations](#) for a TEP and Clinician Committee related to the development of a Patient-Reported Outcome Performance Measure (PRO-PM) to assess preventive screenings for cancers. [Details.](#)
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- **February 22:** The USDA [announced](#) \$1.15 billion in grant funding for rural broadband access. [Details.](#)
- **February 28:** The CDC [announced](#) it is seeking nominations for individuals to serve as members of the Advisory Committee on Breast Cancer in Young Women. [Details.](#)
- **March 7:** CMS [released](#) the Contract Year (CY) 2023 Policy and Technical Changes to Medicare Advantage (MA) and Part D proposed rule. [Details.](#)
- **March 10:** The ACL released two Innovations in Nutrition Programs and Services funding opportunities ([here](#) and [here](#)) to support research and programs improving nutrition services programs for aging adults. [Details.](#)
- **March 11:** The FDA [issued](#) draft guidance on notifying the agency of a permanent discontinuance or interruption in manufacturing of a device. [Details.](#)
- **March 14:** The FDA [issued](#) a request for nominations for voting and nonvoting consumer representatives to serve on advisory committees and panels. [Details.](#)
- **March 15:** AHRQ [released](#) a solicitation for nominations for members of the U.S. Preventive Services Task Force (USPSTF). [Details.](#)
- **March 18:** HRSA [released](#) a notice of funding opportunity (NOFO) for the Rural Public Health Workforce Training Network (RPHWTN) Program. [Details.](#)
- **March 23:** The **ONC** [issued](#) an RFI seeking stakeholder input on whether to adopt additional standards, implementation specifications, and certification criteria regarding electronic prior authorization. [Details.](#)
- **April 19:** HHS [announced](#) the availability of \$13 million to support increased access to behavioral health care services, including treatment for substance use disorder, in rural communities. [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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