

Wynne Health Group Weekly



FRAMING THE WEEK

Today, President Biden will sign the **Infrastructure Investments and Jobs Act (H.R. 3684)** into law. The bipartisan infrastructure deal provides \$65 billion for broadband infrastructure to expand access to reliable high-speed internet, which is widely recognized as a social determinant of health (see our recent [Issue Brief](#) on Medicare telehealth coverage and health equity for a discussion on the intersection of broadband access and health equity). The bill will also create new grant programs to promote digital equity and help households with lower incomes access internet. In addition, the bill requires internet providers to display a “Broadband Nutrition Label” to help families comparison shop and promote competition in areas with inadequate service.

The House may vote on the **Build Back Better Act (BBBA, H.R. 5376)** as soon as this week. House Democrats are waiting on the Congressional Budget Office (CBO) to deliver cost estimates on the health-related provisions (e.g., prescription drug pricing, ACA Marketplace coverage, Medicare hearing benefits), among others included in the Ways and Means, Energy and Commerce, and Education and Labor titles. The CBO score may not be released until Thursday, which could push the vote to the weekend or even early next week. Once in the Senate, BBBA is likely to undergo changes to comply with the Byrd Rule and ensure the Democratic caucus is voting in lockstep. “Timing of consideration of the BBBA in the Senate will largely depend on when the House sends us the bill and when CBO finalizes their scores for all of the committees, which are needed to complete the “Byrd Bath” process, said Senate Majority Leader Chuck Schumer (D-NY) in a [Dear Colleague letter](#) sent yesterday.

Schumer also acknowledged that Congress is unlikely to finalize a **fiscal year (FY) 2022 appropriations spending bill** before December 3, the expiration of the current continuing resolution (CR). The new funding deadline remains to be seen, as Democrats push for a late December 2021 timeframe while Republicans prefer February or March 2022. Lawmakers will also need to address the **debt ceiling**. The date by which Congress must take action is unclear (and referred to as “X date” in Schumer’s letter) since enactment of the bipartisan infrastructure bill is expected to move the date.

Medicare Premiums, Deductibles, and Co-insurance Amounts for 2022

Late last Friday, the Centers for Medicare and Medicaid Services (CMS) announced the premiums, deductibles and coinsurance amounts for Medicare Parts A and B, along with the Part D income-related monthly adjustment amounts, for Calendar Year (CY) 2022 ([Part A notice](#); [Part B notice](#); [fact sheet](#); [press release](#)).

For 2022, the standard Part B monthly premium is set to jump from \$148.50 in 2021 to \$170.10 in 2022 – one of [the largest increases](#) in the program’s history. CMS cites its need to “maintain a contingency reserve for unanticipated increases in health care spending, particularly certain drug costs” – specifically citing the new Alzheimer’s drug (Aduhelm), which accounts for roughly half of the premium increase – as reason for the unprecedented hike in premiums. CMS’ [proposed National Coverage Decision \(NCD\)](#) on Aduhelm and other drugs in this category is pending review, with a proposed decision expected in January, followed by a final decision in April ([details](#)). Other factors contributing to the Part B premium increase include spending increases driven, in large part, by the ongoing COVID-19 pandemic.

For Part A, nearly all (99 percent) of Medicare beneficiaries do not have a Part A premium. The Part A inpatient hospital deductible, however, is set to increase from \$1,484 in 2021 to \$1,556 in 2022.

Additional Regulatory Updates

Last week, the Office of Management and Budget (OMB) [cleared](#) a CMS final rule on [proposed delays](#) to the effective date for when drug manufacturers would be allowed to report multiple best prices connected to a value-based arrangement for a drug. CMS also proposed to delay the effective date for including U.S. territories in the definition of “States” for the Medicaid Drug Rebate Program. Such effective dates were initially finalized under the Trump Administration, though CMS proposed these delays in May 2021 to allow stakeholders more time to make the complex changes needed to implement such changes, especially amidst the ongoing pandemic.

In addition, two key health insurance rules arrived at OMB for review last week. This includes the [proposed rule](#) for the Notice of Benefit and Payment Parameters for 2023. OMB also received an additional [final rule](#) for its Contract Year (CY) 2022 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and PACE. In its [previous final rule](#) for the CY 2022 Policy and Technical Changes, CMS noted it left a number of provisions unfinalized which it stated could be addressed in subsequent rulemaking, including:

- Maximum out-of-pocket limits for Medicare Parts A and B services; and
- Service category cost sharing limits for Medicare Parts A and B services and per member per month actuarial equivalence cost sharing.

THIS WEEK IN HEALTH POLICY

Mon. (11/15)

- **2:00pm – USCC Meeting: Employers and COVID-19 Vaccines** – The US Chamber of Commerce (USCC) holds a meeting titled, “The Role of Employers: Promoting COVID-19 Vaccines and Implementing Mandates.” [Details](#).

Tue. (11/16)

- **9:00am – FDA Meeting: GDUFA** – The Food and Drug Administration (FDA) holds a meeting to discuss proposed recommendations for the reauthorization of the Generic Drug User Fee Amendments (GDUFA) for fiscal years 2023 through 2027. [Details](#).
- **11:00 am – HITAC Meeting: Annual Report** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Work Group. [Details](#).

Wed. (11/17)

- **10:00am – AHRQ Meeting: National Advisory Council** – The Agency for Healthcare Research and Quality (AHRQ) holds a meeting of the National Advisory Council for Healthcare Research and Quality to discuss updates on quality measurement. [Details](#).
- **10:30am – Hearing: COVID-19 Vaccines** – The House Appropriations Committee Labor, Health and Human Services, Education, and Related Agencies Subcommittee holds a hearing titled, “US Role in Global COVID-19 Vaccine Equity.” [Details](#).
- **12:00pm – AHP Briefing: Health Care and Homelessness** – The Alliance for Health Policy holds a briefing titled, “Improving Health Care for People Experiencing Homelessness.” [Details](#).

Thurs. (11/18)

- **10:00am – FDA Meeting: Toxic Element Exposure and Nutrition** – The FDA holds a meeting titled, “Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages.” [Details](#).
- **12:00pm – BPC Webinar: Dual Eligibles** – The Bipartisan Policy Center (BPC) holds a webinar titled, “Integrating Care for Dual Eligible Individuals.” [Details](#).

- **1:00pm – NIH Meeting: Autoimmune Diseases** – The National Institutes of Health (NIH) holds a meeting of the National Institute of Arthritis and Musculoskeletal and Skin Diseases to discuss a report from the Autoimmune and Immune-Mediated Diseases (AMP-AIM) Workgroup. [Details.](#)
- **2:30pm – CDC Briefing: Protecting Mental Health of Health Care Workforce** – The CDC’s DC’s National Institute for Occupational Safety and Health (NIOSH) hosts a virtual event with NIOSH Director Dr. John Howard, Surgeon General Dr. Vivek Murthy, and other national experts from labor and medicine on the mental health of the nation’s critical health workforce. [Details.](#)

Fri. (11/19)

- **9:30am – FDA Meeting: Disease Progression** – The FDA Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research hold a public workshop titled, “Best Practices for Development and Application of Disease Progression Models.” [Details.](#)

Additional Multi-Day Events

- **November 15 and November 17 – 1:00pm – HHS Meeting: HIV/AIDS** – The Department of Health and Human Services (HHS) holds a meeting of the Presidential Advisory Council on HIV/AIDS to discuss updates and recommendations related to HIV/AIDS. [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. (11/9)

- **MedPAC [convened](#)** virtually for Day Two of its November 2021 public meeting and held sessions on ambulatory settings payment rates, and Part D for residents in long-term facilities. All WHG session summaries are available on Policy Hub [here.](#)

Mon. (11/8)

- **MedPAC [convened](#)** virtually for Day One of its November 2021 public meeting and held sessions on accountable care organization benchmarks, safety-net provider payments, and telehealth. All WHG session summaries are available on Policy Hub [here.](#)

REGULATORY LOOKBACK

Fri. (11/12)

- **CMS [released](#)** its final rule formally repealing the Medicare Coverage of Innovative Technology (MCIT) final rule. [Details.](#)

Mon. (11/8)

- **The USPSTF** [published](#) an article that discusses the impact of systemic racism on health and details actions that the Task Force is taking to promote antiracism and health equity in preventive care. [Details](#).

COMMENT & APPLICATION DEADLINES

- **November 19:** HHS [announced](#) that it is proposing to repeal two final rules from the Trump Administration era, including the HHS Good Guidance Practices and the HHS Transparency and Fairness in Civil Administrative Enforcement Actions. [Details](#).
- **November 26:** NIOSH [released](#) an RFI on evidence-based workplace and occupational safety and health interventions to prevent stress, support stress reduction, and foster positive mental health within the health workforce. [Details](#).
- **November 26:** CMS [announced](#) a request for comments on two draft measures. [Details](#).
- **November 27:** HRSA [announced](#) a request for comments on two updated draft recommendations in the [Women's Preventive Services Guidelines](#). Comments are due November 27. [Details](#).
- **November 28:** The FDA [issued](#) draft guidance on the electronic submission template for medical device 510(k) submissions. [Details](#).
- **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](#).
- **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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