

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

This week, President Biden will sign the **Infrastructure Investments and Jobs Act (H.R. 3684)** into law. Meanwhile, House Democrats are waiting for the Congressional Budget Office (CBO) to score the **Build Back Better Act (BBBA, H.R. 5376)**. Five moderate Democrats [vowed](#) to vote for the BBBA “in its current form” if the CBO score aligns with the estimates presented by the White House. House Speaker Nancy Pelosi (D-CA) [plans](#) to hold a vote on BBBA next week, though it is unclear if the CBO score and White House estimates will align or if the CBO score will even be ready.

Last week’s updated legislative text for the BBBA also featured the Democrats’ agreed upon approach for addressing **drug prices** ([WHG summary](#)), including the following provisions:

- Authorize the Department of Health and Human Services (HHS) Secretary to negotiate the cost of single-source Part B and Part D drugs without competition directly with drug manufacturers;
- Impose penalties on drug manufacturers if they increase prices faster than the rate of inflation;
- Redesign the Medicare Part D benefit to lower out-of-pocket costs for beneficiaries and offset greater financial liability onto insurers and manufacturers; and
- Repeal the Trump Administration’s “rebate rule.”

*Vaccine Mandate*

A three-judge panel from the U.S. Court of Appeals for the Fifth Circuit in Louisiana issued a [stay](#) on last week’s **large employer mandate on COVID-19 vaccines** by the Occupational Safety and Health Administration (OSHA) (full summary [here](#)). Opponents of the mandate argue it is unconstitutional and an overstep of regulatory authority, stating Congress did not grant OSHA the authority to “end pandemics.”

The injunction is temporary pending further action by the court. OSHA and the petitioners of the mandate will file two respective briefs, after which the court will review them and determine whether a permanent injunction is warranted or whether to lift the temporary injunction. If the court rules in favor of a permanent injunction, OSHA may take the case to the Supreme Court.

*MedPAC*

The Medicare Payment Advisory Commission (MedPAC) convenes today and tomorrow to discuss various payment policies:

- [Instituting site-neutral payments](#) for certain services delivered in ambulatory settings – which include physician offices, ambulatory surgical centers (ASCs), and hospital outpatient departments – to lower Medicare spending and beneficiary cost sharing;
- [Supporting safety-net providers](#), who rely primarily on Medicare and Medicaid revenues, with additional resources for labor, technology, and other needs; and
- [Balancing benchmark incentives](#) for accountable care organizations (ACOs).

Additionally, commissioners will examine [Part D coverage for nursing home residents](#). While they account for three percent of Part D enrollees, prescriptions for nursing home residents make up five percent of spending before rebates and postsale discounts, according to MedPAC. Commissioners will also discuss [new information on telehealth use](#) and clinicians' and patients' experiences with telehealth during the public health emergency. In the [March 2021 Report to Congress](#), MedPAC recommended a time-limited period in which Medicare coverage of telehealth remains broadly available for beneficiaries, allowing policymakers additional time to examine the impact of telehealth on access, quality, and cost. Along these lines, MedPAC specifically suggests that Medicare should temporarily:

- Pay for specified telehealth services provided to all beneficiaries regardless of their location;
- Cover selected telehealth services in addition to services covered before the PHE if there is potential for clinical benefit; and
- Cover certain telehealth services when they are provided through an audio-only interaction if there is potential for clinical benefit.

## THIS WEEK IN HEALTH POLICY

### Mon. (11/8)

- **11:15am-5:00pm – MedPAC Meeting** – The Medicare Payment Advisory Commission to discuss Medicare issues and policy questions. [Details.](#)
- **12:00pm – NIH Meeting: Hypoglycemia** – The National Institutes of Health (NIH) holds a meeting of the Diabetes Mellitus Interagency Coordinating Committee to discuss “Evolving Concepts in the Assessment and Management of Hypoglycemia.” [Details.](#)

### Tue. (11/9)

- **10:00am-12:30pm – MedPAC Meeting** – The Medicare Payment Advisory Commission to discuss Medicare issues and policy questions. [Details.](#)
- **12:00pm – AHP Summit: Cancer Care** – The Alliance for Health Policy (AHP) holds a summit titled, “Advancing Patient-Centered Cancer Care.” [Details.](#)

### Wed. (11/10)

- **9:30am – ONC Meeting: Health IT** – The Office of the National Coordinator for Health Information Technology (ONC) convenes a meeting of the Health IT Advisory committee. [Details.](#)
- **11:00am – NIH Meeting: Cancer** – The NIH National Cancer Institute holds a meeting of the Clinical Trials and Translational Research Advisory Committee to have a strategic discussion of clinical and translational research goals. [Details.](#)
- **12:00pm – Hearing: Hunger and Veterans** – The House Agriculture Committee Nutrition, Oversight, and Department Operations Subcommittee holds a hearing titled, “Hunger Among Veterans and Servicemembers: Understanding the Problem and Evaluating Solutions.” [Details.](#)

### Thurs. (11/11)

Veterans Day

### Additional Multi-Day Events

- **November 9-November 10 – 9:00am – HRSA Meeting: National Health Service Corps** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Committee on the national Health Service Corps to identify program priorities and propose policy changes. [Details.](#)
- **November 9-November 10 – 10:00am – HRSA Meeting: Heritable Disorders**– HRSA holds a meeting of the Advisory Committee on Heritable Disorders in Newborns and Children to vote on updates to the evidence-based review and decision-making process. [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 117<sup>th</sup> Congress; Side-by-Side Comparison** – In the Policy Hub Insight Bank [here](#).

## CONGRESSIONAL LOOKBACK

### Wed. (11/3)

- **The House Rules Committee** [released](#) updated legislative text for the Build Back Better Act, most notably including language for the Democrats' agreed upon approach for addressing drug prices. [Details](#).

### Tues. (11/2)

- **The Senate Subcommittee on Food and Nutrition** [held](#) a hearing to discuss the current state of nutrition in America. [Details](#).

## REGULATORY LOOKBACK

### Fri. (11/5)

- **HHS** [seeks](#) public comment and nominations to inform the development of the Physical Activity Guidelines (PAG) Midcourse Report on older adults. Comments are due December 8. [Details](#).
- **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. Comments are due December 6. [Details](#).

### Thurs. (11/4)

- **CMS** issued an [interim final rule with comment period](#) (IFC) requiring COVID-19 vaccination for most staff members at health care facilities that participate in Medicare or Medicaid. [Details](#).
- **OSHA** issued an [emergency temporary standard](#) (ETS) to minimize the risk of COVID-19 transmission in the workplace. [Details](#).
- **CMS** released an updated [fact sheet](#) summarizing coverage, cost-sharing, and reimbursement for COVID-19 vaccine administration under Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program (BHP). [Details](#).
- **MCAPAC** published an [issue brief](#) on the use and oversight of upper payment limit (UPL) supplemental payments for providers. [Details](#).

### Wed. (11/3)

- **The FDA** [issued](#) draft guidance on content of premarket submissions for device software functions. Comments are due February 2. [Details](#).

### Tues. (11/2)

- **CMS** [released](#) the calendar year (CY) 2022 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical System (ASC) Payment System Final Rule. [Details](#).
- **CMS** [released](#) its CY 2022 Medicare Physician Fee Schedule (MPFS) final rule. [Details](#).
- **CMS** [released](#) the CY 2022 home health prospective payment system and rate update final rule. [Details](#).

## Mon. (11/1)

- **ASPE** [published](#) a report detailing how the COVID-19 pandemic impacted rates of insurance coverage in the U.S. [Details](#).

## **COMMENT & APPLICATION DEADLINES**

- **November 1:** SFC Chairman Wyden and Ranking Member Crapo [released](#) an RFI seeking input from stakeholders on legislative proposals to improve access to mental health and SUD services. [Details](#).
- **November 7:** HHS [released](#) a draft of its Strategic Plan for fiscal years (FY) 2022-2026. [Details](#).
- **November 7:** The FDA [announced](#) a request for nominations for members to serve on the Tobacco Products Scientific Advisory Committee. [Details](#).
- **November 11:** AHRQ [released](#) a request for supplemental evidence and data submission to inform its review on Telehealth for Women. [Details](#).
- **November 12:** AHRQ released a request for information (RFI) on [telehealth during COVID-19](#). [Details](#).
- **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](#).

WHG Contacts for Inquiries

Alyssa Llamas: [alyssa@wynnehealth.com](mailto:alyssa@wynnehealth.com); (562) 207-8807

Billy Wynne: [billy@wynnehealth.com](mailto:billy@wynnehealth.com); (202) 309-0796

Erin Slifer: [erin@wynnehealth.com](mailto:erin@wynnehealth.com); (410) 984-4552

