

Wynne Health Group Weekly



FRAMING THE WEEK

Infrastructure and Budget Reconciliation

House Democrats will soon face a hard deadline to pass the bipartisan [Infrastructure Investment and Jobs Act](#). The 30-day surface transportation funding extension ([P.L. 117-44](#)) expires on October 31. Absent congressional action, the Department of Transportation would be forced to furlough thousands of workers. House Speaker Nancy Pelosi (D-CA) plans to hold a vote of the bipartisan infrastructure package this Wednesday or Thursday.

Whether the House holds a vote and passes the package is contingent on congressional Democrats (i.e., moderates and progressives) reaching a deal on a trimmed down budget reconciliation package. Lawmakers have not yet agreed on a price tag, though it seems likely to land around \$2 trillion. Expanding Medicare to cover dental, vision, and hearing benefits is at risk of getting cut completely. Democrats are considering temporary solutions for the Medicaid expansion coverage gap and ACA premium tax credits (possibly covering people in the Medicaid gap for three or four years and extending premium tax credits for three years). As for prescription drug pricing, a narrower version of Medicare drug price negotiation may be included ([WHG summary](#) of the most pertinent drug pricing proposal provisions).

Caregiver and Workforce Legislation

Tomorrow, the House Energy and Commerce Subcommittee on Health will convene a [hearing](#) to discuss a slate of bills aimed at bolstering the health care workforce through new grant programs. They focus on the following: caregivers of people living with Alzheimer's disease and other dementias, allied health professions (e.g., physical therapy, occupational therapy), behavioral health professionals, community health workers, public health professionals, and infectious disease specialists. The bills have bipartisan support, unless otherwise noted.

- Alzheimer's Caregiver Support Act ([H.R. 1474](#))
- Dr. Lorna Breen Health Care Provider Protection Act ([H.R. 1667](#))
- Public Health Workforce Loan Repayment Act of 2021 ([H.R. 3297](#))
- Allied Health Workforce Diversity Act of 2021 ([H.R. 3320](#))
- Helping Enable Access to Lifesaving Services (HEALS) Act ([H.R. 5583](#)) (*Republican-support only*)
- Enhancing Community Health Workforce Act ([H.R. 5594](#)) (*Republican-support only*)
- Bolstering Infectious Outbreaks (BIO) Preparedness Workforce Act of 2021 ([H.R. 5602](#))

COVID-19 Vaccine

Tomorrow, the Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee will [review](#) a request from Pfizer to amend its emergency use authorization to all the use of its COVID-19 vaccine in children 5 through 11 years of age. Pfizer's COVID-19 vaccine appears safe and over 90 percent effective in young kids, according to the [company's briefing document](#). The Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) is scheduled to meet on November 2 and 3 to make recommendations on the use of the Pfizer vaccine in children ages 5 through 11.

In anticipation of the vaccines, the White House unveiled its [plan](#) for ensuring newly eligible kids are able to quickly receive the COVID-19 vaccination. The Administration says this plan will ensure convenient and equitable access for children and would "rely heavily" on the coordination of states, Tribes, and territories. The CDC also released a [Pediatric COVID-19 Vaccination Operational Planning Guide](#) to help with ordering supplies, enrolling an adequate network of providers, reporting and monitoring, and communications.

As for COVID-19 vaccinations among adults, the Occupational Safety and Health Administration (OSHA) may issue the [emergency temporary standard](#) (ETS) requiring large employers (with 100+ employees) to mandate COVID-19 vaccinations or weekly testing as soon as this week. The ETS has been under review at the Office of Management and Budget (OMB) since October 12. Tomorrow, the House Education and Labor Committee will convene a joint subcommittee [hearing](#) on vaccine requirements and employee accommodations.

MACPAC

Later this week, the Medicaid and CHIP Payment and Access Commission will [meet](#) to discuss various priorities for their upcoming reports, including:

- Recommendations aimed at increasing vaccine coverage for Medicaid-enrolled adults; and
- Additional recommendations to improve integration of care for dually eligible beneficiaries (as a follow-up to [design consideration for a unified program](#) and [strategies for state contracts with dual eligible special needs plans](#)).

Commissioners will also discuss disproportionate share hospital allotments to states, workforce for home- and community-based services, and their response to the Senate Finance Committee (SFC) request for information on behavioral priorities, among [other topics](#). Last month, SFC Chairman Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-WY) issued a bipartisan [request for information](#) on legislative proposals to improve access to behavioral health services. Comments are due November 1.

THIS WEEK IN HEALTH POLICY

Mon. (10/25)

- **1:00pm – ASPE Meeting: Alzheimer's Disease** – The Office of the Assistant Secretary for Planning and Evaluation (ASPE) holds a meeting of the Advisory Council on Alzheimer's Research, Care, and Services to hear presentations about ways to support and strengthen the long-term services and supports direct care workforce. [Details](#).

Tue. (10/26)

- **8:30am – FDA Meeting: COVID-19 Vaccines for Children** – The Food and Drug Administration (FDA) holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss a request to amend Pfizer's Emergency Use Authorization for administration of their vaccine to children ages 5 to 11. [Details](#).

- **10:00am – NQF Meeting: Health Equity** – The National Quality Forum (NQF) holds a meeting of the Measure Application Partnership Health Equity Advisory Group to provide input on measures under consideration with the goal of reducing differences linked with social determinants of health. [Details.](#)
- **10:15am – Hearing: Vaccine Requirements** – The House Education & Labor Workforce Protections and Civil Rights and Human Services Subcommittees hold a joint hearing titled, “Protecting Lives and Livelihoods: Vaccine Requirements and Employee Accommodations.” [Details.](#)
- **10:30am – Hearing: Caregiver Legislation** – The House Committee on Energy & Commerce Subcommittee on Health holds a hearing titled, “Caring for America: Legislation to Support Patients, Caregivers, and Providers” to discuss 7 bills related to caregivers. [Details.](#)
- **11:30am – BPC Discussion: HCBS** – The Bipartisan Policy Center (BPC) holds a discussion titled, “Streamlining and Simplifying State HCBS Authorities.” [Details.](#)
- **2:00pm – Hearing: VA Electronic Health Record** – The House Veteran’s Affairs Subcommittee on Technology Modernization holds a hearing titled, “Next Steps: Examining Plans for the Continuation of the Department of Veterans Affairs Electronic Health Record Modernization Program.” [Details.](#)

Wed. (10/27)

- **1:00pm – SAMHSA Meeting: Serious Mental Illness** – The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee to discuss issues related to serious mental illness. [Details.](#)

Thurs. (10/28)

- **12:00pm – CDC Meeting: Healthcare Infection** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Healthcare Infection Control Practices Advisory Committee to discuss topics related to infection control and antimicrobial resistance. [Details.](#)
- **12:00pm – NIH Meeting: AIDS Research** – The National Institutes of Health (NIH) Office of AIDS Research holds a meeting of the advisory council to hear updates from the HIV Clinical Guidelines Working Groups and other HIV-related advisory councils. [Details.](#)
- **1:00pm – NQF Meeting: Rural Health** – NQF holds a meeting of the Measure Application Partnership Rural Health Advisory Group to develop rural-relevant measures. [Details.](#)
- **1:00pm – OMH Meeting: COVID-19** – The Office of Minority Health (OMH) holds a meeting of the COVID-19 Health Equity Task Force to present and vote on the Final Report. [Details.](#)

Fri. (10/29)

- **12:00pm – AHP Briefing: Maternal Mental Health** – The Alliance for Health Policy (AHP) holds a briefing titled, “Policy Options to Advance Mental Health Care During Pregnancy.” [Details.](#)

Additional Multi-Day Events

- **October 25-October 27 – HRSA Meeting: Rural Health** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Committee on Rural Health and Human Services to advise the Secretary of Health and Human Services on health care challenges in rural America. [Details.](#)
- **October 28-October 29 – Meeting: MACPAC** – The Medicaid and CHIP Payment and Access Commission (MACPAC) holds a public meeting to discuss Medicaid and CHIP payment and policy issues. [Details.](#)

FEATURED WHG ANALYSIS

- ***NEW* 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

Wed. (10/20)

- **The SFC** held a [hearing](#) to discuss the role of the federal government in health insurance. [Details](#).
- **The House E&C Health Subcommittee** convened a legislative [hearing](#) to examine twelve bills addressing issues affecting children and families. [Details](#).

REGULATORY LOOKBACK

Thurs. (10/21)

- **CMS** released an [informational bulletin](#) to provide best practices and considerations to states on care coordination provided by out-of-state providers for children with medically complex conditions. [Details](#).
- **The FDA** [issued](#) draft guidance on data standards for drug and biological product submissions containing real-world data (RWD). Comments are due January 21. [Details](#).

Wed. (10/20)

- **The White House** [released](#) its plan for ensuring that children ages 5-11 are able to quickly receive the COVID-19 vaccination if it is authorized for use in this population. [Details](#).
- **CMMI** [released](#) its highly anticipated white paper on its refreshed strategic direction for the next decade. [Details](#).

Tues. (10/19)

- **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. Comments are due November 19. [Details](#).
- **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. Comments are due January 18. [Details](#).

COMMENT & APPLICATION DEADLINES

- **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](#).
- **October 18:** HHS released a [notice of proposed rulemaking](#) (NPRM) that implements reporting requirements and enforcement provisions of Title I (No Surprises Act) and Title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021 (CAA). [Details](#).
- **October 22:** The U.S. Citizenship and Immigration Services [announced](#) that it is seeking written comments and related materials regarding public charge inadmissibility. [Details](#).
- **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 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 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 13:** AHRQ released a request for information (RFI) on [climate change](#). [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](#).

WHG Contacts for Inquiries

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

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

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

