

Wynne Health Group Weekly



FRAMING THE WEEK

As Democrats seek to shrink their budget reconciliation package, their strategy on how to trim the health care measures is unclear. The question for Democrats remains: include fewer things with longer authorizations or vice versa? The size of the package will also depend on the savings generated from lowering prescription drug prices.

Medicare and Medicaid

We will see the debate over adding dental, hearing, and vision benefits to Medicare or addressing the Medicaid expansion coverage gap play out in the Senate Finance Committee (SFC) this week. SFC will hold a [hearing](#) on Wednesday to discuss the “current and future role” of Medicare and Medicaid. The witness panel features experts and advocates from the Urban Institute, The Commonwealth Fund, American Action Forum, and Families USA.

Cures 2.0

Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) may formally introduce Cures 2.0 as soon as this week. The duo unveiled a [discussion draft](#) in June that addressed the following areas: telehealth access, coverage and reimbursement for new medical products at the Centers for Medicare and Medicaid Services (CMS), drug regulation at the Food and Drug Administration (FDA), and public health capacity and pandemic preparedness ([WHG summary](#)). Most notably, the bipartisan bill is expected to authorize the creation of the Advanced Research Projects Agency for Health (ARPA-H) as proposed by President Biden. An authorizing provision for ARPA-H has been removed from the budget reconciliation package. Back in July, the House passed appropriations legislation providing \$3 billion in startup costs for ARPA-H.

Public Health

On Wednesday, the House Energy and Commerce Subcommittee will [examine](#) a slate of bipartisan bills (with the exception of one noted below) aimed at advancing scientific research, strengthening public health programs, and improving access to health care services.

- Gabriella Miller Kids First Research Act 2.0 ([H.R. 623](#))
- Cardiovascular Advances in Research and Opportunities Legacy Act ([H.R. 1193](#))
- Increasing Access to Quality Cardiac Rehabilitation Care Act of 2021 ([H.R. 1956](#))
- Children and Media Research Advancement (CAMRA) Act ([H.R. 2161](#))
- Katherine's Law for Lung Cancer Early Detection and Survival Act of 2021 ([H.R. 3749](#)) (*Democratic support only*)
- Oral Health Literacy and Awareness Act of 2021 ([H.R. 4555](#))

- Protecting Access to Lifesaving Screenings (PALS) Act of 2021 ([H.R. 4612](#))
- Stillbirth Health Improvement and Education (SHINE) for Autumn Act of 2021 ([H.R. 5487](#))
- Improving the Health of Children Act ([H.R. 5551](#))
- Lead Poisoning Prevention Act ([H.R. 5552](#))
- Prostate Cancer Prevention Act ([H.R. 5558](#))
- Early Hearing Detection and Intervention Reauthorization Act ([H.R. 5561](#))

COVID-19 Vaccine

Later this week (October 20-21), the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will [meet](#) to discuss who specifically should receive the Moderna COVID-19 booster shot. The third shot was unanimously recommended by the Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC). The FDA's final decision likely authorizing the booster is expected soon.

THIS WEEK IN HEALTH POLICY

Mon. (10/18)

- **1:00pm – NIH Meeting** – The National Institutes of Health (NIH) National Cancer Institute holds a meeting of the Frederick National Laboratory Advisory Committee to provide updates on cancer research. [Details.](#)

Tue. (10/19)

- **11:30am – BPC Discussion: Mental Health Services** – The Bipartisan Policy Center (BPC) holds a virtual discussion titled, "Integration, Expansion, Community Education – How to Improve Access to Mental Health Services." [Details.](#)

Wed. (10/20)

- **9:00am – NIH Conference: Women's Health** – The NIH Advisory Committee on Research on Women's Health holds a conference titled, "Advancing NIH Research on the Health of Women: A 2021 Conference" to discuss clinical practices related to maternal morbidity and mortality, increasing rates of chronic debilitating conditions, and stagnant cervical cancer survival rates. [Details.](#)
- **10:00am – Hearing: Health Insurance** – The Senate Finance Committee holds a hearing titled, "Health Insurance Coverage in America: Current and Future Role of Federal Programs." [Details.](#)
- **10:00am – Hearing: Disabilities** – The House Judiciary Subcommittee on the Constitution, Civil Rights, and Civil Liberties holds a hearing titled, "Oversight of the Americans with Disabilities Act of 1990: The Current State of Integration of People with Disabilities." [Details.](#)
- **10:00am – CDC Meeting: Preventive Services** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Community Preventive Services Task Force to present research on cancer screening, HIV prevention, nutrition and physical activity, social determinants of health, and violence prevention. [Details.](#)
- **10:30am – Hearing: Public Health Legislation** – The House Energy & Commerce Subcommittee on Health holds a hearing titled, "Enhancing Public Health: Legislation to Protect Children and Families" to discuss 12 health-related bills. [Details.](#)

Additional Multi-Day Events

- **October 18-October 19 – 8:30am – VA Meeting: Disability** – The Department of Veterans Affairs (VA) holds a meeting of the Federal Advisory committee on Prosthetics and Special-Disabilities Programs to discuss audiology and speech pathology, blind rehabilitation service, caregiver support program, office of academic affiliations, reasonable accommodations, and prosthetic and sensory aids service. [Details.](#)

- **October 19-October 21 – 11:30am – FDA Summit: Food Safety** – The Food and Drug Administration (FDA) holds a virtual summit titled, “New Era of Smarter Food Safety Summit on E-Commerce: Ensuring the Safety of Foods Ordered Online and Delivered Directly to Consumers.” [Details](#).
- **October 20-October 21 – 10:00am – CDC Meeting: Immunization** – The CDC holds a meeting of the Advisory committee on Immunization to discuss adult immunization schedules, child and adolescent immunization schedules, the Ebola vaccine, hepatitis vaccines, herpes zoster vaccines, Orthopoxviruses vaccine, influenza vaccines, pneumococcal vaccine, cholera vaccine, and tickborne encephalitis vaccine. [Details](#).

FEATURED WHG ANALYSIS

- ***NEW* 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](#).
- **WHG Overview of Recent Development on Federal Telehealth Policy** – In the Policy Hub Insight Bank [here](#).

REGULATORY LOOKBACK

Tues. (10/12)

- **HHS [provided](#)** an outline that draws together its multi-pronged efforts for improving behavioral health care for children and youth. [Details](#).
- **AHRQ released a request for information (RFI) on [telehealth during COVID-19](#)**. Submissions are due November 12. [Details](#).
- **AHRQ released a request for information (RFI) on [climate change](#)**. Submissions are due December 13. [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 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](#).

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