

Wynne Health Group Weekly



FRAMING THE WEEK

With both the House and Senate back in session this week, there is no shortage of to-do items. The must-pass continuing resolution (CR) to keep the government operating past September 30 is still under discussion, with action expected in the Senate next week, followed by the House. The likely end date for the CR is December 16, but at question is what kind of additional provisions could be attached to the measure.

President Biden has requested that emergency funding for COVID, monkeypox, and Ukraine assistance be attached (breakdown of funding request [here](#)), along with several other Health and Human Services programs (details [here](#)). He has also indicated support for including Medicare and Medicaid riders. Typically, CRs are relatively clean and only include provisions with broad bipartisan support. We don't expect anything different this year. As Republicans are opposed to additional funding for testing and therapeutics, the most likely provision to be included on a CR is additional funding for the Ukraine, particularly given the recent advancements Ukrainian forces have made in the region. Any additional Medicare and Medicaid provisions are more likely to be included in a final end of the year package.

Cancer Moonshot

Today, President Biden will deliver a speech on the "Cancer Moonshot" initiative. The [renewed effort](#) aims to reduce the death rate from cancer by at least 50% over the next 25 years and improve the experience of people and their families living with and surviving cancer. In July, the President unveiled the [Cancer Cabinet](#), a volunteer panel of experts who advise the President on how to use federal resources to advance the Cancer Moonshot initiative. The Cancer Cabinet's priorities are (1) close the screening gap, (2) understand and address environmental exposure, (3) decrease the impact of preventable cancers, (4) bring cutting edge research through the pipeline to patients and communities, and (5) support patients and caregivers.

Hearings

On Wednesday, the Senate Health, Education, Labor and Pensions Committee will convene a [hearing](#) to examine the federal response to Monkeypox. As of September 9, there are 21,894 confirmed monkeypox/orthopoxvirus cases and zero deaths in the United States, [according](#) to the Centers for Disease Control and Prevention (CDC). The Department of Health and Human Services has [allocated](#) nearly 1.1 million vials of Bavarian Nordic's JYNNEOS, an FDA-licensed vaccine indicated for prevention of smallpox and monkeypox, across the country. Nearly 773,000 vials free to jurisdictions have been shipped, as of September 7.

The witness panel features senior administration officials that appeared before the Senate HELP Committee to discuss the COVID-19 response, including CDC Director Dr. Rochelle Walensky, FDA Commissioner Robert Califf, Assistant Secretary for Preparedness and Response Dawn O'Connell, and Dr. Anthony Fauci. The senior officials are expected to reiterate the White House's recent request for Congress to provide \$3.9 billion for the monkeypox response in the FY 2023 continuing resolution. This includes:

- \$1.6 billion to procure vaccines and therapeutics, expand domestic vaccine manufacturing capacity;
- \$900 million to support public health activities, such as testing, vaccine administration, and surveillance and epidemiology;
- \$1.2 billion to provide testing, treatment, and vaccination services, including through Ryan White clinics and community health centers; and
- \$200 million for research and development.

The hearing is also an opportunity for the witnesses and members to discuss the COVID-19 response, including the Biden Administration's new [COVID-19 vaccine plan](#) for the fall. This includes calling on Congress to provide \$22.4 billion in additional funding to support vaccines, treatments, personal protective equipment for the Strategic National Stockpile, funding to cover the cost of administration of vaccines for the uninsured and underinsured, improved access to treatment for people with long COVID, and research and development.

On Wednesday, the Senate Judiciary Subcommittee on Immigration, Citizenship, and Border Safety will hold a [hearing](#) to discuss the role of immigrants in bolstering the health care workforce. The House Judiciary Subcommittee on Immigration and Citizenship convened a [hearing](#) on the same topic in February. The panel of witnesses included Dr. David Skorton, President and CEO of the Association of American Medical Colleges (AAMC). AAMC [recommended](#), "expanding the State Conrad 30 J-1 visa waiver program and enacting a permanent pathway to citizenship for Deferred Action for Childhood Arrivals (DACA) participants." Currently, doctors from other countries working the U.S. on J-1 visas are required to return to their home country after their residency has ended for two years before they can apply for another visa or green card. The Conrad 30 program allows doctors to stay in the United States without having to return home if they agree to practice an underserved area for three years. A total of 30 doctors per state can participate in the program.

On Thursday, the House Ways and Means Committee will hold a [hearing](#) on how to prepare the country's health care infrastructure for the climate crisis. The discussion builds on Chairman Richard Neal's (D-MA) previous work exploring the health care industry's impact on the climate crisis. In March 2022, Chairman Neal [requested](#) information from 12 large health systems on:

- The extent to which the organization understands its impact on the climate crisis;
- The organization's efforts to reduce the carbon footprint of its workforce; and
- The steps the organization has taken to hold external partners (e.g., business partners, suppliers, or contractors) accountable for their respective carbon footprints.

MACPAC

The Medicaid and CHIP Payment and Access Commission (MACPAC) returns for the 2022-2023 meeting cycle with sessions on a range of topics:

- Medicaid race and ethnicity data collection and reporting;
- Unwinding continuous coverage requirement;
- Payment within the context of Medicaid managed care, nursing facilities, disproportionate share hospital policies;
- Coverage of monoclonal antibodies for the treatment of Alzheimer's disease; and
- A recent proposed rule to establish requirements for mandatory annual state reporting on several measure sets for Medicaid and CHIP beneficiaries ([WHG summary](#)).

THIS WEEK IN HEALTH POLICY

Mon. (9/12)

- **10:00am – HRSA Meeting: Graduate Medical Education** – The Health Resources and Services Administration (HRSA) holds a meeting of the Council on Graduate Medical Education to discuss program updates. [Details.](#)
- **12:00pm – NIH Meeting: Child Health** – The National Institutes of Health (NIH) Eunice Kennedy Shriver National Institute of Child Health and Human Development holds a meeting of the National Advisory Child Health and Human Development Council to hear the director’s report. [Details.](#)

Tue. (9/13)

- **10:00am – Hearing: Food as Medicine** – The Senate Committee on Agriculture, Nutrition, and Forestry Subcommittee on Food and Nutrition, Specialty Crops, Organics, and Research holds a hearing titled, “Food as Medicine: Current Efforts and Potential Opportunities.” [Details.](#)
- **10:30am – ONC Meeting: Adopted Standards** – The Office of the National Coordinator of Health Information Technology (ONC) holds a meeting of the Health Information Technology Advisory Committee (HITAC) Adopted Standards Taskforce to make recommendations on ONC-adopted standards and implementation specifications. [Details.](#)
- **11:00am – NIH Meeting: Nursing** – the NIH National Institute of Nursing Research holds a meeting of the National Advisory Council for Nursing Research to discuss program policies and issues. [Details.](#)
- **12:45pm – NIH Meeting: Drug Abuse** – The NIH National Institute on Drug Abuse holds a meeting of the National Advisory Council on Drug Abuse to hear presentations. [Details.](#)
- **1:00pm – CMS Listening Session: Emergency Preparedness** – The Centers for Medicare and Medicaid Services (CMS) holds a listening session to gather information from providers and suppliers on experiences providing support during public health emergencies other than COVID-19. [Details.](#)
- **5:00pm – NIH Meeting: Heart, Lung, and Blood** – The NIH National Heart, Lung, and Blood Institute holds a meeting of the National Heart, Lung, and Blood Advisory Council to discuss program updates. [Details.](#)

Wed. (9/14)

- **10:00am – Hearing: Monkeypox** – The Senate Committee on Health, Education, Labor, and Pensions (HELP) holds a hearing titled, “Stopping the Spread of Monkeypox: Examining the Federal Response.” [Details.](#)
- **10:00am – Hearing: Immigrants and the Health Care Workforce** – The Senate Committee on the Judiciary Subcommittee on Immigration, Citizenship, and Border Safety holds a hearing titled, “Flatlining Care: Why Immigrants are Crucial to Bolstering Our Health Care Workforce.” [Details.](#)

Thurs. (9/15)

- **10:00am – Hearing: Health Care and Climate** – The House Ways and Means Committee holds a hearing titled, “Preparing America’s Health Care Infrastructure for the Climate Crisis.” [Details.](#)
- **12:00pm – CMS Meeting: Outreach and Education** – CMS holds a meeting of the Advisory Panel on Outreach and Education to discuss program updates. [Details.](#)
- **2:00pm – AHRQ Meeting: Common Formats** – The Agency for Healthcare Research and Quality (AHRQ) holds a meeting for software developers to discuss the Common Formats for patient safety data collection. [Details.](#)
- **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.](#)

Fri. (9/16)

- **10:30am – ONC Meeting: Public Health Data Systems** – ONC holds a meeting of the Public Health Data Systems Task Force 2022 to identify and prioritize policy and technical gaps associated with information systems relevant to public health and identify improvements that can be made. [Details.](#)

- **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.](#)

Additional Multi-Day Events

- **September 12-September 13 – 9:00am – HHS Meeting: Antibiotic-Resistant Bacteria** – The Department of Health and Human Services (HHS) Office of the Assistance Secretary for Health holds a meeting of the Presidential Advisory Council on Combatting Antibiotic-Resistant Bacteria for a Pandemic Preparedness Workshop. [Details.](#)
- **September 12-September 14 – VA Meeting: Rural Health** – The Department of Veteran’s Affairs (VA) holds a meeting of the Veterans Rural Health Advisory committee to hear updates from leadership. [Details.](#)
- **September 13-September 14 – 9:00am – CDC Meeting: ICD-10** – The Centers for Disease Control and Prevention (CDC) National Center for Health Statistics holds a meeting of the IDC-10 Coordination and Maintenance Committee to discuss coding updates. [Details.](#)
- **September 13-September 15 – 9:00am – HRSA Meeting: Infant and Maternal Mortality** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Infant and Maternal Mortality to discuss indigenous health and program updates. [Details.](#)
- **September 14-September 16 – 9:00am – HRSA Meeting: Rural Health** – HRSA holds a meeting of the National Advisory Committee on Rural Health and Human Services to discuss the Program of All Inclusive Care for the Elderly (PACE) in rural areas. [Details.](#)

FEATURED WHG ANALYSIS

- **WHG Roundup of CMS information releases on long-term services and supports and children’s health** – In the Policy Hub Insight Bank [here.](#)
- **Blog on President Biden’s Executive Order Protecting Access to Reproductive Health Services** – On the Commonwealth Fund’s To the Point [here.](#)
- **WHG Roundup of Recent Telehealth Policy** – In the Policy Hub Insight Bank [here.](#)
- **WHG Regulatory Outlook – Summer 2022 Update** – In the Policy Hub Insight Bank [here.](#)
- **WHG Issue Brief on the Nutrition Policy Landscape** – In the Policy Hub Insight Bank [here.](#)
- **WHG A Suite Of Potential Executive Actions For A Post-Roe World** – In the Policy Hub Insight Bank [here.](#)

CONGRESSIONAL LOOKBACK

Fri. (9/9)

- **A group of eight House representatives** are [seeking](#) input on how to improve upon the Medicare Access and CHIP Reauthorization Act (MACRA). Comments are due October 31. [Details.](#)

REGULATORY LOOKBACK

Fri. (9/9)

- **The White House** announced a new [Climate Mapping for Resilience and Adaptation](#) portal. [Details.](#)
- **The NIH** [announced](#) two new funding opportunities for diagnostic test manufacturers to develop the next generation of COVID-19 tests. [Details.](#)

Thurs. (9/8)

- **The DHS** [released](#) a final rule codifying critical changes to how the federal government determines whether a noncitizen is a “public charge” as grounds for denying admission or lawful permanent residence. [Details.](#)

- **The FDA** [released](#) final guidance recommending a “uniform format” for drug sponsors who include real-world data to generate real-world evidence in their regulatory submissions. [Details](#).
- **HRSA** is seeking [nominations](#) for membership on the Advisory Commission on Childhood Vaccines (ACCV). [Details](#).

Weds. (9/7)

- **HHS OIG** released two data briefs examining the [demographics](#) and [program integrity risk](#) of Medicare telehealth service use during the COVID-19 pandemic. [Details](#).
- **The FDA** [issued](#) revised draft guidance on general clinical pharmacology considerations for pediatric studies of drugs. Comments are due December 7. [Details](#).
- **The USDA** [released](#) a fact sheet detailing its support for the emergency food system. [Details](#).

Tues. (9/6)

- **CMS** issued a [Request for Information](#) seeking public input and feedback on issues related to health equity. Comments are due November 4. [Details](#).
- **SAMHSA** [announced](#) an award of \$2 million to the American Academy of Pediatrics (AAP) to establish a National Center of Excellence on Social Media and Mental Wellness. [Details](#).
- **HHS OIG** [found](#) that Medicare is substantially overpaying for intermittent urinary catheters and recommends that CMS reduce payment rates. [Details](#).

COMMENT & APPLICATION DEADLINES

- **September 13:** CMS [released](#) the CY 2023 Hospital OPPS and ASC Payment System Proposed Rule. Comments are due September 13. [Details](#).
- **September 17:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details](#).
- **September 19:** The FDA [issued](#) draft guidance on the evaluation of therapeutic equivalence. Comments are due September 19. [Details](#).
- **September 19:** HHS [announced](#) it is seeking nominations for individuals to participate as either a voting or non-voting member on the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. [Details](#).
- **September 29:** The FDA [issued](#) draft guidance entitled: Patient Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments (COAs). [Details](#).
- **September 30:** The CDC is [seeking nominations](#) for the Clinical Laboratory Improvement Advisory Committee (CLIAC). [Details](#).
- **September 30:** CMMI [announced](#) a new demonstration model aimed at improving oncology care. [Details](#).
- **October 1:** The CDC [seeks](#) nominations for the CDC/Health Resources & Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHACHSPT). [Details](#).
- **October 26:** The FDA [issued](#) a proposed rule to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). [Details](#).
- **October 31:** A group of eight House representatives are [seeking](#) input on how to improve upon the Medicare Access and CHIP Reauthorization Act (MACRA). [Details](#).
- **November 4:** CMS issued a [Request for Information](#) seeking public input and feedback on issues related to health equity. [Details](#).
- **November 6:** CMS [released](#) a proposed rule entitled, “Streamlining the Medicaid, Children’s Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment and Renewal Processes”. [Details](#).
- **December 7:** The FDA [issued](#) revised draft guidance on general clinical pharmacology considerations for pediatric studies of drugs. [Details](#).

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