

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

With major health care legislation on hold as congressional Democrats figure out how to pass “big chunks” of the Build Back Better Act (BBBA), we look ahead to statutory cliffs and potential legislative vehicles to watch as well as anticipated rulemaking from the Biden Administration in 2022. A fuller account of WHG’s 2022 Legislative & Regulatory Outlook is available [here](#) in PDF form and [here](#) in excel.

Legislative Outlook

With the stopgap funding bill set to expire on February 18, the **fiscal year (FY) 2022 omnibus government funding bill** is the most timely legislative vehicle for lawmakers to squeeze in policy and spending priorities. House Democrats are considering adding supplemental aid to the omnibus package, but whether enough bipartisan support exists is unclear. The White House may submit a request for supplemental COVID-19 resources this week. Any additional measures would likely target specific components of the COVID-19 response, such as increasing the COVID-19 testing supply chain, supporting vaccine distribution, and providing support to hospitals.

Whether the package will provide relief to hospitals and providers in the form of delays to scheduled cuts is an open question. Outstanding policies include:

- **Medicare, March 31, 2022:** Expiration of moratorium on the two percent Medicare sequestration reductions set to expire on March 31, 2022 is an open question. Beginning April, payment cuts to Medicare will be phased in, with one percent cuts beginning April 1, 2022 and two percent cuts beginning July 1 2022.
- **Medicare, December 31, 2022:** Expiration of three percent positive payment adjustment to physician payment, and expiration of waiver for four percent PAYGO cuts to Medicare.

The following items – both of which are addressed in BBBA – are also important timing considerations for congressional Democrats.

- **Medicaid, March 31, 2022:** Expiration of 10-percentage point Federal Medical Assistance Percentage (FMAP) increase for Medicaid home and community-based services (HCBS). BBBA would provide \$130 million in HCBS improving planning grants to states and provide a six-percentage point increase to the FMAP for states implementing a HCBS improvement program through 2030.
- **ACA Coverage, December 31, 2022:** Expiration of enhancements to ACA premium tax credits. BBBA would extend enhancements through 2025.

Other must-pass legislative vehicles to watch:

- **PDUFA and MDUFA Reauthorization, September 30, 2022** – Authority for the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Act (MDUFA) expires on September 30, 2022. Its reauthorization could serve as a vehicle for the bipartisan [Cures 2.0](#), which align with several goals outlined in the [PDUFA VII commitment letter](#) published by the Food and Drug Administration (FDA). They include increasing the use of real-world evidence in evaluating the safety and effectiveness of breakthrough devices, drugs, and biologicals and providing guidance on the use of digital health technologies in clinical trials. Cures 2.0 would also authorize the creation of the Advanced Research Projects Agency for Health (ARPA-H). Additionally, Cures 2.0 would permanently expand a number of telehealth flexibilities enacted during the ongoing COVID-19 public health emergency (PHE).
- **PAHPA Reauthorization, September 30, 2023** – Though more than a year away, the reauthorization of Pandemic and All Hazards Preparedness Act (PAHPA) authority, which expires on September 30, 2023 is of great interest. It could serve as a vehicle for the [bipartisan pandemic preparedness bill](#) spearheaded by the Senate Committee on Health, Education, Labor and Pensions (HELP) if the bill is not advanced in the near term. Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC), who is retiring this year and championed the last PAHPA reauthorization, are expected to soon introduce their bill.

### Regulatory Outlook

Per the recently issued [Fall 2021 Unified Regulatory Agenda](#), the Biden Administration is slated to pursue a variety of regulatory actions across a range of health care priority areas. Key anticipated rulemaking by issue area is outlined below.

#### **Drugs & Devices –**

- **August 2022:** The Food and Drug Administration (FDA) is slated to issue a [proposed rule](#) to clarify existing requirements and procedures related to Biologic License Applications.
- **October 2022:** The Centers for Medicare & Medicaid Services (CMS) is slated to issue a [proposed rule](#) that would establish the criteria for an expedited coverage pathway to provide Medicare beneficiaries with faster access to innovative and beneficial technologies.

#### **Care Coordination, Prevention, Telehealth, and Delivery Reform –**

- **January 2022:** Pursuant to the CARE Act, the Office for Civil Rights (OCR) is slated to issue a [proposed rule](#) to better harmonize the 42 CFR part 2 confidentiality requirements with certain permissions and requirements of the HIPAA Rules and the HITECH Act.
- **August 2022:** CMS is slated to [propose](#) a new mandatory Medicare payment model.
- **September 2022:** The Substance Abuse and Mental Health Association (SAMHSA) is expected to issue a [proposed rule](#) that would permanently extend the current COVID-19 flexibility that permits health care providers to prescribe buprenorphine for opioid use disorder via telehealth.
- **September 2022:** CMS is expected to issue a [proposed rule](#) that would revise the infection control requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs.

- **October 2022:** OCR is expected to [finalize](#) a rule that would strengthen individuals' rights to access their own protected health information and improve information sharing for care coordination, as well as increase family and caregiver involvement, among other changes.

#### Health IT, Interoperability, and Prior Authorization –

- **February 2022:** CMS is expected to issue a [proposed rule](#) that would place new requirements on Medicare Advantage plans, Medicaid managed care plans, CHIP managed care entities, Medicaid and CHIP fee-for-service entities, and Qualified Health Plans to improve electronic exchange of health care data and implement electronic prior authorization programs. As a reminder, the Trump Administration proposed a similar regulation in 2020 that did not include MA and was ultimately withdrawn.
- **June 2022:** The Administration for Children and Families (ACF) is expected to issue a [proposed rule](#) that would designate data exchange standards for certain categories of information required to be shared under applicable Federal law for agencies operating the Temporary Assistance for Needy Families (TANF), child support enforcement, child welfare services, and foster care and adoption assistance programs.
- **July 2022:** ONC is expected to issue a [proposed rule](#) regarding updates to the ONC Health IT Certification Program pursuant to the 21<sup>st</sup> Century Cures Act.

#### Medicaid –

- **April 2022:** CMS is slated to issue a [proposed rule](#) that would streamline eligibility and enrollment processes for all Medicaid and CHIP populations and create new enrollment pathways.
- **October 2022:** CMS is expected to issue a [proposed rule](#) that would assure and monitor equitable access in Medicaid and the Children's Health Insurance Program (CHIP).

#### Commercial Insurance –

- **November 2021:** Though the target date has already passed, the Internal Revenue Service (IRS) is planning to issue a [proposed rule](#) that would address the family glitch.
- **November 2021:** The IRS is also planning to issue a [proposed rule](#) that would provide health coverage reporters an extension in which to furnish certain statements and an alternative manner of allowing certain health coverage reporters to provide information to covered individuals.
- **February 2022:** CMS is planning to [propose](#) amendments to the final rules regarding religious and moral exemptions and accommodations regarding coverage of certain preventive services under the Affordable Care Act.
- **July 2022:** CMS is slated to [propose](#) amendments to the final rules implementing the Mental Health Parity and Addiction Equity Act pursuant to the Consolidated Appropriations Act of 2021, which requires health plans to prepare comparative analysis of any nonquantitative treatment limits (NQTLs) that apply.
- **August 2022:** CMS is expected to [propose](#) amendments to the definition of "short-term, limited-duration insurance" in such a way that protects enrollees with pre-existing conditions.

#### Organs –

**May 2022:** Following its recently issued request for information, CMS is slated to issue a [proposed rule](#) that would modify the standards used to evaluate and recertify organ procurement organizations.

## THIS WEEK IN HEALTH POLICY

### Tue. (1/25)

- **10:00am – NIH Meeting: Sickle Cell** – The National Institutes of Health (NIH) National Heart, Lung, and Blood Institute holds a meeting of the Sickle Cell Disease Advisory Committee to provide presentations and program updates. [Details.](#)
- **10:00am – NIH Meeting: Dental and Craniofacial Research** – The NIH National Institute of Dental and Craniofacial Research holds a meeting of the National Advisory Dental and Craniofacial Research Council to hear the director's report. [Details.](#)
- **10:30am – ONC Meeting: Interoperability** – The Office of the National Coordinator for Health Information Technology (ONC) holds a meeting of the Interoperability Standards Workgroup to discuss how to improve interoperability. [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.](#)
- **2:30pm – NQF Meeting: Rural Health** – The National Quality Forum (NQF) holds a meeting of the Measure Application Partnership (MAP) Rural Health Workgroup to discuss measures relating to rural health. [Details.](#)

### Wed. (1/26)

- **10:00am – NIH Meeting: Aging** – The NIH National Institute on Aging holds a meeting of the National Advisory Council on Aging to discuss program updates. [Details.](#)
- **10:00am – NIH Meeting: Diabetes** – The NIH National Institute of Diabetes and Digestive and Kidney Diseases holds a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council to hear the Director's report and other presentations. [Details.](#)
- **12:30 pm – BPC Discussion: Employer-Sponsored Health Care** – The Bipartisan Policy Center (BPC) holds a panel discussion titled, "The Future of Employer-Sponsored Health Care." [Details.](#)
- **1:00pm – FEMA Meeting: COVID-19 Supply Chain** – The Federal Emergency Management Agency (FEMA) holds a meeting to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic. [Details.](#)
- **2:00pm – NQF Webinar: Virtual Healthcare Quality** – The NQF Action Team on Virtual Healthcare Quality holds a Capstone webinar to discuss how to advance high-quality virtual healthcare service. [Details.](#)

### Thurs. (1/27)

- **10:00am – NIH Meeting: NIH Updates** – The NIH Office of the Director holds a meeting of the Council of Councils to hear NIH updates and scientific talks. [Details.](#)
- **12:00pm – NCD Meeting: Disability** – The National Council on Disability (NCD) holds a meeting to hear updates on policy projects and vote on the Health Equity Framework. [Details.](#)

### Fri. (1/28)

- **12:00pm – AHP Briefing: State Policy** – The Alliance for Health Policy (AHP) holds a briefing titled, "Health Policy Roundup: State Policy Analysis and Priorities." [Details.](#)

### Additional Multi-Day Events

- **January 24-January 25 – 10:30am – HHS Meeting: Health Statistics** – The Department of Health and Human Services (HHS) holds a meeting of the National Committee on Vital and Health Statistics to provide updates on the project focused on standardization of information for burden reduction post-pandemic. [Details.](#)
- **January 27-January 28 – 10:00am – NIH Meeting: Deafness and Communication Disorders** – The NIH National Institute on Deafness and Other Communication Disorders holds a meeting of the National Deafness and Other Communication Disorders Advisory Committee to provide program updates. [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

### Fri. (1/21)

- **MACPAC [convened](#)** virtually for Day Two of its January 2022 public meeting and held sessions on CMS proposed rule for D-SNPs. All WHG session summaries are available on Policy Hub [here](#).

### Thurs. (1/20)

- **MACPAC [convened](#)** virtually for Day One of its January 2022 public meeting and held sessions on improving access monitoring, improving access to vaccines, integrating care for duals, and restarting eligibility redeterminations. All WHG session summaries are available on Policy Hub [here](#).

## REGULATORY LOOKBACK

### Fri. (1/21)

**The ONC [issued](#)** an RFI seeking stakeholder input on whether to adopt additional standards, implementation specifications, and certification criteria regarding electronic prior authorization. Comments are due March 23. [Details](#).

**ASPE recently [published](#)** a report on prescription drug affordability among Medicare beneficiaries. [Details](#).

**The FDA announced** the launch of a new [public dashboard](#) for medications with an approved Risk Evaluation and Mitigation Strategy (REMS). [Details](#).

**HRSA [announced](#)** the recipients of \$103 million in American Rescue Plan (ARP) funding to reduce burnout and promote mental health among the health care workforce. [Details](#).

### Thurs. (1/20)

**The USDA FNS [released](#)** highlights of the Agency's efforts to promote equity and inclusion in nutrition assistance programs. [Details](#).

### Wed. (1/19)

- HHS [announced](#) the availability of \$13 million to support increased access to behavioral health care services, including treatment for substance use disorder, in rural communities. Applications are due April 19. [Details](#).
- HHS OIG [released](#) a study finding that the Centers for Medicare and Medicaid Services (CMS) should improve oversight of state performance in conducting nursing home surveys. [Details](#).
- CMS [released](#) a guide to the criteria used by CMS staff for review and approval of state contracts with Medicaid managed care plans. [Details](#).

## **Tues. (1/18)**

- **CMS** hosted a national stakeholder meeting with Administrator Chiquita Brooks-LaSure and other CMS leaders to provide updates on the [CMS Strategic Vision](#). [Details](#).
- **The CBO** [released](#) an updated model of how drug price negotiations would impact new drug development. [Details](#).
- **ASPE** [released](#) an issue brief examining trends in health insurance [deductibles](#) among HealthCare.Gov enrollees. [Details](#).
- **CMS** [released](#) an extension of the timeline for publication of a final rule that would make changes to the CLIA PT regulations related to analytes and acceptable performance. [Details](#).

## **COMMENT & APPLICATION DEADLINES**

- **January 24:** HHS, DOL, the Treasury, and OPM [issued](#) an IFC to implement the health insurance plan reporting requirements on prescription drug and health care spending. [Details](#).
- **January 25:** NIOSH published a [notice](#) extending the public comment period for the previously announced request for information (RFI) on interventions to support health worker mental health. [Details](#).
- **January 27:** CMS released the 2023 HHS Notice of Benefit Payment Parameters [proposed rule](#). [Details](#).
- **February 2:** The FDA [issued](#) draft guidance on content of premarket submissions for device software functions. [Details](#).
- **February 10:** CMS [proposed](#) a NCD to cover FDA approved monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease through coverage with evidence development. [Details](#).
- **February 11:** The GAO [released](#) a request for nominations for appointments to MedPAC. [Details](#).
- **February 15:** The FDA [issued](#) a request for nominations for voting members to serve on the Medical Devices Advisory Committee device panels. [Details](#).
- **February 22:** The USDA [announced](#) \$1.15 billion in grant funding for rural broadband access. [Details](#).
- **February 28:** The CDC [announced](#) it is seeking nominations for individuals to serve as members of the Advisory Committee on Breast Cancer in Young Women. [Details](#).
- **March 7:** CMS [released](#) the Contract Year (CY) 2023 Policy and Technical Changes to Medicare Advantage (MA) and Part D proposed rule. [Details](#).
- **March 10:** The ACL released two Innovations in Nutrition Programs and Services funding opportunities ([here](#) and [here](#)) to support research and programs improving nutrition services programs for aging adults. [Details](#).
- **March 11:** The FDA [issued](#) draft guidance on notifying the agency of a permanent discontinuance or interruption in manufacturing of a device. [Details](#).
- **March 15:** AHRQ [released](#) a solicitation for nominations for members of the U.S. Preventive Services Task Force (USPSTF). [Details](#).
- **March 18:** HRSA [released](#) a notice of funding opportunity (NOFO) for the Rural Public Health Workforce Training Network (RPHWTN) Program. [Details](#).
- **March 23:** **The ONC** [issued](#) an RFI seeking stakeholder input on whether to adopt additional standards, implementation specifications, and certification criteria regarding electronic prior authorization. [Details](#).
- **April 19:** HHS [announced](#) the availability of \$13 million to support increased access to behavioral health care services, including treatment for substance use disorder, in rural communities. [Details](#).
- **April 22:** The NIH [announced](#) a \$1 million prize competition for innovative diagnostics technologies to help improve maternal health. [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

