

Wynne Health Group Weekly



FRAMING THE WEEK

With Congress in recess for the next two weeks, we look ahead to what happens to the different flexibilities put in place during the COVID-19 public health emergency (PHE) when the emergency declaration ends. A path for the bipartisan \$10 billion COVID-19 supplemental bill, on hold due to disputes over the “Title 42” policy, is likely to remain uncertain until lawmakers return to Washington. The Centers for Medicare and Medicaid Services (CMS) may release Fiscal Year (FY) 2023 payment updates for the Skilled Nursing Facility (SNF) prospective payment system (PPS).

COVID-19 Flexibilities

The PHE is currently scheduled to expire on April 16, 2022. However, early in the Biden Administration, the Department of Health and Human Services (HHS) [promised](#) to provide states with 60 days’ notice of a decision to terminate the PHE or let it expire. Since HHS did not give any indications by the 60-day mark on February 15, 2022, the Administration is expected to extend the PHE at least until July 15, 2022.

During the PHE, HHS has waived several requirements enabling the health care system to respond more swiftly to the evolving pandemic, which have reshaped the way health care providers and others deliver care in the United States. As a result, many are deliberating on the extent to which federal policymakers should permit certain flexibilities to continue beyond the PHE. To support these efforts, **WHG has compiled a chart that delineates a comprehensive set of temporary flexibilities pursuant to the COVID-19 PHE (accessible [here](#))**. In brief, we capture flexibilities across the following domains:

- Medicare telehealth flexibilities;
- Emergency Use Authorizations (EUAs) and vaccines;
- Health care provider flexibilities;
- Medicaid federal medical assistance percentage (FMAP) increases;
- Medicaid continuous coverage/redetermination;
- Medicaid home- and community-based services (HCBS) waivers;
- Medicaid long-term services and supports (LTSS) flexibilities;
- Medicaid reimbursement increases;
- Other Medicaid flexibilities;
- Nutrition flexibilities; and
- Housing flexibilities.

COVID-19 Supplemental Funding

Whether Senate Democrats and Republicans will resolve their dispute over the Biden Administration’s [termination](#) of the Trump-era “Title 42” policy in order to overcome a filibuster and vote on the bipartisan \$10 billion COVID-19 supplemental bill upon their return from recess remains to be seen. Senate

Republicans are pushing for an amendment to the supplemental bill that prevents the Administration from terminating the Title 42 policy.

The Title 42 policy, enacted by the Trump Administration at the outset of the COVID-19 pandemic, allowed the U.S. to block entry of migrants, including people seeking asylum, for the purposes of “protect[ing] the public health from an increased risk of the introduction of COVID-19.” CDC has determined that the restrictive measure is “no longer necessary to protect the public health.” The termination will take effect on May 23, 2022.

The [bipartisan COVID-19 supplemental appropriations package](#) would provide \$10 billion to Public Health and Social Services Emergency Fund at the Department of Health and Human Services (available until September 30, 2025). Of this amount, \$9.25 billion would be allocated to the Biomedical Advanced Research and Development Authority (BARDA) for research and development, manufacturing, and purchase of vaccines, therapeutics, diagnostics, and supplies. The remaining \$750 million would support research and clinical trials for the development of vaccines against emerging variants. Unspent COVID funds (mostly related to small businesses and aviation) would be used to fully pay for the supplemental bill.

Medicare Payment Updates

The proposed rule for the fiscal year (FY) 2023 skilled nursing facility (SNF) prospective payment system (PPS) has [cleared review](#) by the Office of Management and Budget (OMB). This means we can expect to see CMS release its proposal as early as today.

In addition to the FY 2023 SNF PPS proposed rule, CMS must soon also issue its proposed rule for the FY 2023 inpatient prospective payment system (IPPS) – the final proposal to round out the FY Medicare payment update proposals. As a reminder, CMS has already issued proposed rules for updating FY 2023 Medicare payments to hospices, inpatient rehabilitation facilities, and inpatient psychiatric facilities (WHG summaries [here](#), [here](#), and [here](#), respectively).

THIS WEEK IN HEALTH POLICY

Mon. (4/11)

- **10:00am – CDC Meeting: Injury Prevention** – The Centers for Disease Control and Prevention (CDC) National Center for Injury Prevention and Control holds a meeting of the Board of Scientific Counselors to hear updates on traumatic brain injury research, older adult falls research, and health equity. [Details](#).

Tue. (4/12)

- **9:00am – FDA Meeting: PDUFA** – The Food and Drug Administration (FDA) holds a meeting titled, “Prescription Drug User Fee Act (PDUFA) of 2017; Electronic Submissions and Data Standards.” [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](#).
- **2:00pm – Hearing: Prescription Drug Costs** – The Senate Special Committee on Aging holds a hearing titled, “No Time to Wait: Proposals to Lower Prescription Drug Costs.” [Details](#).

Wed. (4/13)

- **10:00am – ONC Meeting: Health IT** – ONC holds a meeting of the Health Information Technology Advisory Committee (HITAC) to discuss ongoing projects. [Details](#).
- **1:00pm – HHS Meeting: Serious Mental Illness** – The Department of Health and Human Services (HHS) holds a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee to provide information on federal efforts related to serious mental illness and serious emotional disturbance. [Details](#).

Additional Multi-Day Events

- **April 11-April 13 – 12:00pm – 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 discuss rural access to emergency medical services and rural human services programs. [Details.](#)
- **April 12-April 14 – 10:00am – CMS Conference: Quality** – The Centers for Medicare and Medicaid Services (CMS) holds the 2022 Quality Conference to discuss how to develop solutions to health system challenges. [Details.](#)
- **April 13-April 14 – 10:00am – ONC Meeting: Annual Meeting** – ONC holds the 2022 ONC Annual Meeting with panel discussions focusing on equity, social determinants of health, and patient engagement. [Details.](#)
- **April 13-April 14 – 1:00pm – NIH Meeting: Autism Spectrum Disorder** – The National Institutes of Health (NIH) National Institute of Mental Health holds a meeting of the Interagency Autism Coordinating committee to discuss updates and issues related to autism spectrum disorder research and service. [Details.](#)
- **April 13-April 14 – 11:00am – CDC Meeting: Clinical Laboratory Improvement** – The CDC holds a meeting of the Clinical Laboratory Improvement Advisory Committee to hear agency updates from CMS, FDA, and the CDC. [Details.](#)

FEATURED WHG ANALYSIS

- ***NEW* WHG Tracker of COVID-19 PHE Flexibilities** – In the Policy Hub Insight Bank [here.](#)
- ***NEW* WHG Memo on PBM Regulatory and Legislative Landscape** – In the Policy Hub Insight Bank [here.](#)
- **WHG Memo on Possible CMMI Action on Drug Pricing** – In the Policy Hub Insight Bank [here.](#)
- **WHG Roundup of Recent Telehealth Policy** – In the Policy Hub Insight Bank [here.](#)
- **WHG 2022 Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank [here.](#)
- **WHG Issue Brief on Health Equity Implications of Potential Telehealth Reform Under Medicare** – In the Policy Hub Insight Bank [here.](#)

CONGRESSIONAL LOOKBACK

Fri. (4/8)

- **MedPAC** convened virtually for Day Two of its April 2022 public meeting and held sessions on streamlining APMs, and aligning FFS rates across ambulatory settings. All WHG session summaries are available on Policy Hub [here.](#)
- **MACPAC** [convened](#) virtually for Day Two of its April 2022 public meeting and held a session to vote on recommendations for the June report. All WHG session summaries are available on Policy Hub [here.](#)

Thurs. (4/7)

- **Senator Warnock (D-GA)** [introduced](#) legislation that would establish a \$2,000 annual OOP cap and redesign the Part D benefit. [Details.](#)
- **MedPAC** convened virtually for Day One of its April 2022 public meeting and held sessions on Part B drug prices, Part D DIR data, PDP segmentation, and policies to address the SDOH. All WHG session summaries are available on Policy Hub [here.](#)
- **MACPAC** [convened](#) virtually for Day One of its April 2022 public meeting and held sessions on access monitoring, advancing health equity, vaccine access, directed payment, health IT adoption, and churn and coverage transitions. All WHG session summaries are available on Policy Hub [here.](#)

Weds. (4/6)

- **The House E&L Committee** [convened](#) a hearing to discuss President Biden's FY 2023 HHS budget request. [Details.](#)
- **The E&C Health Subcommittee** [convened](#) a hearing to discuss 19 bills addressing mental health and substance use disorder (SUD) issues. [Details.](#)

Tues (4/5)

- **The Senate Finance Committee** [convened](#) a hearing to discuss President Biden's FY 2023 HHS budget request. [Details](#).

REGULATORY LOOKBACK

Fri. (4/8)

- **ASPE** [released](#) an issue brief examining antipsychotic medication prescribing in long term care facilities (LTCFs) during the COVID-19 pandemic.
- **The FDA** [issued](#) draft guidance on cybersecurity in medical devices and quality system considerations. Comments are due July 7. [Details](#).
- **HRSA** [released](#) a RFI on ways to strengthen and improve the Organ Procurement and Transplantation Network (OPTN). Comments are due May 9. [Details](#).
- **CMS** [plans](#) to launch the online independent dispute resolution (IDR) portal the week of April 11th. [Details](#).

Thurs. (4/7)

- **CMS** [announced](#) the graduated end of several temporary long-term care (LTC) emergency declaration blanket waivers issued during the COVID-19 PHE. [Details](#).
- **CMS** [finalized](#) its NCD to cover FDA-approved monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease (AD) through coverage with evidence development. [Details](#).
- **CMS** [issued](#) an IFC to implement a maximum OOP and cost sharing limits in MA. Comments are due July 13. [Details](#).

Weds. (4/6)

- **CMS** [released](#) a proposed rule to indefinitely delay the start date of the Radiation Oncology (RO) model. [Details](#).
- **HHS OCR** [issued](#) a RFI to solicit comments on the HITECH Act. Responses are due June 6. [Details](#).
- **The National Academy of Medicine** [convened](#) to discuss the findings and recommendations from its new report: [The National Imperative to Improve Nursing Home Quality](#). [Details](#).
- **ASPE** [released](#) three documents supporting the HHS strategic approach to address SDOH. [Details](#).
- **CMS** [announced](#) that it will cover a second COVID-19 booster shot without cost sharing for eligible individuals with Medicare or Medicaid coverage. [Details](#).

Tues (4/5)

- **The Treasury Department and the IRS** issued a [proposed rule](#) to revise criteria for ACA premium tax credit (PTC) eligibility in the individual market. Comments are due June 6. [Details](#).
- **The CDC** [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). Nominations are due September 17. [Details](#).

Mon. (4/4)

- **CMS** [announced](#) the Contract Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D rate announcement. [Details](#).
- **CMS** announced that it will provide coverage for up to eight over the counter COVID-19 tests each calendar month with no cost sharing. [Details](#).
- **CMS** [announced](#) it is exercising enforcement discretion during the COVID-19 PHE for state submissions of access monitoring review plans (AMRPs). [Details](#).
- **HRSA** [released](#) a NOFO to strengthen the public health workforce under the Public Health Scholarship Program. Applications are due June 1. [Details](#).

COMMENT & APPLICATION DEADLINES

- **April 11:** The CDC [announced](#) it is requesting comments on the proposed clinical practice guideline, “CDC Clinical Practice Guideline for Prescribing Opioids.” [Details](#).
- **April 12:** The NIH [issued](#) an RFI to gather public input on developing the NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA). Comments are due April 12. [Details](#).
- **April 16:** HRSA released a NOFO to support long term improvements in early developmental health through the Transforming Pediatrics for Early Childhood program. [Details](#).
- **April 18:** CMS [released](#) an RFI on access to care and coverage for Medicaid and CHIP enrollees. Comments are due April 18. [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 19:** AHRQ [released](#) an RFI from the public on its proposed strategic framework for its Patient-Centered Outcomes Research Trust Fund (PCORTF) investments. [Details](#).
- **April 22:** The NIH [announced](#) a \$1 million prize competition for innovative diagnostics technologies to help improve maternal health. [Details](#).
- **April 25:** The FTC [issued](#) a request for public comments on the ways that [pharmacy](#) benefit managers (PBMs) affect drug affordability and access. [Details](#).
- **April 28:** AHRQ posted a request for supplemental data and evidence on postpartum home blood pressure monitoring and postpartum treatment of hypertensive disorders. [Details](#).
- **May 2:** The HHS Office of the Surgeon General is [seeking](#) input on the impact and prevalence of health misinformation in the digital information environment during the COVID-19 pandemic. [Details](#).
- **May 9:** HRSA [released](#) a RFI on ways to strengthen and improve the Organ Procurement and Transplantation Network (OPTN). [Details](#).
- **May 9:** The NIH [released](#) a notice of proposed rulemaking to update the NIH Loan Repayment Programs (LRP) to reflect changes made by the 21st Century Cures Act. [Details](#).
- **May 17:** SAMHSA [posted](#) three grant opportunities related to mental health. [Details](#).
- **May 17:** SAMHSA [posted](#) a notice of funding opportunity for the Infant and Early Childhood Mental Health Grant Program. [Details](#).
- **May 24:** The FDA [issued](#) a proposed rule to amend the device CGMP requirements. [Details](#).
- **May 31:** CMS [released](#) the FY 2023 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule. Comments are due May 31. [Details](#).
- **May 31:** CMS [released](#) the FY 2023 inpatient psychiatric facility (IPF) prospective payment system (PPS) proposed rule. Comments are due May 31. [Details](#).
- **May 31:** CMS [released](#) the FY 2023 hospice payment rate update proposed rule. [Details](#).
- **June 1:** HRSA [released](#) a NOFO to strengthen the public health workforce under the Public Health Scholarship Program. [Details](#).
- **June 6:** The Treasury Department and the IRS issued a [proposed rule](#) to revise criteria for ACA premium tax credit (PTC) eligibility in the individual market. [Details](#).
- **June 6:** HHS OCR [issued](#) a RFI to solicit comments on the HITECH Act. [Details](#).
- **June 7:** The FDA [issued](#) a request for comments on changes to the agency’s previously proposed quality metrics (QM) reporting program. [Details](#).
- **July 7:** The FDA [issued](#) draft guidance on cybersecurity in medical devices and quality system considerations. [Details](#).
- **July 13:** CMS [issued](#) an IFC to implement a maximum OOP and cost sharing limits in MA. [Details](#).
- **September 17:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details](#).

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