

Wynne Health Group Weekly



FRAMING THE WEEK

In this issue of the Weekly, we focus on the COVID-19 public health emergency (PHE). The PHE is currently set to expire on October 13, 2022. Since the Biden Administration did not provide its promised 60-day notice that the PHE would end on August 14th (60-days prior to the current expiration date), we anticipate that the PHE will be extended another 90 days to January 11, 2023.

Following this implicit decision to extend the PHE declaration at least one more time, the Administration [announced](#) last week its most comprehensive set of resources to-date on its plan for how to proceed once the PHE ends. Specifically, CMS is communicating via this new [roadmap](#) which Medicare flexibilities, requirements, and payments it continues to carry forward on a permanent basis. CMS does so by outlining the current flexibilities available on a provider/entity-specific basis and indicating in what ways it intends to make these permanent. Fact sheets are available for [physicians and other clinicians](#), [hospitals](#), [long-term care facilities](#), [Medicare Advantage and Part D plans](#), [end stage renal disease facilities](#), and more.

Notable topics addressed include items such as coverage for COVID vaccines, monoclonal antibodies, and antivirals, as well as flexibilities regarding remote patient monitoring and practitioner locations. A brief outline of the post-PHE landscape as described by CMS is included below.

Issue	Current Policy	Post-PHE Policy
Vaccine Coverage	CMS covers all FDA-approved COVID vaccines under Part D without cost-sharing. CMS also implemented provisions ensuring private health insurance coverage of COVID vaccines without cost-sharing for plans participating in the Health Insurance Marketplace.	CMS will continue to pay approximately \$40 per dose for administering COVID-19 vaccines in outpatient settings for Medicare beneficiaries through the end of the calendar year that the PHE ends. Effective January 1 of the year following the year that the PHE ends, CMS will set the payment rate for administering COVID-19 vaccines to align with the payment rate for administering other Part B preventive vaccines.
Monoclonal Antibodies	CMS covers and pays for these monoclonal antibodies the same way it covers and pays for COVID-19 vaccines when furnished consistent with the emergency use authorization. There is also no cost sharing and no deductible for COVID-19 monoclonal antibody products when providers administer them.	Effective January 1 of the year following the year that the PHE ends, CMS Will pay for monoclonal antibodies the same way it pays for biologics.

Remote patient monitoring (RPM)	CMS allows permitted clinicians to bill for RPM services furnished to both new and established patients, and to patients with both acute and chronic conditions	Clinicians will once again have to have an established relationship prior to providing RPM services. However, CMS will continue to allow RPM services to be furnished to patients with both acute and chronic conditions.
Practitioner Locations	CMS waived the Medicare requirement that a physician or non-physician practitioner must be licensed in the state in which they are practicing if the physician or practitioner 1) is enrolled as such in the Medicare program, 2) has a valid license to practice in the state reflected in their Medicare enrollment, 3) is furnishing services — whether in person or via telehealth — in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity, and 4) is not affirmatively excluded from practice in the state or any other state that is part of the section 1135 emergency area.	When the PHE ends, current regulations will continue to allow for deferral to state law.

Medicaid

The Administration is also continuing to prepare for the end of the PHE with respect to Medicaid coverage requirements. Stakeholders remain concerned with the anticipated loss of coverage for many Medicaid beneficiaries whose program eligibility will be redetermined once the PHE ends. This will mean a loss in coverage for many members of vulnerable populations who have had access to continuous coverage during the PHE period. Additionally, there is concern that many will lose coverage on a procedural basis – e.g., because individuals have moved and their eligibility forms will be mailed to the wrong address, challenges due to securing proof of earnings, etc. In response to this, the Administration recently issued [guidance](#) outlining strategies states could adopt to protect beneficiaries from inappropriate coverage loss.

More recently, the Office of Management and Budget (OMB) began [reviewing](#) a new proposed rule to streamline Medicaid and CHIP eligibility determinations. The proposed rule is also anticipated to create new enrollment pathways to maximize enrollment and retention of eligible individuals. We anticipate the proposed rule may incorporate stakeholder feedback on this year’s earlier [request for information](#) on access to care and coverage for Medicaid and CHIP enrollees. CMS said at that time the responses would be used to inform the development of its comprehensive strategy to ensure more equitable access to for all Medicaid and CHIP populations and inform future policy, monitoring, and regulatory actions.

Telehealth

Questions still remain around what the long-term future of telehealth coverage under Medicare will be. The House recently passed the [Advancing Telehealth Beyond COVID-19 Act of 2021 \(H.R. 4040\)](#), introduced by Reps. Liz Cheney (R-WY) and Debbie Dingell (D-MI), that would further extend several temporary Medicare telehealth flexibilities through December 31, 2024. The bill passed with overwhelming support (416-12). The legislation would enact the following flexibilities:

- Eliminating the statutory geographic and originating site requirements for all telehealth services;
- Expanding the list of practitioners eligible to furnish telehealth services;
- Extending telehealth services for federally qualified health centers and rural health clinics;
- Delaying the in-person requirements under Medicare for mental health services furnished through telehealth;
- Allowing the furnishing of audio-only telehealth services; and

- Allowing a hospice physician or nurse practitioner to continue conducting face-to-face encounters required for recertification,

In the FY 2022 omnibus appropriations package ([P.L. 117-103](#)) enacted in March, Congress permitted these flexibilities to continue for a 151-day period following the end of the COVID PHE, which we expect to continue through at least January 11, 2023. Per these recent statutory changes, this means the COVID-19 telehealth flexibilities would end 152 days later on June 12, 2023.

As noted above, however, the modified Cheney-Dingell bill would establish a concrete, two-year extension of these flexibilities that is not contingent on the end date of the PHE. Given its broad support, it is possible this bill will be incorporated into a year-end spending package before the current Congressional session ends. The two-year extension included in this legislation would provide policymakers additional time to study the effects of expanded Medicare coverage of telehealth on access, quality, outcomes, costs, patient safety, and fraud. Notably, this two-year extension aligns with recommendations advanced by the Medicare Payment Access Commission (MedPAC) last year ([details](#)). The legislation has yet to be taken up in the Senate.

Some stakeholders have continued to urge caution on broad telehealth expansions. Based on a recent Congressional Budget Office (CBO) scoring of the 151-day telehealth extension, [stakeholders warn](#) that a 10-year extension of Medicare telehealth flexibilities would cost \$25 billion. See more in our recent telehealth roundup [here](#).

THIS WEEK IN HEALTH POLICY

Tue. (8/23)

- **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](#).
- **12:00pm – CDC Meeting: Healthcare Infection Control** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Healthcare Infection Control Practices Advisory Committee to discuss workgroup updates. [Details](#).

Wed. (8/24)

- **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](#).
- **12:00pm – CMS Webinar: Continuous Enrollment Unwinding** – The Centers for Medicare and Medicaid Services (CMS) holds a webinar titled, “Medicaid and CHIP Continuous Enrollment Unwinding: What to Know and How to Prepare, A Partner Education Monthly Series.” [Details](#).
- **2:00pm – CMS Information Session: The Gravity Project** – CMS holds an information session to discuss how The Gravity Project is developing data standards to improve how information is shared on social determinants of health. [Details](#).

Fri. (8/26)

- **10:00am – HRSA Meeting: Community-Based Linkages** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Interdisciplinary Community-Based Linkages to discuss program updates. [Details](#).

Additional Multi-Day Events

- **August 22-August 23 – 9:30am – CMS Meeting: Outpatient Payment** – CMS holds a meeting of the Advisory Panel on Hospital Outpatient Payment to advise CMS concerning the clinical

integrity of the Ambulatory Payment Classification groups and their associated weights and supervision of hospital outpatient therapeutic services. [Details](#).

FEATURED WHG ANALYSIS

- **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](#).

REGULATORY LOOKBACK

Fri. (8/19)

- **GAO** released a report on COVID-19-related medical surge and related efforts by the Department of Health and Human Services. [Details](#).
- **CMS** a new informational bulletin (CIB) informing states that the Department of Agriculture (USDA) Food and Nutrition Service (FNS) is issuing a new solicitation for participation in demonstration projects for states to evaluate the impact of using Medicaid eligibility data to directly certify students for free and reduced price school meals. [Details](#).

Thur. (8/18)

- **CMS** announced its roadmap for the end of the COVID-19 public health emergency (PHE). [Details](#).
- **CMS** issued a proposed rule to establish requirements for mandatory annual State reporting on several measure sets for Medicaid and CHIP beneficiaries. [Details](#).

Wed. (8/17)

- **CMS** announced it is discontinuing the use of Certificates of Medical Necessity and Durable Medical Equipment (DME) Information Forms as part of its ongoing efforts to increase access to care and to reduce unnecessary administrative burden for stakeholders. [Details](#).
- **CMS** has approved Medicaid and Children's Health Insurance Program (CHIP) coverage for twelve months postpartum in Hawaii, Maryland, and Ohio. [Details](#).
- **FDA** announced an additional delay of the required warnings for cigarette packages and advertisements final rule, pursuant to a decision from the U.S. District Court for the Eastern District of Texas. [Details](#).

Tue. (8/16)

- **FDA** issued a final rule and final guidance to improve access to hearing aids through the establishment of an over-the-counter (OTC) hearing aid category and the corresponding regulatory requirements. [Details](#).

COMMENT & APPLICATION DEADLINES

- **August 23:** The FDA [issued](#) draft guidance on considerations for rescinding breakthrough therapy designation (BTD). [Details](#).
- **August 27:** CMS [released](#) its CY 2023 ESRD prospective payment system (PPS) proposed rule. [Details](#).
- **August 29:** CMS [issued](#) a proposed rule that would establish conditions of participation (CoPs) for rural emergency hospitals (REHs) and make updates to the CoPs for critical access hospitals (CAHs). [Details](#).

- **August 31:** The FDA [announced](#) the extension of the comment period for the draft guidance on risk management plans to mitigate the potential for drug shortages. [Details.](#)
- **August 31:** CMS [issued](#) a RFI on ways to strengthen and improve Medicare Advantage. [Details.](#)
- **September 1:** The CDC [seeks](#) nominations for the National Center for Injury Prevention and Control (NCIP) [Board of Scientific Counselors \(BSC\).](#) [Details.](#)
- **September 2:** CMS is seeking [nominations](#) for two Technical Expert Panels (TEPs). [Details.](#)
- **September 6:** CMS is seeking [nominations](#) for two Technical Expert Panels (TEPs). [Details.](#)
- **September 6:** The CDC [released](#) a notice of grant funding to establish and fund regional Tuberculosis (TB) Centers of Excellence (COE). [Details.](#)
- **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.](#)

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