

[This Week in Health Policy](#), [Congressional Lookback](#), [Regulatory Lookback](#), [Comment & Application Deadlines](#)

Wynne Health Group Weekly



FRAMING THE WEEK

OMB Updates

The White House Office of Management and Budget (OMB) recently completed its [review](#) of a final rule that would establish the Consolidated Appropriations Act of 2021's (CAA) provisions to extend Medicare Part B coverage of immunosuppressive drugs beyond 36 months after transplant and simplify Medicare enrollment rules, including the proposed creation of several special enrollment periods (SEPs). The rule could be released as early as today. Our summary of the proposed rule is available [here](#).

In addition, OMB is currently reviewing two other noteworthy regulations, both focused on the individual market:

- A [Request for Information](#) (RFI) on the Essential Health Benefits (EHBs). Though no details on the RFI are included, it may be in response to the recent court decision that partially struck down the Affordable Care Act's (ACA's) requirement that insurers cover certain types of preventive care without cost sharing ([details](#)).
- The [proposed rule](#) for the 2024 Notice of Benefit and Payment Parameters, which would propose annual changes and updates to ACA Marketplace rules.

WHG Roundup: Looking Ahead on Medicaid

Amid the looming expiration of COVID-19 public health emergency (PHE), the Centers for Medicare and Medicaid Services (CMS) has released numerous guidance documents and tools to help states prepare for the unwinding of the continuous coverage requirements for Medicaid. This week, we provide a roundup of new Medicaid resources, policy developments, and anticipated policy changes. The Medicaid and CHIP Payment and Access Commission (MACPAC) will also meet later this week to continue their discussions about the unwinding of the PHE, among other topics. Notably, MACPAC will also begin work on potential recommendations for structuring disproportionate share hospital allotments during economic crises.

Agency Resources

Health and Human Services Secretary Xavier Becerra recently renewed the PHE another 90 days through January 11, 2023. If the Biden Administration does not give states 60 days advance notice by November 14, 2022, then we could expect the PHE to be extended again in January until April 11, 2023. However, if the PHE is not renewed, then states could begin to disenroll people as soon as February 1, 2023. See [timeline](#) from the Center for Children & Families of the Georgetown University Health Policy Institute.

An [estimated 6.8 million](#) will lose Medicaid coverage despite still being eligible after the expiration of the PHE, according to the Assistant Secretary for Planning and Evaluation. **CMS recently released resources to further help states mitigate administration churn:**

- [COVID-19 Public Health Emergency Unwinding Frequently Asked Questions for State Medicaid and CHIP Agencies](#) answers questions regarding [prior guidance](#) on the timing of the unwinding period, state requirements for redeterminations and renewals, and waivers, among other topics.
- [Ending Coverage in the Optional COVID-19 Group: Preparing States for the End of the Public Health Emergency](#) explains the steps states will need to take when ending coverage for the optional COVID-19 group. The Families First Coronavirus Response Act (FFCRA) gave states the option to cover individuals who would not normally be eligible for Medicaid but are uninsured for COVID-19-related services. Fifteen states and three territories chose to implement this coverage.

Authority for states to cover the optional group ends on the last day of the PHE and states may not claim federal funds to pay for services for this group after that date. However, states that claimed additional federal matching during the pandemic may not terminate enrollment before the end of the month in which the PHE ends, so states must be careful to not submit claims data for the optional coverage group after the last day of the PHE. States may, but are not required to, use state funds to pay for services after the last day of the PHE.

- [Ex Parte Renewal: Strategies to Maximize Automation, Increase Renewal Rates, and Support Unwinding Efforts](#) lays out best practice state policy and operational processes for *ex parte* renewal, also known as auto-renewal, passive renewal, or administrative renewal.

Regulatory Update

On the regulatory front, CMS reopened the public comment period for the [interim final rule \(IFR\)](#) that established requirements for states receiving the temporary 6.2 percentage point increase in the federal Medicaid matching fund ([WHG summary](#)). CMS seeks comments on whether states should be required to maintain the same amount, duration, and scope of coverage for beneficiaries enrolled in Medicaid through the end of the month in which the COVID-19 public health emergency (PHE) ends. Current regulations permit states to make certain changes to coverage and cost-sharing. The proposed changes would strengthen protections for beneficiaries. Comments are due October 27.

CMS also issued a proposed rule aimed at streamlining the Medicaid, CHIP, and Basic Health Plan application, eligibility determination, enrollment and renewal processes ([WHG summary](#)). Comments are due November 6. The proposed rule is intended to accomplish the following:

- Remove barriers and facilitate enrollment;
- Align enrollment and renewal requirements for most individuals in Medicaid;
- Create beneficiary protections with respect to returned mail;
- Create timeliness requirements for Medicaid and CHIP redeterminations;
- Make transitions between programs easier;
- Eliminate access barriers for children enrolled in CHIP; and
- Modernize recordkeeping requirements to ensure that eligibility and enrollment are properly documented

In addition, OMB began [reviewing](#) a proposed rule that would place new requirements on Medicaid managed care plans and Medicaid fee-for-service, as well as Medicare Advantage (MA) plans, CHIP managed care entities, 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.

MACPAC

Later this week, MACPAC will discuss their responses to CMS' proposed eligibility, enrollment, and renewal rule as well as the request for information on health equity ([WHG summary](#)). CMS seeks public input and feedback on: (1) accessing healthcare and related challenges, (2) understanding provider experiences; (3) advancing health equity; and (4) the impact of the COVID-19 PHE waivers and flexibilities. In addition to topics noted above, MACPAC will also convene [sessions](#) on:

- Medicaid race and ethnicity data collection and reporting;
- Improving access to Medicaid coverage and care for adults leaving incarceration;
- Potential changes to the consideration of access in actuarial soundness;
- Trends in Medicaid drug spending and rebates; and
- Streamlining delivery of home- and community-based services and maintenance needs allowances for beneficiaries receiving these services.

THIS WEEK IN HEALTH POLICY

Mon. (10/24)

- **9:30am – HHS Meeting: Alzheimer's** – The Department of Health and Human Services (HHS) holds a meeting of the Advisory Council on Alzheimer's Research, Care, and Services to hear presentations on access to long-term services and supports as well as end-of-life challenges for people living with Alzheimer's Disease and Related Dementias (ADRD). [Details.](#)
- **11:00am – CDC Meeting: Health Statistics** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS) to review NCHS's updates on data collection, analysis, and reporting activities. [Details.](#)

Tue. (10/25)

- **10:00am – NQF Meeting: Scientific Methods Panel** – The National Quality Forum (NQF)'s Scientific Methods Panel holds a measure evaluation meeting for the Fall 2022 cycle to discuss home dialysis retention, hospice care index and patient-reported measures among adults with breast cancer. [Details.](#)
- **12:00pm – Discussion: KFF** – The Kaiser Family Foundation (KFF) holds a discussion titled 'How the Pandemic Continues to Shape Medicaid Spending, Enrollment, and Policy – Findings From KFF's 22nd Annual Medicaid Budget Survey.' [Details.](#)

Wed. (10/26)

- **10:00am – NIH Meeting: Autism Spectrum Disorder Research** – The National Institutes of Health (NIH) holds a meeting of the National Institute of Mental Health to discuss business, updates, and issues related to autism spectrum disorder research and services activities. [Details.](#)
- **10:00am – ONC Meeting: Public Health Data Systems** – The Office of the National Coordinator for Health IT (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.](#)

Thurs. (10/27)

- **12:00pm – NIH Meeting: Aids Research** – NIH holds a meeting of the Office of AIDS Research Advisory Council to discuss updates from the Clinical Guidelines Working Groups and updates from NIH HIV-related advisory councils. [Details.](#)
- **1:00pm – Discussion: Bipartisan Policy Center** – The Bipartisan Policy Center holds a discussion titled “Taming Health Insurance Costs for Employers and Employees.” [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. (10/28)

- **10:00am – FDA Meeting: Oncologic Drugs** – The Food and Drug Administration holds a meeting of the Oncologic Drugs Advisory Committee to discuss biologics license application 761176, for ¹³¹I-omburtamab solution for injection, submitted by Y-mAbs Therapeutics, Inc. for the treatment of central nervous system/leptomeningeal (CNS/LM) metastases in pediatric patients with neuroblastoma following standard multimodality treatment for CNS disease. [Details.](#)
- **12:00pm – Discussion: AHP** – The Alliance for Health Policy (AHP) holds a virtual discussion highlighting how behavioral health and primary care integration can help improve the overall health and well-being of individuals, exploring opportunities and challenges in policy and practice including potential federal policy levers for better enabling integration. Sponsored with support from the Commonwealth Fund. [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.](#)

FEATURED WHG ANALYSIS

- ***NEW* WHG 2022 Midterm Elections Preview** – In the Policy Hub Insight Bank [here.](#)
- ***NEW* WHG Tracker of Climate Change Provisions in the IRA** – In the Policy Hub Insight Bank [here.](#)
- **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.](#)

REGULATORY LOOKBACK

Fri. (10/21)

- **CMS [announced](#)** that it is increasing scrutiny and oversight over the country’s poorest-performing nursing facilities. [Details.](#)
- **SAMHSA [announced](#)** more than \$100 million in funding from the Bipartisan Safer Communities Act for mental health services. [Details.](#)
- **The White House ONDCP [released](#)** a new report entitled, “Substance Use Disorder in Pregnancy: Improving Outcomes for Families. [Details.](#)
- **CMS [released](#)** a power point with guidance on *ex parte* Medicaid renewal. [Details.](#)
- **The FDA [issued](#)** final guidance on multiple endpoints in clinical trials. [Details.](#)
- **The FDA [extended](#)** the comment period to November 25 for proposed rule that would establish requirements for a nonprescription drug product with an ACNU. [Details.](#)
- **HHS [issued](#)** a request for written comments on proposed Healthy People 2030 objectives. Comments are due December 2. [Details.](#)
- **The CDC is [seeking](#)** nominations for membership on the Advisory Committee on Breast Cancer in Young Women (ACBCYW). Nominations are due December 29. [Details.](#)

Thurs. (10/20)

- **The GAO** [released](#) two reports on maternal health. [Details](#).
- **AHRQ** [issued](#) an RFI on strategies for integrating behavioral health. [Details](#).
- **The FNS** [announced](#) it provide nearly \$6.5 million for SNAP Employment and Training (E&T) programs. [Details](#).
- **The U.S. Surgeon General** [issued](#) a framework to promote workplace mental health well-being. [Details](#).
- **The FDA** [issued](#) draft guidance on proposed select updates for the Breakthrough Devices Program Guidance. Comments are due December 20. [Details](#).

Weds. (10/19)

- **The FDA** [announced](#) the establishment of the Advancing Real-World Evidence (RWE) Program. [Details](#).
- **HHS OIG** [released](#) a report on how HHAs met the challenges of COVID-19. [Details](#).
- **The FNS** [announced](#) that it has awarded three new grants to modernize the WIC programs. [Details](#).
- **The GAO** [released](#) a report on national adult vaccination rates. [Details](#).
- **HHS OIG** [released](#) a report on how the IHS did not ensure that Tribal programs complied with all requirements during early COVID-19 vaccination program administration. [Details](#).

Tues. (10/18)

- **HHS Secretary Becerra** formally [renewed](#) the COVID-19 PHE for an additional 90 days through January 11, 2023. [Details](#).
- **The White House** [released](#) a new pandemic preparedness and biodefense strategy aimed at ensuring the country is ready to respond to outbreaks of any sort. [Details](#).
- **CMS** [released](#) a power point with guidance for states ending coverage for the optional COVID-19 group at the end of the PHE. [Details](#).
- **The GAO** [released](#) a report on public health preparedness. [Details](#).

Mon. (10/17)

- **SAMHSA** [announced](#) a new funding opportunity for states to develop and transform Certified Community Behavioral Health Clinics (CCBHs). [Details](#).
- **MACPAC** [issued](#) comments on the CMS proposed rule on requiring states to report certain Medicaid measures. [Details](#).
- **The FDA** issued three oncology related guidance documents ([here](#), [here](#), and [here](#)). [Details](#).

COMMENT & APPLICATION DEADLINES

- **October 25:** SAMHSA [announced](#) a new \$35 million grant opportunity to further support the 988 Suicide and Crisis Lifeline. [Details](#).
- **October 27:** CMS is considering modifying one of the requirements states must follow to receive a temporary 6.2 percentage point increase in the federal Medicaid matching fund. CMS is reopening the public comment period for the interim final rule (IFR) that established these requirements in November 2020. [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 4:** The Department of the Treasury [released](#) a set of RFIs to inform the implementation of the Inflation Reduction Act's clean energy incentives. [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](#).

- **November 14:** FDA [issued](#) draft guidance on computer software assurance for production and quality system assurance. [Details](#).
- **November 15:** The Departments of Labor, HHS, and Treasury [issued](#) a RFI to inform future rulemaking for advanced explanation of benefits (AEOB) and good faith estimate (GFE) requirements. [Details](#).
- **November 15:** The AHRQ [issued](#) a RFI on the current state of comprehensive, longitudinal, person-centered care planning for people with Multiple Chronic Conditions. [Details](#).
- **November 25:** The FDA [issued](#) a proposed rule to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). [Details](#).
- **December 2:** HHS [issued](#) a request for written comments on proposed Healthy People 2030 objectives. [Details](#).
- **December 6:** CMS [issued](#) an RFI on the current state of health care provider directories. [Details](#).
- **December 7:** The FDA [issued](#) revised draft guidance on general clinical pharmacology considerations for pediatric studies of drugs. [Details](#).
- **December 13:** The FDA [issued](#) a request for public comments on a recently released [discussion paper](#) on areas associated with Distributed Manufacturing (DM) and Point-of-Care (POC) manufacturing. [Details](#).
- **December 20:** The FDA [issued](#) draft guidance on proposed select updates for the Breakthrough Devices Program Guidance. [Details](#).
- **December 29:** The CDC is [seeking](#) nominations for membership on the Advisory Committee on Breast Cancer in Young Women (ACBCYW). [Details](#).
- **December 31:** AHRQ [issued](#) a supplemental solicitation for nominations of members from Populations Underrepresented in Medicine (URIM) to serve on the Initial Review Group (IRG). [Details](#).
- **January 9:** AHRQ announced a challenge competition to explore the resources and infrastructure needed to integrate real-world data from healthcare systems into systematic review findings. [Details](#).

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