

Wynne Health Group Weekly



FRAMING THE WEEK

Regulatory Update

The Office of Management and Budget (OMB) has completed its review of two major Medicare payment update rules for calendar year 2023 – the Medicare Physician Fee Schedule and the Hospital Outpatient Prospective Payment System. The Centers for Medicare & Medicaid Services (CMS) could release those rules as early as this afternoon, though the timing is not certain. However, CMS has been known to deliver tricks and treats in the past, with the release of major payment rules on Halloween (most recently in 2019)

In addition, CMS [announced](#) late last Friday that it is delaying the timeline for publication of its final rule regarding Medicare Advantage risk adjustment for another three months until February 1, 2023. The rule was originally proposed in 2018 (WHG summary [here](#)) and would revise the MA Risk Adjustment Data Validation (RADV) regulations in order to better recoup overpayments to MA plans. CMS previously extended the publication timeline for an additional year in October 2021. The agency cites “ongoing exceptional circumstances” as the cause for this most recent decision to delay the rule’s publication.

Unwinding the Public Health Emergency

Health and Human Services Secretary Xavier Becerra recently renewed the public health emergency (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 Medicaid beneficiaries who no longer meet coverage requirements as soon as February 1, 2023.

At last week’s MACPAC [session](#) on unwinding the PHE, Commissioners asserted the importance of monitoring states’ progress towards unwinding the continuous coverage provision given administrative and operational complexity and the potential for inappropriate loss of coverage for Medicaid beneficiaries. The session focused on the different CMS, federal, and state monitoring requirements, but noted that it is unclear what data on conducting eligibility redeterminations will be made public. Several Commissioners expressed concern with the lack of commitment by CMS and states to release data and called for increased data transparency.

WHG Roundup: Looking Ahead on Medicare

This week, CMS Administrator Brooks-LaSure will hold a [National Stakeholder Call](#) to provide an update on recent accomplishments and progress on the agency’s Strategic Plan ([WHG summary](#)). With Democrats expecting a more difficult legislative environment after the upcoming midterm elections, the Administration’s focus will likely shift towards agency action. The Administrator’s call could provide some additional insight into what CMS has planned over the coming months.

Implementation of the Inflation Reduction Act

The implementation of the Inflation Reduction Act features several drug pricing reforms that are intended to improve the affordability of prescription drugs for Medicare beneficiaries. CMS recently released an [implementation timeline](#) that starts with October 1, 2022 provisions and goes through 2029. Below we highlight recent implementations actions. All other implementation dates occur in 2023 and beyond.

- **Establishment of the Medicare Drug Rebate and Negotiations Group** – The Department of Health and Human Services (HHS) recently [announced](#) the establishment of the Medicare Drug Rebate and Negotiations Group within the Center for Medicare to implement the drug price negotiations program and the inflation rebate program. Additional details and responsibilities of the Group can be found [here](#).
- **Medicare Part D Drug Rebates** – October 1 marks the start of the first 12-month period for which drug manufacturers will be required to pay rebates to Medicare if the price for Part D drugs exceeds the rate of inflation. Rebates for the first two 12-month rebate periods will be invoiced to manufacturers by December 31, 2025.
- **Temporary Payment Increase Biosimilars** – A provision that provides a [temporary payment increase for biosimilars](#) whose list price does not exceed the reference biologic list price went into effect October 1. Qualifying biosimilars will be reimbursed at the average sales prices (ASP) of the reference biologic plus 8 percent, compared to the typical 6 percent, for a period of five years.

MedPAC

The [Medicare Payment Advisory Commission \(MedPAC\)](#) will hold its third meeting of the 2022-2023 cycle this Thursday and Friday. Commissioners will examine differences in quality measures across race/ethnicity categories and income level and provide direction for future work. Commissioners will also review and discuss policy options for increasing Medicare payments to primary care clinicians as well as the alignment of fee-for-service payment rates across ambulatory settings.

Additionally, the Commission will continue its discussion on the following topics:

- Prototype prospective payment system (PPS) for all post-acute care (PAC) providers (report due June 30, 2023) ([WHG summary](#));
- Options to better support safety-net clinicians ([WHG summary](#)); and
- Standardizing benefits in Medicare Advantage plans ([WHG summary](#)).

THIS WEEK IN HEALTH POLICY

Tue. (11/01)

- **3:00pm – CMS Stakeholder Call: Strategic Plan** – The Administrator of the Centers for Medicare and Medicaid Services (CMS), Chiquita Brooks-LaSure holds a fourth National Stakeholder Call in 2022 to provide an update on CMS's recent accomplishments and CMS's Strategic Plan. [Register](#).
- **3:00pm – HA Discussion: AHRQ** – Health Affairs holds a virtual “One-On-One” discussion with the Department of Health and Human Services (HHS) Agency for Healthcare Research and Quality (AHRQ) Director Robert Otto Valdez, as part of the Policy Spotlight Series. [Details](#).

Wed. (11/02)

- **2:00pm – HHS Webinar: Environmental Justice Index** – The Department of Health and Human Services (HHS) Office of Environmental Justice (OEJ), in conjunction with the Centers for Disease Control and Prevention (CDC)'s Agency for Toxic Substances and Disease Registry (ATSDR) hold a webinar that will teach attendees how to use the new Environmental Justice Index. [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. (11/03)

- **12:00pm – CDC Meeting: HICPAC** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) to discuss updates on healthcare personnel guideline, neonatal intensive care and pediatric surveillance workgroups. [Details.](#)
- **3:00pm – ONC Meeting: Annual Report Workgroup** – ONC holds a meeting of the Health Information Technology Advisory Committee (HITAC) Annual Report Workgroup to develop recommendations for an annual report. [Details.](#)
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [Details.](#)

Fri. (11/04)

- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [Details.](#)

Additional Multi-Day Events

- **November 1-November 3 – HRSA Meeting: CHAC** – The Health Resources and Services Administration (HRSA) holds a meeting of the Secretary’s Advisory Committee on HIV, Viral Hepatitis and STS Prevention and Treatment (CHAC) to discuss objectives, strategies, policies, and priorities for the prevention and treatment of HIV, viral hepatitis, and other STDs. [Details.](#)
- **November 2-November 3 – CDC Meeting: ACD** – CDC holds a meeting of the Advisory Committee to the Director (ACD) to discuss data modernization, laboratory quality and health equity. The ACD will have presentations on the COVID-19 and Monkeypox responses, Social Determinants of Health, and CDC’s Moving Forward Initiative. [Details.](#)
- **November 2-November 3 – HRSA Meeting: NACMH** – The Health Resources and Services Administration (HRSA) holds a meeting of the Secretary’s National Advisory Council on Migrant Health (NACMH) to discuss partnerships serving migrant health centers and the migrant health center workforce. [Details.](#)
- **November 3-November 4 – HRSA Meeting: ACHDNC** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) to discuss the Department of Defense’s Newborn Screening System, the recommended uniform screening panel, and a Krabbe disease review update. [Details.](#)

FEATURED WHG ANALYSIS

- ***NEW* WHG Roundup of Recent Reproductive Health Developments** In the Policy Hub Insight Bank [here.](#)
- **WHG 2022 Midterm Elections Preview** – In the Policy Hub Insight Bank [here.](#)
- **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.](#)

CONGRESSIONAL LOOKBACK

Fri. (10/28)

- **MACPAC** [convened](#) virtually for Day Two of its September 2022 public meeting and held a sessions on HCBS, DSH, and promoting equity. All WHG session summaries are available on Policy Hub [here](#).

Thurs. (10/27)

- **MACPAC** [convened](#) virtually for Day One of its September 2022 public meeting and held sessions on race and ethnicity data collection, improving Medicaid coverage for adults leaving incarceration, unwinding the PHE, trends in prescription drug spending, and HCBS. All WHG session summaries are available on Policy Hub [here](#).

REGULATORY LOOKBACK

Fri. (10/28)

- **CMS** released a [final rule](#) to implement CAA provisions to extend Medicare Part B coverage of immunosuppressive drugs beyond 36 months after transplant and establish five new Medicare SEPs. [Details](#).
- **The GAO** [released](#) a report on available information on the behavioral health workforce and federal actions to support recruiting and retaining behavioral health providers. [Details](#).

Weds. (10/26)

- **The FDA** [announced](#) the establishment of the Rare Disease Endpoint Advancement Pilot Meeting Program. [Details](#).
- **CMS** is [seeking](#) nominations for a TEP focused on refining the nursing home antipsychotic medication measures. Nominations are due November 11. [Details](#).
- **HHS OIG** [released](#) an audit finding that some Medicare Part C and Part D sponsors may have paid ineligible providers for services to Medicare beneficiaries. [Details](#).

Tues. (10/25)

- **The CDC** [held](#) a meeting of the BSC to review NCHS's updates on data collection, analysis, and reporting activities. [Details](#).
- **The White House** [announced](#) that President Biden will get his updated COVID-19 vaccine and called on state, local, education, and business leaders to do their part. [Details](#).

COMMENT & APPLICATION DEADLINES

- **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 11:** CMS is [seeking](#) nominations for a TEP focused on refining the nursing home antipsychotic medication measures. [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.](#)

WHG Contacts for Inquiries

Alyssa Llamas: alyssa@wynnehealth.com; (562) 207-8807

Josh LaRosa: josh@wynnehealth.com; (703) 309-4248

Erin Slifer: erin@wynnehealth.com; (410) 984-4552

Billy Wynne: billy@wynnehealth.com; (202) 309-0796

