

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

Congress remains in recess and will return next week. In the meantime, we look ahead to anticipated regulations from the Biden Administration and key comment deadlines. The fiscal year (FY) 2023 inpatient prospective payment system (IPPS) proposed rule, which has cleared review at the Office of Management and Budget (OMB), is expected imminently this week. As part of the Biden Administration's [initiatives](#) to address maternal health, the IPPS proposed rule will include a proposal to establish a "Birthing-Friendly" hospital designation to highlight hospitals that have participated in maternity care quality improvement collaboratives and implemented best practices that advance health care quality, safety, and equity for pregnant and postpartum patients.

Once the comment periods elapse for each FY 2023 Medicare proposed update, we can expect the final rules for each payment system to be released in August. Meanwhile, the Centers for Medicare & Medicaid Services (CMS) will work to release its proposed Medicare payment updates for the calendar year (CY) 2023 set of rules – e.g., the Physician Fee Schedule and the Hospital Outpatient Prospective Payment System, among others. Those proposed rules are expected to arrive later in June.

Beyond the proposed Medicare payment updates, a number of other notable rules are currently under review at the Office of Management and Budget (OMB), indicating the Administration is working to prepare them for release in the *Federal Register*. These rules include:

- The [final rule](#) for the 2023 Notice of Benefit and Payment Parameters (WHG summary on the proposed rule is available [here](#));
- The [final rule](#) for the Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (WHG summary on the proposed rule is available [here](#));
- A [proposed rule](#) to establish mandatory reporting requirements for the Medicaid and CHIP Core Sets (Of note, the comment period for the CMS [request for information](#) on access to care and coverage for Medicaid and CHIP closes today, April 18); and
- A [proposed rule](#) to modify the Trump Administration's changes to implementation of section 1557 of the Affordable Care Act (ACA), which curtails the scope of application of section 1557 protections and creates uncertainty and ambiguity as to what constitutes prohibited discrimination in covered health programs and activities.

Finally, several comment period deadlines end in the next few weeks, including:

- **April 25:** The Federal Trade Commission [issued](#) a request for public comments on the ways that [pharmacy](#) benefit managers (PBMs) affect drug affordability and access. [Details](#).

- **April 28:** The Agency for Healthcare Research and Quality 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.](#)

## THIS WEEK IN HEALTH POLICY

### Mon. (4/18)

- **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 policy and program development. [Details.](#)

### Tue. (4/19)

- **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.](#)
- **12:00pm – FDA Meeting: Medical User Fee Amendments** – The Food and Drug Administration (FDA) holds a meeting to discuss Medical Device User Fee Amendments (MDUFA) for fiscal years 2023-2027. [Details.](#)
- **12:30pm – NIH Meeting: Toxicology** – The National Institutes of Health (NIH) holds a meeting of the National Toxicology Program Board of Scientific Counselors to review and provide advice on programmatic activities. [Details.](#)

### Thurs. (4/21)

- **2:30pm – CHCS Webinar: Telehealth** – The Center for Health Care Strategies (CHCS) holds a webinar titled, “Using Telehealth to Support Equitable Access to Health Care in Medicaid.” [Details.](#)

### Fri. (4/22)

- **10:00am – AHP Panel: Medicare** – The Alliance for Health Policy (AHP) holds the first of a series of three discussions on the future of Medicare titled, “The Future of Medicare: Medicare 101.” [Details.](#)

## FEATURED WHG ANALYSIS

- **WHG Tracker of COVID-19 PHE Flexibilities** – In the Policy Hub Insight Bank [here.](#)
- **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

## REGULATORY LOOKBACK

### Fri. (4/8)

- **The ONC [held](#)** the 2022 annual meeting which included a focus on health equity. [Details.](#)

- **HRSA** [announced](#) the availability of \$226.5 million in American Rescue Plan (ARP) funding to launch the new Community Health Worker Training Program (CHWTP). Applications are due June 14. [Details](#).
- **CMS** [released](#) a series of Cross-Cutting Initiatives (CCIs) that will drive the strategic vision to advance health equity, expand coverage, and improve health outcomes. [Details](#).
- **AHRQ** [extended](#) the comment period for its RFI on its proposed strategic framework for the Patient-Centered Outcomes Research Trust Fund (PCORTF) investments until May 24. [Details](#).
- **The USDA** [released](#) its Equity Action Plan pursuant to President Biden's *Executive Order*. [Details](#).

#### **Thurs. (4/7)**

- **The Biden-Harris Administration** [released](#) Equity Action Plans for more than 90 federal agencies, HHS, HUD, and the USDA. [Details](#).
- **The FDA** [issued](#) final guidance on general considerations for bioavailability (BA) studies. [Details](#).
- **The FNS** [released](#) proposed scientific questions to inform the development of the *Dietary Guidelines for Americans 2025-2030*. Comments are due May 12. [Details](#).

#### **Weds. (4/6)**

- **HRSA** [announced](#) that it is distributing the \$1.75 billion in Provider Relief Fund (PRF) Phase 4 payments for the fifth batch of payments. [Details](#).
- **The HHS Interdepartmental Serious Mental Illness Coordinating Committee** [convened](#) a meeting to discuss working group recommendations to better coordinate the administration of mental health services for adults. [Details](#).
- **The FDA** [issued](#) draft guidance on diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations in clinical trials. Comments are due June 13. [Details](#).
- **The USPSTF** issued draft recommendation statements in favor of screening for [major depressive disorder \(MDD\)](#) and [anxiety](#) among children and adolescents. Comments are due May 9. [Details](#).

#### **Tues (4/5)**

- **The White House** [announced](#) new actions to decrease medical debt and increase consumer protection. [Details](#).
- **CMS** [approved](#) a New Jersey SPA to ensure that the state covers routine patient costs for items and services furnished associated with clinical trial participation. [Details](#).

#### **Mon. (4/4)**

- **CMS** [released](#) the FY 2023 SNF PPS proposed rule. Comments are due June 10. [Details](#).
- **ASPE** [published](#) an issue brief examining trends in COVID-19 vaccination intentions. [Details](#).
- **ICER** [published](#) a report on ensuring innovation and affordability for the next generation of rare disease drug policy. [Details](#).

#### **COMMENT & APPLICATION DEADLINES**

- **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:** The USPSTF issued draft recommendation statements in favor of screening for [major depressive disorder \(MDD\)](#) and [anxiety](#) among children and adolescents. [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 21<sup>st</sup> Century Cures Act. [Details.](#)
- **May 12:** The FNS [released](#) proposed scientific questions to inform the development of the *Dietary Guidelines for Americans 2025-2030*. [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 24:** AHRQ [extended](#) the comment period for its RFI on its proposed strategic framework for the Patient-Centered Outcomes Research Trust Fund (PCORTF) investments. [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.](#)
- **June 10:** CMS [released](#) the FY 2023 SNF PPS proposed rule. [Details.](#)
- **June 13:** The FDA [issued](#) draft guidance on diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations in clinical trials. [Details.](#)
- **June 14:** HRSA [announced](#) the availability of \$226.5 million in American Rescue Plan (ARP) funding to launch the new Community Health Worker Training Program (CHWTP). [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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