

Wynne Health Group Weekly



FRAMING THE WEEK

President Biden is expected to sign the Inflation Reduction Act of 2022 ([H.R. 5376](#); [WHG summary](#)) into law this week. The sweeping FY 2022 budget reconciliation package to lower health care costs, reform tax policy, reduce the deficit, and invest in initiatives to combat the climate crisis delivers a major legislative victory to Democrats. It could be the last big win for the White House if Democrats lose control of one or both chambers. Democrats are [slightly favored](#) to win the Senate, and Republicans are [favored](#) to win the House, as of August 15, according to FiveThirtyEight.

Without control of Congress, the Biden Administration’s ability to advance its policy agenda will be mostly limited to regulatory reform. In this issue of the Weekly, we provide an update on the Administration’s regulatory agenda.

Regulatory Outlook

To date, the Centers for Medicare & Medicaid Services (CMS) have released all fiscal year (FY) 2023 final Medicare payment rules, as well as all calendar year (CY) 2023 proposed Medicare payment rules. The remaining rulemaking for the 2023 Medicare payment update cycle therefore includes only the CY 2023 final Medicare payment rules, which are expected later this fall. Highlights of the Medicare payment update rulemaking are included in the table below.

Medicare Payment System	Key Highlights
<i>FY 2023 Final Rules</i>	
Inpatient Prospective Payment System (IPPS)	<ul style="list-style-type: none"> • Finalized 4.3 percent increase in payments to hospitals • Finalized a “Birthing-Friendly” hospital designation • Included stakeholder responses to requests for information (RFI) on how the agency can help hospitals determine the threat climate change presents to operations, what CMS should consider when using measurement and stratification to advance health equity, and potential changes to a definition of digital quality measures.
Skilled Nursing Facility (SNF) PPS	<ul style="list-style-type: none"> • Finalized 2.7 percent increase in payments for SNFs • Included stakeholder responses to RFIs on equity-focused measures in the SNF Quality Reporting Program, the inclusion of the National Healthcare Safety Network COVID-19 Vaccination Coverage among Healthcare Personnel measure in the SNF Value-Based Reporting Program (VBP), and including a measure in the SNF VBP on staff turnover.
Hospice Payment Rate	<ul style="list-style-type: none"> • Finalized a 3.8 percent payment rate increase for hospices
Inpatient Psychiatric Facility (IPF) PPS	<ul style="list-style-type: none"> • Finalized a 2.5 percent payment rate update for IPFs
Inpatient Rehabilitation Facility (IRF) PPS	<ul style="list-style-type: none"> • Finalized a 3.2 percent payment rate update for IRFs

<i>CY 2023 Proposed Rules</i>	
Medicare Physician Fee Schedule (MPFS)	<ul style="list-style-type: none"> Proposed the addition of several new services to the Medicare telehealth list on a temporary basis Proposed several mental health-focused changes, including flexibilities for mental health workers to practice at the top of their license; reimbursing psychologists and social workers to help manage mental health needs as part of primary care teams; and increasing payments for Opioid Treatment Programs Proposed changes to the Medicare Shared Savings Program (MSSP) that would allow participating ACOs to use shared savings payments to address Medicare beneficiaries' social needs Proposed coverage of certain medically necessary dental services
Hospital Outpatient Prospective Payment System (OPPS)	<ul style="list-style-type: none"> Proposed to establish payment rates and provider enrollment procedures for rural emergency hospitals (REHs), a new provider designation established by the Consolidated Appropriations Act, 2021 Proposed to continue payment for remote behavioral health services provided by clinical staff of hospital OPDs after the conclusion of the COVID-19 public health emergency Included several requests for information (RFIs) as well, seeking feedback related to: how data can be further utilized to promote competition and quality improvement; principles for measuring healthcare quality disparities across CMS quality programs; and alternative methodologies for counting organs to calculate Medicare's share of organ acquisition costs
End Stage Renal Disease (ESRD) PPS	<ul style="list-style-type: none"> Proposed a 3.1 percent increase to ESRD facilities No major policy changes proposed in this rule – mainly refinements to the ESRD Quality Incentive Program and the ESRD Treatment Choices Model Included an RFI on ways to improve health equity through the ESRD QIP – e.g., by potentially including new measures related to social needs screening
Home Health PPS	<ul style="list-style-type: none"> Proposed a -7.69 percent payment adjustment to the 30-day payment rate to account for behavioral changes under the Patient-Driven Groupings Model Sought feedback on how to incorporate health equity into the home-health quality reporting program and value-based purchasing model and on how to collect data on the use of telehealth for home health

Looking ahead, the Administration targeted a number of rules for promulgation in the near term in its latest [Unified Agenda update](#). Whether these rules will actually be released on their expected timeline is unclear, as there are often delays for various reasons to the timelines set forth by the Administration in its Unified Agenda (note that only one rule is under review at the Office of Management and Budget (OMB)). With that caveat in mind, we list out the potential rulemaking we may see in the coming weeks and months below.

- August 2022:** The HHS Office for Civil Rights (OCR) is slated to [propose a rule](#) to better harmonize the 42 CFR part 2 (part 2) confidentiality requirements with certain permissions and requirements of the HIPAA Rules and the HITECH Act.
- August 2022:** CMS intends to [propose a rule](#) that would streamline eligibility and enrollment processes for all Medicaid and CHIP populations and create new enrollment pathways to maximize enrollment and retention of eligible individuals.
- August 2022:** CMS is expected to [propose](#) amendments to the definition of “short-term, limited-duration insurance” in such a way that protects enrollees with pre-existing conditions.

- **August 2022:** CMS is planning to [propose](#) amendments to the final rules regarding religious and moral exemptions and accommodations regarding coverage of certain preventive services under the Affordable Care Act (*rule is currently under review at the OMB*).
- **August 2022:** FNS is expected to issue a [final rule](#) that will codify several waivers and flexibility to streamline program administration in the Summer Food Service Program.

THIS WEEK IN HEALTH POLICY

Wed. (8/17)

- **10:30am-3:00pm – ONC Meeting: Health IT** – The Office of the National Coordinator of Health Information Technology (ONC) convenes a meeting of the Health Information Technology Advisory Committee (HITAC) to discuss interoperability, privacy and security, patient access, and use of technologies that support public health. [Details.](#)
- **3:30pm – WaPo Live: Mental Health** – The Washington Post (WaPo) hosts a live conversation with U.S. Surgeon General Vivek H. Murthy, MD and UNICEF senior mental health technical advisor Zeinab Hijazi on the state of youth mental health. [Details.](#)

Thurs. (8/18) –

- **10:00am – SAMHSA Meeting: Mental Health** – The Substance Abuse and Mental Health Administration (SAMHSA) convenes a meeting of the Center for Mental Health Services (CMHS) National Advisory Council to hear updates from the CMHS director, updates from the Office of the Assistant Secretary, and council discussions. [Details.](#)

Additional Multi-Day Events

- **August 16-August 18 – FDA Meeting: Tuberculosis** – The Food and Drug Administration (FDA) hosts a three-day meeting titled, “Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines.” [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

Weds. (8/10)

- **CMS** is seeking [nominations](#) for two Technical Expert Panels (TEPs). Nominations are due September 2 and September 6. [Details.](#)
- **HHS** Office of Environmental Justice unveiled its new [Environmental Justice Index](#). [Details.](#)

COMMENT & APPLICATION DEADLINES

- **August 15:** The FDA [issued](#) a request for nominations for voting and nonvoting consumer representatives to serve on advisory committees and panels. [Details.](#)
- **August 16:** CMS [issued](#) the cycle year (CY) 2023 home health prospective payment system and rate update proposed rule. [Details.](#)
- **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 OPSS 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.](#)

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

