

Wynne Health Group Weekly



FRAMING THE WEEK

Congress is out on spring recess and returns next week to resume work on various health care and public health policy priorities.

The Senate Health, Education, Labor and Pensions (HELP) Committee [plans](#) to mark-up drug pricing legislation on April 19 focused on pharmacy benefit managers and generic drugs, though the markup has not yet been officially scheduled. The package is likely to feature provisions that increase transparency of PBM practices and support the development of biosimilar and generic drugs. The bill may include provisions from the following:

- **The Pharmacy Benefit Manager Transparency Act (S. 127)**, which prohibits spread pricing and clawbacks; increases transparency; and allows for reporting exemption if rebates are passed through and certain information is disclosed
- **The Drug Price Transparency in Medicaid Act (H.R. 1613)**, which prohibits spread pricing in Medicaid
- **The Stop STALLING Act (S. 148)**, which prohibits sham FDA citizen petitions.
- **The Preserve Access to Affordable Generics and Biosimilars Act (S. 142)**, which prohibits pay for delay agreements between brand and generic or biosimilar manufacturers.
- **The Increasing Transparency in Generic Drug Applications Act (S.775)**, which streamlines the approval process for generic drugs by requiring the FDA to disclose differences between the generic and brand drug during the approval process.
- **The Affordable Prescriptions for Patients Act of 2023 (S. 150)**, which prohibits product hopping, where manufacturers switch the patient population to a follow-on product, when the reference product's patent is set to expire.

Additionally, the Senate HELP Committee is working on bipartisan bills to [address the health care workforce shortage](#) and [reauthorize the Pandemic and All-Hazards Preparedness Act \(PAHPA\)](#). The House Energy and Commerce Subcommittee on Health is also preparing for [PAHPA reauthorization](#).

Regulatory Update

We are waiting for several rules on Medicare payments for acute care hospitals and long-term care hospitals, reproductive health care privacy, and health IT and interoperability. They have all cleared review at the Office of Management and Budget (OMB).

- **Medicare Payments** – The [proposed rule](#) for inpatient and long-term care hospital prospective payment systems (PPS) is the last of the fiscal year 2024 Medicare payment updates. Our

summaries of PPS proposed rules are available here: [inpatient psychiatric facilities](#); [inpatient rehabilitation facilities](#); [skilled nursing facilities](#); and [hospices](#).

- **Reproductive Health Care Privacy** – The Department of Health and Human Services is expected to issue [proposed modifications](#) to the HIPAA Privacy Rule to support reproductive health care privacy. Following the Supreme Court decision in *Dobbs v. Jackson Women’s Health Organization*, HHS issued [guidance](#) on how the HIPAA Privacy Rule applies to information relating to reproductive health care. The guidance explains that disclosures for purposes not related to health care, such as disclosures to law enforcement officials, are permitted only in narrow circumstances tailored to protect the individual’s privacy and support their access to health care, including abortion care. The forthcoming proposed rule will likely seek to strengthen privacy protections, particularly within the context of states with bans or severe restrictions on abortions.
- **Health IT and Interoperability** – The Office of National Coordinator for Health Information Technology (ONC) will release a [proposed rule](#) implementing certain provisions of the 21st Century Cures Act, including:
 - Electronic Health Record Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program;
 - Process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement (TEFCA) to attest to such adoption of the framework and agreement;
 - Enhancements to support information sharing under the information blocking regulations.

The rule will also proposals for new standards and certification criteria under the Certification Program related to the United States Core Data for Interoperability, real-time benefit tools, electronic prior authorization, and potentially other revisions to the Certification Program.

MedPAC

Later this week, the Medicare Payment Advisory Commission (MedPAC) will [convene](#) to discuss a range of issues relating to prescription drug prices, payment systems, telehealth, and behavioral health. MedPAC will vote on recommendations for the June 2023 Report to Congress on:

- Addressing the high prices of drugs covered under Medicare Part B,
- Reforming Medicare’s prospective payment system’s use of wage indexes,
- Aligning fee-for-service payment rates across ambulatory settings, and
- Establishing a unified post-acute care prospective payment system.

MACPAC

The Medicaid and CHIP Payment and Access Commission (MACPAC) will also [convene](#) to continue discussions regarding:

- Integrating care for dually eligible beneficiaries,
- Access to Medicaid coverage and care for adults leaving incarceration,
- Unwinding of continuous enrollment requirements,
- Home and community-based services, and
- Managed care.

MACPAC will also vote on recommendations for automatic adjustments to disproportionate share hospital allotments, which will be included in the June 2023 Report to Congress. Lastly, MACPAC will discuss the [proposed rule](#) on Medicaid disproportionate share hospital third-party payer policy.

THIS WEEK IN HEALTH POLICY

Tue. (4/11)

- **1:00pm – NIH Meeting: Muscular Dystrophy** – The National Institutes of Health (NIH) hold a meeting of the Muscular Dystrophy Coordinating Committee Meeting to discuss plans for renewal of the Action Plan for the Muscular Dystrophies and strategic plans developed by advocacy groups. [Details.](#)

Wed. (4/12)

- **9:30am – NIH Meeting: Research on Women’s Health** – NIH holds a meeting of the Advisory Committee on Women’s Health to discuss presentations on translational science including the NIH-wide Strategic Plan on Research on the Health of Women. [Details.](#)
- **10:00am – HITAC Meeting: Health IT Advisory Committee** – The Health Information Technology Advisory Committee (HITAC) holds a meeting to discuss program updates. [Details.](#)

Thurs. (4/13)

- **1:00pm – US News & World Reports Webinar: Hospitals/Autism** – The U.S. News & World Reports hold a webinar to discuss how hospitals are supporting individuals on the autism spectrum. [Details.](#)
- **Meeting: MedPAC** – The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. [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. (4/14)

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

Additional Multi-Day Events

- **April 12-April 13 – CDC Meeting: Clinical Laboratory Improvement** – The Centers for Disease Control and Prevention (CDC) hold a meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to discuss workgroup updates and the laboratory’s role in advancing health equity. [Details.](#)

FEATURED WHG ANALYSIS

- **WHG Tracker of COVID-19 PHE Flexibilities** – In the Policy Hub Insight Bank [here](#)
- **WHG Health Policy Guide to the 118th Congress** – In the Policy Hub Insight Bank [here.](#)
- **WHG Roundup of Surprise Billing and Transparency Updates**– In the Policy Hub Insight Bank [here.](#)
- **WHG Maternal Health Policy Update: November – December 2022** – In the Policy Hub Insight Bank [here.](#)

REGULATORY LOOKBACK

Thurs. (4/6)

- **HHS released** a fact sheet outlining the progress the Biden-Harris Administration has made in the whole-of-government response the longer effects of COVID-19. [Details.](#)

- **The FDA [issued](#)** draft guidance entitled: “Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments (COAs) Into Endpoints for Regulatory Decision-Making.” Comments are due July 5. [Details](#).

Weds. (4/5)

- **CMS [released](#)** the CY 2024 Policy and Technical Changes to the MA and Part D programs final rule. [Details](#).
- **The AHRQ [issued](#)** a request for supplemental evidence and data to inform its systematic review of *Psychosocial and Pharmacologic Interventions for Disruptive Behavior in Children and Adolescents*. Comments are due May 6. [Details](#).
- **The HHS OCR [issued](#)** a letter reminding states of their obligations under federal civil rights laws as the PHE for COVID-19 comes to end. [Details](#).

Tues. (4/4)

- **CMS [released](#)** the FY 2024 SNF PPS proposed rule. Comments are due June 5. [Details](#).
- **CMS [released](#)** the FY 2024 IPF PPS proposed rule. Comments are due June 5. [Details](#).

Mon. (4/3)

- **CMS [released](#)** the FY 2024 IRF PPS proposed rule. Comments are due June 2. [Details](#).
- **The FDA [issued](#)** an RFI to assess whether in-home disposal products can mitigate the risk of nonmedical use or overdose of opioid analgesics. Submissions are due August 28. [Details](#).
- **HHS [released](#)** a National Cancer Plan to advance the fight against cancer and to realize the vision laid out by President Biden’s Cancer Moonshot. [Details](#).

COMMENT & APPLICATION DEADLINES

- **April 12:** The OMB [requests](#) comments on initial proposals to improve the quality and usefulness of race and ethnicity data collected and reported across federal agencies. [Details](#).
- **April 14:** CMS [issued](#) a proposed rule to require the disclosure of certain ownership, managerial, and other information regarding Medicare SNFs and Medicaid nursing facilities. [Details](#).
- **April 14:** The CDC [is seeking](#) nominations for membership on the Board of Scientific Counselors, Deputy Director for Infectious Diseases. [Details](#).
- **April 24:** The FCC released both a [proposed rule](#) and a [final rule](#) for the Rural Health Care Program. [Details](#).
- **April 25:** CMS [issued](#) a proposed rule to implement requirements under section 203 of the Consolidated Appropriations Act, 2021 (CAA), which relate to Medicaid shortfall and third-party payments. [Details](#).
- **April 27:** HRSA [announced](#) a funding opportunity through its Nurse Education, Practice, Quality and Retention (NEPQR)-Pathway to Registered Nurse Program (PRNP). [Details](#).
- **April 28:** CMS [issued](#) a proposed rule that seeks to further clarify the treatment of inpatient days associated with Medicaid Section 1115 demonstrations in the calculation of Medicare disproportionate share hospital (DSH) payments. [Details](#).
- **May 1:** The NIH [announced](#) a number of grants to address health disparities and advance health equity. Applications are due May 1. [Details](#).
- **May 1:** The NTIA [issued](#) a request for comments on the Digital Equity Act of 2021 Program. [Details](#).
- **May 8:** SAMHSA [released](#) grant opportunity for cooperative agreements to implement the Zero Suicide intervention and prevention model in health systems. [Details](#).
- **May 22:** The AHRQ [issued](#) a request for nominations for new members of the National Advisory Council for Healthcare Research and Quality. [Details](#).
- **May 24:** The FNS [released](#) a proposed rule to support online ordering in WIC. [Details](#).
- **May 26:** The AHRQ [issued](#) a request for nominations for new members of the National Advisory Council for Healthcare Research and Quality. [Details](#).
- **May 30:** CMS [released](#) the FY 2024 hospice payment rate update proposed rule. [Details](#).

- **June 2:** CMS [released](#) the FY 2024 IRF PPS proposed rule. [Details](#).
- **August 28:** The FDA [issued](#) an RFI to assess whether in-home disposal products can mitigate the risk of nonmedical use or overdose of opioid analgesics. Submissions are due August 28. [Details](#).
- **September 6:** The FDA [issued](#) a proposed rule to establish tobacco product manufacturing practice (TPMP) requirements. [Details](#).

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