

Wynne Health Group Weekly



FRAMING THE WEEK

The House is on recess this week, after Speaker Kevin McCarthy successfully passed *The Limit, Save Grow Act*, the House Republicans' plan to raise the debt limit through May of 2024 while also cutting discretionary federal spending by approximately 22% down to FY 2022 levels ([text/summary/section by section](#)), rescinding unspent COVID-19 funds, and imposing controversial policies such as requiring Medicaid recipients to work 80 hours a month. Speaker McCarthy managed to pass the bill by a two-vote margin with 4 Republicans voting against it.

The Democratic controlled Senate has pronounced the bill “dead on arrival” and in a [letter](#) to Senate Democratic colleagues, Senate Majority Leader Chuck Schumer (D-NY) said the Senate will hold hearings on the bill “to expose the true impact of this reckless legislation on everyday Americans.” However, the power dynamic in the broader negotiations to raise the debt ceiling has been changed as the House Republican package is the only passed legislation that raises the debt ceiling, the Senate has yet to introduce a bill. For now, Senate Democrats the Administration are sticking with their insistence on a clean plan to raise the debt ceiling and avoid default, and any spending cuts be a separate discussion.

Markups:

On Tuesday, the Senate Health, Education, Labor and Pensions (HELP) Committee will have a markup to consider the following legislation aimed at pharmacy benefit managers (PBMs) and generic drugs:

- S. 1067, Ensuring Timely Access to Generics Act of 2023 – Introduced in the Senate by Sen. Jeanne Shaheen (D-NH) (press release) and cosponsored by Sens. Susan Collins (R-ME), Michael Bennett (D-CO), Marco Rubio (R-FL), Tammy Baldwin (D-WI), and Mike Braun (R-IN). This bipartisan bill would empower the FDA to deny citizen petitions submitted either to primarily delay competition or that do not raise valid scientific or regulatory issues, in order to increase competition in the marketplace and lower costs for patients.
- S. 1114, Expanding Access to Low-Cost Generics Act of 2023 – Introduced by Sen. Tina Smith (D-MN) and Sen. Mike Braun (R-IN) (press release), the bill would seek to eliminate the practice of “parking” in which brand name manufacturers agree not to sue “first filers” of generics, so long as the generic applicant agrees to delay bringing the generic competitor to market. The bill allows companies that are not first filers the ability to receive 180-day market exclusivity for their generic if the first filer does not come to market in a timely fashion.
- S. 1214, RARE Act – Introduced in the Senate by Sen. Tammy Baldwin (D-WI) this bill aims to clarify that the exclusivity period of orphan drugs, which currently lasts for seven years, would prevent the approval of other drugs for the same approved use or indication, rather than for the same disease or condition. This refers to the use or indication licensed under section 351 of the Public Health Service Act for a drug designated under section 526 for a rare disease or

condition. The bill would apply to any drug designated under section 526 in the Federal, Drug, and Cosmetic Act, regardless of the date on which the drug was designated, approved, or licensed.

- S____, Pharmacy Benefit Manager Reform Act – Introduced by Sens. Sanders and Cassidy, the bill establishes robust PBM reporting requirements, bans spread pricing, and requires 100 percent rebate pass through.

Hearings

Senate Finance Committee: On Wednesday, May 3, the Senate Finance Committee will hold a [hearing](#) titled “Barriers to Mental Health Care: Improving Provider Directory Accuracy to Reduce the Prevalence of Ghost Networks.” Witnesses include Keris Jän Myrick, Inseparable; Jack Resneck Jr., MD, American Medical Association; Robert L. Trestman, Ph.D., MD, Carilion Clinic and Virginia Tech Carilion School of Medicine; Mary Giliberti, Mental Health America, and Jeff Rideout, MD, Integrated Healthcare Association.

Senate Labor-HHS Appropriations: On Thursday, May 4, the Senate Labor-HHS Appropriations Subcommittee will hold a [hearing](#) on the FY 2024 NIH budget request. Acting NIH Director Lawrence Tabak will testify, along with Dr. Monica Bertagnolli, Director of the National Cancer Institute; Dr. Joshua Gordon, Director of the National Institutes of Mental Health; Dr. Richard Hodes, Director of the National Institute on Aging; and Dr. Nora Volkow, Director of the National Institute on Drug Abuse.

Senate HELP Committee: On Thursday, the Senate HELP Committee will hold a [hearing](#) to examine preparing for the next public health emergency, focusing on reauthorizing the Pandemic and All-Hazards Preparedness Act.

Regulatory Update

The Office of Management and Budget (OMB) has started to review calendar year 2024 Medicare payment policies. Specifically, OMB is reviewing proposed updates to the [Physician Fee Schedule](#) and payment and policy updates for [hospital outpatient departments and ambulatory surgical centers](#), [home health agencies](#), and [end-stage renal disease facilities](#). OMB is also reviewing a [proposed rule](#) that would establish criteria for an alternative coverage pathways to provide transitional coverage for emerging technologies under Medicare.

Additionally, the Centers for Medicare and Medicaid Services is expected to issue a proposed rule that would roll back Trump-era policies that expanded the availability of short-term limited duration insurance (STLDI) plans. The [2018 final rule](#) expanded the maximum duration of STLDI plans from three months to 364 days and allowed insurers to renew plans up to 3 years.

THIS WEEK IN HEALTH POLICY

Mon. (5/1)

- **12:00pm – HHS Meeting: People with Intellectual Disabilities Issues** – The Department of Health and Human Services (HHS) Administration for Community Living (ACL) holds a meeting of the President’s Committee for People with Intellectual Disabilities (PCPID) to discuss workgroup updates related to home and community-based services and other program updates. [Details](#).

Tue. (5/2)

- **10:00am – NSF Meeting: Biological Sciences** – The National Science Foundation (NSF) holds a meeting of the Advisory Committee for Biological Sciences to discuss updates from the Advisory Committee on Environmental Research and Education and other Committee updates. [Details](#).
- **10:00am – Markup: Generic Drug and Pharmaceutical Middlemen Bills** – The Senate Health, Education, Labor, and Pensions (HELP) Committee holds a markup to consider a set of

bipartisan bills that aim to promote access to generic drugs and medicines for rare diseases, and address pharmacy benefit managers business practices. [Details](#).

- **10:00am – Hearing: Federal Grants for Underserved Communities** – The Senate Homeland Security and Governmental Affairs Committee holds a hearing to examine improving access to federal grants for underserved communities. [Details](#).
- **1:00pm – US News Webinar: Maternal and Infant Health** – The U.S. News and World Report holds a webinar to discuss solutions to tackle the crisis of inequitable maternal and infant health outcomes. [Details](#).

Wed. (5/3)

- **10:00am – Hearing: Mental Health Care Ghost Networks** – The Senate Finance Committee holds a hearing to examine reducing barriers to mental health care by improving provider directory accuracy to reduce the prevalence of ghost networks. [Details](#).

Thurs. (5/4)

- **10:00am – Hearing: President’s Budget Request for NIH** – The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies holds a hearing to examine the President’s proposed budget request for fiscal year (FY) 2024 for the National Institutes of Health (NIH). NIH Acting Director, Dr. Lawrence Tabak, and the National Cancer Institute and National Institutes of Mental Health Directors will be testifying. [Details](#).
- **1:00pm – Hearing: Pandemic and All-Hazards Preparedness Act** – The Senate HELP Committee holds a hearing to examine preparing for the next public health emergency, focusing on reauthorizing the Pandemic and All-Hazards Preparedness Act. [Details](#).
- **1:30pm – Policy Center for Maternal Mental Health Briefing: Federal Maternal Health Policy** – The Policy Center for Maternal Mental Health (formerly 2020 MOM) holds a Congressional briefing to present the latest national maternal mental health statistics and discuss the inaugural Maternal Mental Health state report cards released for the first time in May 2023. Briefing will also feature a roadmap of the top 10 federal and state policy levers to improve maternal mental health outcomes. [Details](#).
- **2:00pm – HHS Meeting: Biodefense Preparedness** – HHS holds a meeting of the National Biodefense Science Board to discuss lessons learned from COVID-19 and present recommendations on several topics, including uses of virtual health care during disaster response and disaster response challenges specific to rural and underserved communities. [Details](#).

Additional Multi-Day Events

- **May 2-May 3 – CMS Meeting: CMMS Ambulance Billings** – The Centers for Medicare and Medicaid Services holds a meeting of the Ground Ambulance and Patient Billing Advisory Committee to make recommendations with respect to the disclosure of charges and fees for ground ambulance services and insurance coverage and other Committee updates. [Details](#).
- **May 2-May 4 – HITAC Meeting: Health Data, Technology, and Interoperability Proposed Rule** – The Health Information Technology Advisory Committee (HITAC) holds a meeting of the HTI-1 Proposed Rule Task Force 2023 to evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule. [Details](#).
- **May 4-May 5 – HRSA Meeting: Newborn and Children Heritable Disorders** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) to discuss criteria for pilot studies and the Center for Disease Control and Prevention’s (CDC) Enhancing Data Driven Disease Detection in Newborns (ED3N) Project. [Details](#)

FEATURED WHG ANALYSIS

- ***NEW*** **WHG Chart: PBM Legislation Under Consideration** – In the Policy Hub Insight Bank [here](#).
- **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](#).

CONGRESSIONAL LOOKBACK

Weds. (4/26)

- **The House E&C Subcommittee on Health** [convened](#) a hearing to discuss a slate of bills aimed at lowering health care costs by increasing transparency and competition in health care. [Details](#).
- **The House W&M Subcommittee on Oversight** [held](#) a hearing to examine tax-exempt hospitals and the community benefit standard. [Details](#).
- **The House Appropriations Labor-HHS Subcommittee** [held](#) a hearing with the HRSA Administrator to discuss the PRF and health care workforce shortages. [Details](#).

Tues. (4/25)

- **The Senate HELP Committee** [announced](#) a May 2 markup to consider the following legislation aimed at PBMs and generic drugs. [Details](#).

REGULATORY LOOKBACK

Fri. (4/28)

- **HRSA** [announced](#) the award of over \$147 million to 49 recipients to support the Biden-Harris Administration’s Ending the HIV Epidemic in the U.S. (EHE) initiative. [Details](#).
- **The CDC** [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). Nominations are due September 29. [Details](#).

Thurs. (4/27)

- **CMS** [released](#) a proposed rule aimed at strengthening access to and quality of care across Medicaid services. Comments are due July 3. [Details](#).
- **CMS** [opened](#) two public comment opportunities related to quality measure development for inpatient psychiatric facilities (IPFs) and Medicaid home and community based service. [Details](#).

Weds. (4/26)

- **CMS** [issued](#) a fact sheet detailing the agency’s enforcement of hospital price transparency regulations to date. [Details](#).

Tues. (4/25)

- **The GAO** released a report on characteristics and health care expenditures among Medicaid beneficiaries with I/DD with long-term care needs. [Details](#).

Mon. (4/24)

- **CMS** [released](#) a proposed rule to revise the definition of “lawfully present” in order to expand eligibility for health insurance coverage through the Exchange, Medicaid, and Basic Health Program to recipients of the Deferred Action for Childhood Arrivals (DACA) program. Comments are due June 23. [Details](#).

COMMENT & APPLICATION DEADLINES

- **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.](#)
- **June 9:** CMS [released](#) the FY 2024 IPPS and LTCH PPS proposed rule. [Details.](#)
- **June 16:** HHS OCR [released](#) a proposed rule to modify HIPAA Privacy Rule to better protect sensitive information related to reproductive health care. Comments are due June 16. [Details.](#)
- **June 20:** HHS ONC [issued](#) a proposed rule to revise and enhance the ONCE Health IT Certification Program. Comments are due June 20. [Details.](#)
- **June 23:** CMS [released](#) a proposed rule to revise the definition of “lawfully present” in order to expand eligibility for health insurance coverage through the Exchange, Medicaid, and Basic Health Program to recipients of the Deferred Action for Childhood Arrivals (DACA) program. [Details.](#)
- **June 30:** The NIH [issued](#) an RFI inviting input on research opportunities and best practices for Food is Medicine research program. [Details](#)
- **July 3:** CMS [released](#) a proposed rule aimed at strengthening access to and quality of care across Medicaid services. [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.](#)
- **September 29:** 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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