[This Week in Health Policy](#Events), [Congressional Lookback](#Congressional), [Regulatory Lookback](#Regulatory), [Comment & Application Deadlines](#Deadlines)

***Wynne Health Group Weekly***

 

**Framing the Week**

Over the weekend, Senate Democrats successfully passed a modified version of the Inflation Reduction Act, including priority provisions such as Medicare drug negotiations and an extension to the Affordable Care Act (ACA) premium subsidies. This comes after Democrats faced major hurdles before the final vote, including rulings from the Senate Parliamentarian on which provisions could be included in a budget reconciliation package, as well as a whirlwind vote-a-rama in which Republicans raised several failed amendments to the bill.

The legislation differs in only a few though substantial ways from what Senate Democrats [introduced](https://mypolicyhub.com/content_entry/democrats-to-use-inflation-reduction-act-for-budget-reconciliation-features-drug-pricing-aca-premium-subsidy-extension-and-tax-and-energy/) just over a week ago:

* **Inflation Rebates:** The Senate Parliamentarian ruled against extending the inflation rebate provisions to the private market, limiting them instead to Medicare sales.
* **Insulin:** Senate Democrats added a provision that would cap copays for monthly supplies of insulin at $35 for Medicare beneficiaries. Democrats had originally intended to implement a similar cap in private markets, though Republicans successfully voted against such a change.
* **Taxes:** To garner Sen. Krysten Sinema (D-AZ)’s vote, Senate Democrats agreed to the removal of a provision that would narrow the carried interest loophole for some investment income – a provision would have saved approximately $14 billion.
* **Rebate Rule:** Democrats moved to delay implementation of the Trump Administration rebate rule until 2032 rather than fully repealing it as under previous versions.

Aside from these changes, the signature provisions of the legislation remained in tact, including the mentioned drug negotiations program and ACA subsidy extensions, as well as provisions to redesign the Medicare Part D benefit, changes to address climate change and clean energy, and tax reform.

**Our full summary of the updated Inflation Reduction Act is available** [**here**](https://mypolicyhub.com/wp-content/uploads/2022/08/WHG-Summary-of-Full-Inflation-Reduction-Act_8.8.22.pdf)**.**

**Next Steps:** The House is expected to return from recess and vote on the legislation as soon as this Friday and is expected to pass.

*Monkeypox*

Following the Biden Administration [declaring](https://www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html) monkey a public health emergency, we could see additional announcements on how the Department of Health and Human Services (HHS) is supporting states and jurisdictions. As of August 4, HHS [delivered](https://aspr.hhs.gov/SNS/Pages/JYNNEOS-Distribution.aspx) more than 602,000 doses of Bavarian Nordic’s JYNNESO vaccine for the prevention of monkeypox and smallpox, to support local response efforts. Details on the amount of JYNNEOS vaccine that has been allocated, requested, and shipped to jurisdictions nationwide is available [here](https://aspr.hhs.gov/SNS/Pages/JYNNEOS-Distribution.aspx). The Centers for Disease Control and Prevention (CDC) has also ramped up the [release](https://www.cdc.gov/poxvirus/monkeypox/whats-new.html) of guidance and resources on monkeypox.

*COVID-19 PHE*

It is expected that the Biden Administration will again extend the COVID-19 PHE declaration for another 90-day period, though those close to the situation have cautioned that this could change leading up until the date by which the Administration must provide notice that it will allow the PHE declaration to expire.

**This Week in Health Policy**

**Mon. (8/8)**

* **12:00pm – SAMHSA Meeting: Substance Abuse** – The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a meeting of the Center for Substance Abuse Prevention National Advisory Council to discuss program updates. [Details](https://public-inspection.federalregister.gov/2022-14311.pdf).

**Tue. (8/9)**

* **9:00am – CDC Meeting: CDC Advisory Committee** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Advisory Committee to the Director to discuss data modernization, laboratory quality, and health equity. [Details](https://www.federalregister.gov/documents/2022/07/13/2022-14932/advisory-committee-to-the-director-centers-for-disease-control-and-prevention).
* **10:30am – ONC Meeting: Adopted Standards –** The Office of the National Coordinator of Health Information Technology (ONC) holds a meeting of the Health Information Technology Advisory Committee (HITAC) Adopted Standards Taskforce to make recommendations on ONC-adopted standards and implementation specifications. [Details](https://www.healthit.gov/hitac/events/adopted-standards-task-force-2022-4).
* **2:00pm – NQF Meeting: EHR** – The National Quality Forum (NQF) holds a meeting of the Electronic Health Record (EHR) Care Coordination Committee to discuss updates to the final report. [Details](file:///C%3A%5CUsers%5Caudre%5CDownloads%5Cehr_care_coordination_agenda_08092022.pdf).

**Wed. (8/10)**

* **10:00am – HRSA Meeting: Nursing** – The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on Nurse Education and Practice to discuss program updates. [Details](https://www.federalregister.gov/documents/2021/12/15/2021-27127/meeting-of-the-national-advisory-council-on-nurse-education-and-practice).
* **12:00pm – NQF Meeting: Opioids and Behavioral Health** – NQF holds a meeting of the Opioids and Behavioral Health Committee to discuss updates to the final report. [Details](file:///C%3A%5CUsers%5Caudre%5CDownloads%5Cobh_agenda_08102022.pdf).

**Additional Multi-Day Events**

* **August 10-August 11 – 3:00pm – CMS Webinar: Digital Quality Measurement** – The Centers for Medicare and Medicaid Services (CMS) holds a webinar titled, “Strategic Roadmap for Advancing Digital Quality Measurement.” [Details](https://mmshub.cms.gov/2022/2022-07/strategic-roadmap-advancing-digital-quality-measurement-august-10-2022).

**Featured WHG Analysis**

* \*NEW\* **Blog on President Biden’s Executive Order Protecting Access to Reproductive Health Services** – On the Commonwealth Fund’s To the Point [here](https://www.commonwealthfund.org/blog/2022/president-bidens-executive-order-protecting-access-reproductive-health-services).
* \*NEW\* **WHG Roundup of Recent Telehealth Policy** – In the Policy Hub Insight Bank [here](https://mypolicyhub.com/insights/roundup-of-recent-telehealth-policy-august-2022-update/).
* **WHG Regulatory Outlook – Summer 2022 Update** – In the Policy Hub Insight Bank [here](https://mypolicyhub.com/insights/whg-regulatory-outlook-summer-2022-update/).
* **WHG Issue Brief on the Nutrition Policy Landscape** – In the Policy Hub Insight Bank [here](https://mypolicyhub.com/insights/issue-brief-on-the-nutrition-policy-landscape-includes-farm-bill-and-cnr-priorities/).
* **WHG A Suite Of Potential Executive Actions For A Post-Roe World** – In the Policy Hub Insight Bank [here](https://mypolicyhub.com/content_entry/round-up-of-recent-actions-related-to-the-phe-declaration/).
* **WHG** **Round-up of Recent Actions Related to the PHE Declaration** – In the Policy Hub Insight Bank [here](https://mypolicyhub.com/content_entry/round-up-of-recent-actions-related-to-the-phe-declaration/).
* **WHG Tracker of COVID-19 PHE Flexibilities** – In the Policy Hub Insight Bank [here](https://mypolicyhub.com/insights/tracker-of-covid-19-phe-flexibilities/).
* **WHG Memo on PBM Regulatory and Legislative Landscape** – In the Policy Hub Insight Bank [here](https://mypolicyhub.com/insights/overview-of-the-pharmacy-benefit-manager-regulatory-and-legislative-landscape/).

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## Congressional Lookback

**Mon. (8/1)**

* **The House Ed and Labor Committee** [marked up](https://www.youtube.com/watch?v=hhFIzj2S5sQ) the Healthy Meals, Healthy Kids Act of 2022 ([H.R. 8450](https://www.congress.gov/bill/117th-congress/house-bill/8450?s=1&r=1)). [Details](https://mypolicyhub.com/content_entry/house-committee-marks-up-healthy-meals-healthy-kids-act-of-2022-votes-to-advance-child-nutrition-reauthorization/).

## Regulatory Lookback

**Fri. (8/5)**

* **CMS** [released](https://www.medicaid.gov/covid-19-phe-unwinding-section-1902e14a-waiver-approvals/index.html) updated information on strategies that the agency has approved to facilitate the COVID-19 PHE unwinding and subsequent Medicaid redeterminations. [Details](https://mypolicyhub.com/content_entry/agency-releases-update-on-flexibilities-being-used-for-medicaid-redetermination/).

**Thurs. (8/4)**.

* **President Biden** signed an [Executive Order](https://www.whitehouse.gov/briefing-room/presidential-actions/2022/08/03/executive-order-on-securing-access-to-reproductive-and-other-healthcare-services/) on Securing Access to Reproductive and Other Healthcare Services. [Details](https://mypolicyhub.com/content_entry/president-biden-signs-second-eo-to-further-protect-access-to-reproductive-health-services-considers-using-section-1115-medicaid-waivers/).
* **HHS** [announced](https://www.hhs.gov/about/news/2022/08/03/biden-harris-administration-releases-two-new-reports-long-covid-support-patients-further-research.html) two new reports that examine Long COVID. [Details](https://mypolicyhub.com/content_entry/set-of-reports-outline-biden-administrations-approach-to-long-covid/).

**Mon. (8/1)**

* **CMS** [released](https://public-inspection.federalregister.gov/2022-16472.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list) the FY 2023  IPPS and LTCH PPS final rule. [Details](https://mypolicyhub.com/content_entry/y-2023-ipps-and-ltch-pps-rule-finalizes-4-3-overall-increase-for-hospitals-includes-new-equity-measures-establishes-birthing-friendly-designation/).
* **CMS** [released](https://public-inspection.federalregister.gov/2022-16457.pdf?utm_campaign=pi+subscription+mailing+list&utm_source=federalregister.gov&utm_medium=email) the FY 2023 2023 SNF PPS final rule**.** [Details](https://mypolicyhub.com/content_entry/overall-2-7-percent-increase-in-payments-finalized-for-snfs-in-fy-2023/).
* **CMS** [released](https://www.cms.gov/newsroom/press-releases/cms-offers-roadmap-states-help-connect-children-complex-medical-conditions-critical-medicaid) guidance on a new Medicaid home health benefit for children with medically complex conditions.[Details](https://mypolicyhub.com/content_entry/cms-announces-new-home-health-spa-option-for-children-with-medically-complex-conditions/).
* **The White House** [released](https://www.whitehouse.gov/briefing-room/statements-releases/2022/07/29/fact-sheet-biden-harris-administration-announces-two-new-actions-to-address-youth-mental-health-crisis/) a fact sheet outlining two new actions the Administration is taking to address youth mental health. [Details](https://mypolicyhub.com/content_entry/administration-announces-new-actions-on-youth-mental-health-previews-additional-work-to-come/).
* **CMS** [released](https://www.cms.gov/newsroom/news-alert/cms-releases-2023-projected-medicare-basic-part-d-average-premium) the projected Part D average premium for 2023.[Details](https://mypolicyhub.com/content_entry/agency-estimates-1-8-percent-decrease-for-2023-part-d-average-basic-monthly-premium/).

### Comment & Application Deadlines

* **August 12:** CMS is seeking [nominations](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Currently-Accepting-Nominations#SNF001) for a Technical Expert Panel (TEP) related to the development of a HQRP and HHQRP health equity structural composite measure. [Details](https://mypolicyhub.com/content_entry/tep-nominations-sought-for-development-of-a-hospice-and-home-health-equity-measure-due-aug-12/).
* **August 15:** The FDA [issued](https://public-inspection.federalregister.gov/2022-14135.pdf?utm_campaign=pi+subscription+mailing+list&utm_source=federalregister.gov&utm_medium=email) a request for nominations for voting and nonvoting consumer representatives to serve on advisory committees and panels. [Details](https://mypolicyhub.com/content_entry/fda-seeks-consumer-representative-to-serve-on-advisory-committees-nominations-due-august-15/).
* **August 16:** CMS [issued](https://public-inspection.federalregister.gov/2022-13376.pdf) the cycle year (CY) 2023 home health prospective payment system and rate update proposed rule. [Details](https://mypolicyhub.com/content_entry/agency-releases-cy-2023-home-health-home-prospective-payment-system-proposed-rule-payments-expected-to-decrease-by-4-2-percent/).
* **August 23:** The FDA[issued](https://public-inspection.federalregister.gov/2022-13528.pdf?utm_medium=email&utm_campaign=pi+subscription+mailing+list&utm_source=federalregister.gov) draft guidance on considerations for rescinding breakthrough therapy designation (BTD). [Details](https://mypolicyhub.com/content_entry/draft-guidance-issued-on-considerations-for-rescinding-breakthrough-therapy-designation-comments-are-due-aug-23/).
* **August 27:** CMS [released](https://public-inspection.federalregister.gov/2022-13449.pdf) its CY 2023 ESRD prospective payment system (PPS) proposed rule. [Details](https://mypolicyhub.com/content_entry/agency-anticipates-3-1-percent-increase-for-esrd-facilities-in-cy-2023/).
* **August 29:** CMS [issued](https://public-inspection.federalregister.gov/2022-14153.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list) 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](https://mypolicyhub.com/content_entry/agency-proposes-cops-for-rural-emergency-hospitals-and-details-possible-changes-to-cops-for-critical-access-hospitals/).
* **August 31:** The FDA [announced](https://public-inspection.federalregister.gov/2022-14809.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list)the extension of the comment period for the draft guidance on risk management plans to mitigate the potential for drug shortages. [Details](https://mypolicyhub.com/content_entry/comment-period-extended-for-draft-guidance-on-risk-management-plan-to-mitigate-potential-drug-shortages-to-august-31/).
* **August 31:** CMS[issued](https://public-inspection.federalregister.gov/2022-16463.pdf) a RFI on ways to strengthen and improve Medicare Advantage. [Details](https://mypolicyhub.com/content_entry/comments-due-aug-31-for-rfi-on-ways-to-improve-medicare-advantage/).
* **September 1:** The CDC[seeks](https://public-inspection.federalregister.gov/2022-14714.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list) nominations for the National Center for Injury Prevention and Control (NCIP) [Board of Scientific Counselors (BSC)](https://www.cdc.gov/injury/bsc/index.html). [Details](https://mypolicyhub.com/content_entry/nominations-sought-for-cdc-injury-center-board-of-scientific-counselors/).
* **September 6:** The CDC [released](https://www.grants.gov/web/grants/view-opportunity.html?oppId=336618) a notice of grant funding to establish and fund regional Tuberculosis (TB) Centers of Excellence (COE). [Details](https://mypolicyhub.com/content_entry/agency-to-provide-grant-funding-for-tuberculosis-centers-of-excellence/).
* **September 13:** CMS [released](https://public-inspection.federalregister.gov/2022-15372.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list) the CY 2023 Hospital OPPS and ASC Payment System Proposed Rule. Comments are due September 13. [Details](https://mypolicyhub.com/content_entry/cy-2023-hopps-and-asc-proposed-rule-includes-reh-payment-and-enrollment-details-post-phe-remote-behavioral-health-services/).
* **September 17:** The CDC [issued](https://public-inspection.federalregister.gov/2022-07236.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [Details](https://mypolicyhub.com/content_entry/nominations-due-sept-17-for-healthcare-infection-control-practices-advisory-committee/).
* **September 19:** The FDA [issued](https://public-inspection.federalregister.gov/2022-15612.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list) draft guidance on the evaluation of therapeutic equivalence. Comments are due September 19. [Details](https://mypolicyhub.com/content_entry/draft-guidance-issued-on-evaluation-of-therapeutic-equivalence-comments-due-sept-19/).
* **September 19:** HHS [announce](https://public-inspection.federalregister.gov/2022-16346.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list)d 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](https://mypolicyhub.com/content_entry/department-seeks-nominations-for-the-advisory-council-on-antibiotic-resistant-bacteria-nominations-due-sept-19/).
* **September 29:** The FDA [issued](https://public-inspection.federalregister.gov/2022-13952.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list) draft guidance entitled: Patient Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments (COAs). [Details](https://mypolicyhub.com/content_entry/draft-guidance-issued-on-selecting-developing-or-modifying-fit-for-purpose-clinical-outcome-assessments-comments-are-due-sept-29/).
* **September 30:** The CDC is [seeking nominations](https://public-inspection.federalregister.gov/2022-15740.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list) for the Clinical Laboratory Improvement Advisory Committee (CLIAC). [Details](https://mypolicyhub.com/content_entry/nominees-for-clinical-laboratory-improvement-advisory-committee-due-sept-30/).
* **September 30:** CMMI [announced](https://www.cms.gov/newsroom/fact-sheets/enhancing-oncology-model) a new demonstration model aimed at improving oncology care. [Details](https://mypolicyhub.com/content_entry/innovation-center-announces-follow-up-cancer-focused-demonstration-the-enhancing-oncology-model/).
* **October 1:** The CDC [seeks](https://public-inspection.federalregister.gov/2022-11815.pdf?utm_medium=email&utm_campaign=pi+subscription+mailing+list&utm_source=federalregister.gov) nominations for the CDC/Health Resources & Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHACHSPT). [Details](https://mypolicyhub.com/content_entry/nominees-sought-for-cdc-hrsa-advisory-committee-on-hiv-viral-hepatitis-and-std-prevention-and-treatment/).
* **October 26:** The FDA [issued](https://public-inspection.federalregister.gov/2022-13309.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list) a proposed rule to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). [Details](https://mypolicyhub.com/content_entry/proposed-rule-issued-to-establish-requirements-for-nonprescription-drug-products-with-an-additional-condition-for-nonprescription-use-comments-are-due-oct-26/).

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