

Wynne Health Group Weekly



FRAMING THE WEEK

The Senate could hold a vote this week on the Inflation Reduction Act of 2022 – the fiscal year (FY) 2022 budget reconciliation package negotiated by Senate Majority Leader Chuck Schumer (D-NY) and Sen. Joe Manchin (D-WV). The House is on recess and could temporarily return to session to vote on the package following the Senate vote. This week, the Senate Finance Committee will hold a hearing as part of its probe into the Organ Procurement and Transplantation Network. On the regulatory front, the final rule for the FY 2023 inpatient prospective payment system could be released as soon as today. Lastly, we recap the House committee markup of a Medicare Advantage prior authorization bill and Medicaid and CHIP Payment and Access Commission meeting on the unwinding of the COVID-19 Public Health Emergency, which was last extended through October 13, 2022.

Budget Reconciliation

The FY 2022 budget reconciliation package includes drug pricing provisions, a three-year extension to Affordable Care Act (ACA) premium tax credit enhancements, tax reforms, and investments to address the climate crisis ([WHG summary](#)). However, we are stilling awaiting the Senate Parliamentarian's ruling on the provisions to ensure the proposal meet the reconciliation criteria.

Changes to the final package are possible, especially to ensure the crucial vote of Sen. Kyrsten Sinema (D-AZ), who has not yet signed off on the bill. Additionally, a proposal by Sens. Jeanne Shaheen (D-NH) and Susan Collins (R-ME) to cap monthly insulin out-of-pocket costs at \$35 could be added ([WHG summary](#)). Advocates are also pushing Senate Democrats to include Sen. Raphael Warnock's (D-GA) bill ([S. 2315](#)) to close the Medicaid coverage gap with a new federal Medicaid program. In addition, the Sen. Kyrsten Sinema (D-AZ).

Organ Procurement and Transplants

On Wednesday, the Senate Finance Committee (SFC) will hold a [hearing](#) on "addressing organizational failures" of the [Organ Procurement and Transplantation Network](#) (OPTN), a public-private partnership that connects all professionals involved in the U.S. donation and transplantation system. The [United Network for Organ Sharing](#) (UNOS) is under contract with the Health Resources and Services Administration (HRSA) to serve as the OPTN. The panel features senior representatives from UNOS, OPTN, a transplant center, and a transplant advocacy organization.

In February 2020, Sen. Chuck Grassley (R-IA), then SFC Chairman, and Sen. Ron Wyden (D-OR), current SFC Chairman, along with Sens. Todd Young (R-IN) and Ben Cardin (D-MD) [started](#) an investigation into OPTN in response to "numerous inspector general audits and news reports [that] raised questions about the adequacy of patient safety standards, suggested thousands of available organs are not being used, and highlighted questionable financial practices of some organ procurement organizations (OPOs)."

Regulatory Update

Last week, the final rule for the FY 2023 inpatient prospective payment system (IPPS) [cleared review](#) at the Office of Management and Budget (OMB). We expect to see the Centers for Medicare & Medicaid Services (CMS) release the final rule as early as this afternoon. Highlights from the proposed rule (WHG summary [here](#)) include the following proposals:

- Adding a measure to assess a hospital's commitment to health equity, as well as measures to screen for social drivers of health;
- A new designation for "Birthing-Friendly" hospitals; and
- The implementation of a permanent five percent cap on wage index decreases.

Prior Authorization

Last Wednesday, the House Ways & Means Committee marked up the Improving Seniors' Timely Access to Care Act of 2022 ([H.R. 8487](#)) that would require Medicare Advantage (MA) plans to establish an electronic prior authorization program, increase transparency for MA prior authorization policies, and establish beneficiary protection standards regarding prior authorization in MA. The bill was favorably forwarded by voice vote to the House. The House is expected to vote on the legislation in the fall after the August recess. The Senate version of the bill ([S. 3018](#)) has 39 cosponsors (19 D and 20 R) and has not yet been marked up. It is possible the bill could be included in a year-end package given its bipartisan and bicameral support.

Medicaid

Last week, MACPAC convened a special meeting to discuss the challenges state Medicaid programs may face when COVID-19 PHE ends and Medicaid eligibility redeterminations resume. Staff [presented](#) an update on state concerns about the timing and process of unwinding continuous coverage, as well as the financial impact of a shift back to a lower FMAP. Although staff explained that many states they spoke with appear to be well prepared, Commissioners identified several areas of focus for future work on redeterminations in the fall, including:

- A potential glide path back to a lower FMAP;
- Further exploration of states' disenrollment practices and administration of eligibility data, including ex parte renewals; and
- Proactive support and monitoring of transitions to other types of coverage.

THIS WEEK IN HEALTH POLICY

Tue. (8/2)

- **10:00am – HRSA Meeting: Primary Care and Dentistry** – The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Training and Primary Care Medicine and Dentistry to discuss program updates. [Details](#).
- **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](#).

Wed. (8/3)

- **2:30pm – Hearing: Organ Transplants** – The Senate Finance Committee holds a hearing titled, "A System in Need of Repair: Addressing Organizational Failures of the US's Organ Procurement and Transplant Network. [Details](#)

FEATURED WHG ANALYSIS

- **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](#).
- **WHG Round-up of Recent Actions Related to the PHE Declaration** – In the Policy Hub Insight Bank [here](#).
- **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](#).

CONGRESSIONAL LOOKBACK

Fri. (7/29)

- **Sens. Schumer and Manchin** [announced](#) an agreement to add the Inflation Reduction Act of 2022 to the fiscal year 2022 Budget Reconciliation bill. [Details](#).

REGULATORY LOOKBACK

Fri. (7/29)

- **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. Nominations are due September 19. [Details](#).

Thurs. (7/28)

- **HHS and the Treasury** issued [guidance](#) to reiterate contraceptive coverage requirements for non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. [Details](#).
- **CMS** [issued](#) a RFI on ways to strengthen and improve Medicare Advantage. Comments are due August 31. [Details](#).

Weds. (7/27)

- **CMS** [released](#) the FY 2023 hospice payment rate update final rule. [Details](#).
- **CMS** [released](#) the FY 2023 IRF prospective payment system final rule. [Details](#).
- **CMS** [released](#) the FY 2023 IPF prospective payment system final rule. [Details](#).
- **CMS** [released](#) its Maternity Care Action Plan. [Details](#).

Tues (7/26)

- **MACPAC** released an [issue brief](#) on the effects of coverage churn on preventable hospital use. [Details](#).

Mon. (7/25)

- **The Advisory Council on Alzheimer's Research, Care, and Services** [convened](#) its July meeting to discuss its annual subcommittee recommendations for Alzheimer's Disease. [Details](#).
- **The FNS** [announced](#) that it is awarding more than \$70 million in grants to improve the Farm to School Program. [Details](#).

COMMENT & APPLICATION DEADLINES

- **August 5:** The FDA [issued](#) a request for industry organizations to serve as nonvoting representatives on certain panels of the Medical Device Advisory Committee. [Details](#).
- **August 12:** CMS is seeking [nominations](#) for a Technical Expert Panel (TEP) related to the development of a HQRP and HHQRP health equity structural composite measure. [Details](#).
- **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 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 OPPS 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.](#)

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