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Wynne Health Group Weekly



FRAMING THE WEEK

With Congress back this week, we are tracking the Senate especially closely, as we could soon see key developments regarding budget reconciliation and mental health legislation. Leader Chuck Schumer (D-NY) is pushing to pass a budget reconciliation package before the scheduled summer recess on August 8. While Senate Democrats have reached a deal on drug pricing provisions ([WHG summary](#)), they appear to not yet have consensus on other major components.

As for mental health legislation, discussion drafts from the Senate Finance Committee's three remaining workgroups – workforce, parity, and care integration – are expected in the coming weeks. If the Committee does not release these remaining drafts before the end of the summer, it is unclear whether a more comprehensive mental health package would be able to pass before the end of the current Congress. Full summaries of Senate Finance Committee's youth mental health and telemental proposals are available [here](#) and [here](#).

In both chambers, congressional Democrats will continue to keep the fight to protect abortion rights top of mind. The House will hold two votes on bills to safeguard abortion access, though are highly unlikely to be taken up in the Senate.

On the regulatory front, the Centers for Medicare and Medicaid Services (CMS) may release the long-awaited proposed rule Medicare hospital outpatient prospective payment system for calendar year 2023.

Budget Reconciliation: Drug Pricing and Premium Subsidies

Last week, the Senate Finance Committee released an updated version of the drug pricing provisions intended for inclusion in a forthcoming "skinny" budget reconciliation package. The provisions largely mirror the version introduced in December 2021 ([details](#)), though featured key changes such as how the drug negotiation framework would treat insulin (i.e., including it within the drug and biologic categories); a delay to the start date for Medicare Part D inflation rebates; and expanding the Part D Low-Income Subsidy eligibility to include additional beneficiaries, among other tweaks.

Shortly thereafter, the Congressional Budget Office (CBO) [released updated scoring](#) for the savings these provisions would generate for the Medicare program. Based on these revised provisions, CBO now estimates that the Senate's drug pricing package would generate approximately \$288 billion in savings – a decrease from the \$317.6 billion in savings expected from the original package featured in Build Back Better last year.

This raises questions as to how Democrats intend to allocate these offsets across various legislative priorities. Three leading health-related proposals – extending the Affordable Care Act (ACA) premium subsidies, which are set to expire this year; closing the Medicaid coverage gap; and requiring all states to provide 12 months of continuous Medicaid eligibility to postpartum individuals – remain among stakeholders top priorities for inclusion in the package.

In theory, these new savings estimates would allow Democrats to offset the costs of the three spending proposals (see table below). However, Democrats may instead be forced to allocate some of the drug pricing-generated savings to other priorities as they contemplate which changes would be most impactful to Americans, especially as they head into the November midterm elections.

Health-Related Cost Provisions		Drug Pricing Offsets	
Provision	Cost/10 years		
ACA Marketplace Subsidies	\$73.9 billion	<i>Total</i>	<i>\$287.6 billion/10 years</i>
Medicaid Coverage Gap	\$57 billion		
Mandatory One-Year Postpartum in Medicaid	\$2.2 billion		
<i>Total</i>	<i>\$133 billion</i>		

Reproductive Health

This week, the House is expected to vote on two bills to protect access to abortion, including residents of states where abortion is banned who travel to a different state to obtain an abortion. The House Rules Committee will [meet](#) on Tuesday to tee up votes.

- **Women’s Health Protection Act of 2022 (H.R. 8296)**, introduced by Reps. Judy Chu (D-CA), Ayanna Pressley (D-MA), Lois Frankel (D-FL), and Veronica Escobar (D-TX), would establish a statutory right for health care providers to provide, and their patients to receive, abortion care. The House passed a nearly identical bill ([H.R. 3755](#)) in September 2021 by a 218-211 vote. The new version mentions the Supreme Court’s recent decision to overturn *Roe v. Wade*. The Senate failed to overcome the filibuster threshold in a 46-48 vote.
- **Ensuring Access to Abortion Act of 2022 (H.R. 8297)**, introduced by Reps. Lizzie Fletcher (D-TX), Marilyn Strickland (D-WA), and Jamie Raskin (D-MD), would prohibit states from punishing individuals for traveling to a different state to obtain abortion services.

While these bills are expected to pass in the House, they are not viable in the Senate due to the 60-vote filibuster threshold. A path forward for sweeping legislation to protect abortion rights is highly unlikely in the evenly divided Senate. Tomorrow’s Senate Judiciary Committee [hearing](#) to discuss the legal consequences of the Supreme Court decision overturning *Roe v. Wade* is unlikely to lead to any progress in the near term.

In the absence of legislative action, President Biden signed an [Executive Order \(EO\) on Protecting Access to Reproductive Health Care Services](#) ([fact sheet](#); [WHG summary](#)). The Biden Administration is also [considering](#) declaring a [public health emergency](#) for abortion access, which would provide access to the Public Health Emergency Fund and provide some additional legal authorities. However, whether such a declaration would be impactful is unclear.

The EO directs the U.S. Department of Health and Human Services (HHS) and other federal agencies to undertake actions to protect health care service delivery and promote access to reproductive health care services, including abortion. Specifically, the EO includes directives that will:

- Safeguard access to reproductive health care services, including abortion and contraception;
- Protect the privacy of patients and their access to accurate information;
- Promote the safety and security of patients, providers, and clinics; and
- Coordinate the implementation of Federal efforts to protect reproductive rights and access to health care.

In support of the EO, CMS will hold a [call](#) tomorrow with hospitals, staff, and physicians to discuss their obligations and protections under the Emergency medical Treatment and Labor Act (EMTALA). The EO

directs HHS to consider updates to current EMTALA guidance to ensure pregnant women and those experiencing pregnancy loss receive full protections for emergency medical care under EMTALA.

Medicare Payment

CMS may soon release the proposed updates to the Medicare hospital outpatient prospective payment system for calendar year 2023. Though the [proposed rule](#) has not cleared review at the Office of Management and Budget (OMB), its release was forecasted for June 2022.

Last week, CMS released its other major calendar year 2023 proposed payment update – the Medicare Physician Fee Schedule – which included proposed changes to continue increasing Medicare coverage for telehealth services; reforms to expand access to behavioral health services; and health equity-oriented changes to the Medicare Shared Savings Program ([details](#)).

THIS WEEK IN HEALTH POLICY

Tue. (7/12)

- **10:00am – Hearing: Abortion** – The Senate Judiciary Committee holds a hearing titled, “A Post-Roe America: The Legal Consequences of the Dobbs Decision.” [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. (7/13)

- **9:00am – NQF Meeting: Perinatal and Women’s Health** – The National Quality Forum (NQF) holds a meeting of the Perinatal and Women’s Health Standing Committee to evaluate measures related to perinatal and women’s health. [Details](#).
- **12:00pm – Briefing: Diabetes** – The Congressional Diabetes Caucus and Diabetes Advocacy Alliance hold a briefing to discuss the recommendations in the National Clinical Care Commission report to Congress. [Details](#).

Thurs. (7/14)

- **10:00am – ONC Meeting: Health IT** – ONC holds a meeting of the Health Information Technology Advisory Committee (HITAC) to discuss ongoing projects. [Details](#).
- **1:00pm – NIH Meeting: Novel Technology** – The National Institutes of Health (NIH) Office of the Director holds a meeting of the Novel and Exceptional Technology and Research Advisory Committee to discuss program updates. [Details](#).

Additional Multi-Day Events

- **July 12-July 13 – 10:00am – FDA Meeting: Patient Engagement** – The Food and Drug Administration (FDA) holds a meeting of the Patient Engagement Advisory Committee to provide advice on issues relating to medical devices, the regulation of devices, and their use by patients. [Details](#).

FEATURED WHG ANALYSIS

- **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

Wed. (7/6)

- **The SFC** released an [updated version](#) of the drug pricing provisions to be included in a new version of the budget reconciliation package. [Details](#).

REGULATORY LOOKBACK

Fri. (7/8)

- **President Biden** signed an [Executive Order](#) on Protecting Access to Reproductive Health Care Services. [Details](#).
- **The CBO** [released](#) its estimated budgetary effects of subtitle I of reconciliation recommendations for prescription drug legislation. [Details](#).
- **The CDC** [seeks](#) nominations for the National Center for Injury Prevention and Control (NCIP) [Board of Scientific Counselors \(BSC\)](#). Nominations are due September 1. [Details](#)

Thurs. (7/7)

- **CMS** [released](#) its CY 2023 Medicare Physician Fee Schedule (MPFS) propose rule. Comments are due September 5. [Details](#).
- **CMS** [released](#) a suite of resources to improve oversight of Medicaid and CHIP managed care. [Details](#).
- **FNS** [released](#) the results of the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Infant and Toddler Feeding Practices Study-2. [Details](#).

Wed. (7/6)

- **CMS** [posted](#) updated Hospital Price Transparency resources that provide additional guidance for complying with regulations. [Details](#).
- **HHS OIG** [released](#) an audit on the impact of the reduced outlier threshold for transfer claims on Medicare payments to hospitals. [Details](#).
- **The EPA** [released](#) a request for nominations for appointment to the Children’s Health Protection Advisory Committee (CHPAC). [Details](#).
- **CMS** [reached](#) out to hospitals participating in the Hospital OQR Program to solicit stakeholder feedback on facility-specific reports. [Details](#).

Tues. (7/5)

- **CMMI** [published](#) a blog in *Health Affairs* that overviewed a recent analysis it conducted of implicit bias in three key demonstration models. [Details](#).
- **The FDA** [issued](#) draft guidance on DSCSA standards for interoperable exchange of information for tracing. [Details](#).
- **The FDA** [issued](#) a request for industry organizations to serve as nonvoting representatives on certain panels of the Medical Device Advisory Committee. Nominations are due August 5. [Details](#).
- **The CDC** [released](#) a notice of grant funding to establish and fund regional Tuberculosis (TB) Centers of Excellence (COE). Applications are due September 6. [Details](#).

COMMENT & APPLICATION DEADLINES

- **July 11:** The GAO [announced](#) a request for nominations for the Physician-Focused Payment Model Technical Advisory Committee (PTAC). [Details](#).
- **July 13:** CMS [issued](#) an IFC to implement a maximum OOP and cost sharing limits in MA. [Details](#).

- **July 15:** HHS and USDA [announced](#) the intention to establish the 2025 Dietary Guidelines Advisory Committee and solicit nominations for membership. [Details.](#)
- **July 15:** The OASH and OMH [announced](#) a NOFO titled, “*Community-Driven Approaches to Address Factors Contributing to Structural Racism in Public Health.*” [Details.](#)
- **July 15:** The OASH and OMH [announced](#) a funding opportunity to promote equitable access to language services in Health and Human Services. [Details.](#)
- **July 17:** The FDA [issued](#) draft guidance on risk management plans to mitigate the potential for drug shortages. [Details.](#)
- **July 22:** The GAO [issued](#) a request for nominations for the Health Information Technology Advisory Committee (HITAC). [Details.](#)
- **August 1:** The USDA [announced](#) a \$20 million cooperative agreement opportunity to improve participation and retention in the WIC program. [Details.](#)
- **August 1:** HHS [issued](#) a request for information on ways to strengthen primary care in the U.S. Responses are due August 1. [Details.](#)
- **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 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.](#)
- **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 17:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [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:** 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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