

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

This week, we continue to track key developments regarding the slimmed down budget reconciliation package, expected to only include drug pricing provisions ([WHG summary](#)) and a two-year extension to ACA premium subsidy enhancements. The Senate Parliamentarian is expected to review the legislative text later this week to ensure it complies with the Byrd Rule, which prohibits the inclusion of “extraneous matters,” such as provisions that make “incidental” changes to spending or revenue. Given the procedures required for reconciliation, a Senate vote is anticipated the first week of August before recess.

Meanwhile, the House will vote on a [six-bill appropriations minibus](#), which we view as a starting point for negotiations on FY 2023 government funding later this year. Due in part to time constraints and political factors, we anticipate Congress will pass a continuing resolution for FY 2023, level funding the government until at least after the midterm elections and possibly through early December. The Senate Appropriations Committee [aims](#) to release their FY 2023 bills by the end of July. Additionally, House Democratic leaders continue to keep the fight for abortion rights and gun safety top of mind.

*Reproductive Health*

Tomorrow, the House Energy and Commerce Subcommittee on Oversight and Investigations will hold a [hearing](#) on the impacts of U.S. Supreme Court reversing *Roe v. Wade*. The panel includes perspectives from both sides of the debate, including abortion advocates, such as the American Medical Association, as well as the CEO-Elect of the American Association of Pro-life Obstetricians and Gynecologists ([hearing memorandum](#)).

The House will also vote on (and is expected to pass) the **Right to Contraception Act (H.R. 8373)**. Similar to the two bills (**H.R. 8296** and **H.R. 8297**) on abortion access passed last week, this bill is unlikely to be considered in the Senate due to the 60-vote filibuster threshold. In the meantime, the Biden Administration is trying to bolster access to reproductive health services through the President’s Executive Order ([WHG summary](#)). The Department of Health and Human Services (HHS) Secretary recently issued [guidance](#) explaining the enforcement of the Emergency Medical Treatment and Active Labor Act (EMTALA) with respect to the recent Supreme Court decision overturning *Roe v. Wade*.

*Gun Safety*

On Wednesday, the House Judiciary Committee will hold the first [markup](#) on assault weapons ban legislation in two decades. The **Assault Weapons Ban of 2021 (H.R. 1808)**, introduced by Rep. David Cicilline (D-RI) and sponsored by 212 Democrats, would make it unlawful for a person to import, sell, manufacture, or transfer of certain semi-automatic weapons. The Committee will also consider the **Equal Access to Justice for Victims of Gun Violence Act (H.R. 2814)**, introduced by Rep. Adam Schiff (D-CA) and supported by 62 Democrats, which would allow victims of gun violence to pursue civil cases in state and federal courts against gun makers, distributors, sellers or trade associations. While both bills are expected to pass the House, they are highly unlikely to be taken up in the Senate, due in part to the recent enactment of the **Bipartisan Safer Communities Act (BSCA) (P.L. 117-159)** ([WHG summary](#)).

## Regulatory Update

With last week's release of the calendar year (CY) 2023 hospital outpatient prospective payment system (HOPPS) proposed rule ([WHG summary](#)), the Administration has concluded its major proposed rulemaking for the 2023 Medicare payment update cycle. We now await finalization of these proposals later this summer and fall.

In the meantime, the Administration recently announced its broader suite of intended rulemaking in its 2022 spring update to the Unified Agenda. This resource outlines the proposed and final rulemaking the Administration plans to advance as well as the timeframe in which it plans to promulgate each new regulatory action. The updated Unified Agenda features rulemaking across the Administration's various health care priorities, including equity, mental health, data interoperability, tobacco, Medicaid access, and more. A full analysis of the Administration's previewed rulemaking by priority area is available [here](#).

## **THIS WEEK IN HEALTH POLICY**

### **Tue. (7/19)**

- **10:00am – Hearing: Abortion** – The House Energy & Commerce Committee Oversight and Investigations Subcommittee holds a hearing titled, "Roe Reversal: The Impacts of Taking Away the Constitutional Right to an Abortion." [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](#).
- **1:00pm – CMS Call: Strategic Plan** – The Centers for Medicare and Medicaid Services (CMS) hold a stakeholder call with Administrator Chiquita Brooks La-Sure to provide updates on the Strategic Plan. [Details](#).

### **Wed. (7/20)**

- **9:00am – AHP Summit: Mental Health** – The Alliance for Health Policy (AHP) holds the Summit on Mental Health in America to discuss equity, innovation, and workforce capacity. [Details](#).
- **12:00pm – KFF Panel: Medication Abortion** – The Kaiser Family Foundation (KFF) holds a panel titled, "Medication Abortion in a Post-Roe v. Wade America." [Details](#).
- **3:00pm – Hearing: EHR** – The Senate Committee on Veterans' Affairs (VA) holds a hearing titled "Examining the Status of VA's Electronic Health Record (EHR) Modernization Program." [Details](#).

### **Thurs. (7/21)**

- **12:30pm – AHRQ Meeting: Healthcare Quality** – The Agency for Healthcare Research and Quality holds a meeting of the National Advisory Council for Healthcare Research and Quality to discuss quality across delivery systems. [Details](#).
- **2:00pm – CMS Webinar: QPP and APMs** – CMS holds a webinar to discuss the Quality Payment Program (QPP) and Alternative Payment Model (APM) incentive payments. [Details](#).

### **Additional Multi-Day Events**

- **July 18-July 19 – 9:00am – CMS Meeting: Clinical Diagnostic Laboratory Tests** – The CMS hold a meeting of the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests to discuss the CY 2023 Clinical Laboratory Fee Schedule. [Details](#).
- **July 19-July 20 – 9:00am – HHS Meeting: Tick-Borne Illness** – The Department of Health and Human Services (HHS) holds a meeting of the Tick-Borne Disease Working Group to discuss an upcoming report. [Details](#).

## **FEATURED WHG ANALYSIS**

- **\*NEW\* 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

### Thurs. (7/14)

- **Senate HELP Ranking Member Burr** [introduced](#) the FDA Simple Reauthorization Act, which is a clean reauthorization of the FDA user fee programs. [Details](#).

### Tues. (7/12)

- **The Senate Judiciary Committee** held a [hearing](#) on the legal consequences of the Supreme Court's decision in *Dobbs v. Jackson Women's Health* that overturned *Roe v. Wade*. [Details](#).

## REGULATORY LOOKBACK

### Fri. (7/15)

- **CMS** [released](#) the CY 2023 Hospital OPPS and ASC Payment System Proposed Rule. Comments are due September 13. [Details](#).
- **HHS OIG** [released](#) a study showing that the CDC was able to understand and address COVID-19 health disparities despite challenges with existing data. [Details](#).
- **The U.S.** [will](#) transition to the new 988 suicide and crisis line on July 16, 2022. [Details](#).

### Thurs. (7/14)

- **The FDA** [issued](#) final guidance entitled "Instructions for Use: Patient Labeling for Human Prescription Drug and Biological Products." [Details](#).

### Wed. (7/13)

- **HHS** [issued](#) guidance clarifying that retail pharmacies that receive federal funds cannot deny access to reproductive health care services. [Details](#).
- **CMS** [released](#) a report to Congress that prototypes a unified payment for Medicare-covered post-acute care. [Details](#).

### Tues. (7/12)

- **The USDA FNS** [announced](#) that 27 states and territories are set up to provide summer pandemic electronic benefits transfer (P-EBT) to provide food service benefits to children during the summer months. [Details](#).

### Mon. (7/11)

- **The FDA** [announced](#) the extension of the comment period for the draft guidance on risk management plans to mitigate the potential for drug shortages. Comments are now due August 31. [Details](#).

## COMMENT & APPLICATION DEADLINES

- **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.](#)
- **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.](#)
- **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 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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