This Week in Health Policy, Congressional Lookback, Regulatory Lookback, Comment & Application Deadlines

Wynne Health Group Weekly

FRAMING THE WEEK

With Congress in recess this week, we provide a status update on various health-related legislative priorities – including, drug pricing, ACA premium subsidies, mental health, COVID-19, public health, Food and Drug Administration (FDA) user fees, and government funding. Overall, lawmakers have made some progress – most notably, passing gun safety reform and providing youth mental health resources in the Bipartisan Safer Communities Act (P.L. 117-159). Still, Congress has a lot to do before the summer recess. The House adjourns on August 1, and the Senate adjourns a week later.

In the wake of several landmark Supreme Court rulings, lawmakers are also operating in a more politically charged environment that has further raised the stakes for the upcoming midterm elections, and therefore could influence policymaking in the near term. The decision to overturn *Roe v. Wade*, a nearly 50-year precedent establishing a constitutional right to abortion, in *Dobbs v. Jackson Women's Health Organization* could have further ramifications for access to contraception and same-sex marriage. Additionally, the Supreme Court curtailed the Environmental Protection Agency's power to regulate carbon emissions in *West Virginia v. EPA*. This decision could set the stage for further limitations on the regulatory power of other agencies, such as the Centers for Medicare and Medicaid Services and Centers for Disease Control and Prevention.

Budget Reconciliation: Drug Pricing and Premium Subsidies

Senate Majority Leader Chuck Schumer (D-NY) and Sen. Joe Manchin (D-WV) appear to be nearing a deal on a budget reconciliation package containing drug pricing reforms similar to what the House passed at the end of the last year. The provisions are expected to cover:

- Medicare negotiation of drug prices beginning in 2023;
- Part D OOP cap at $2k with smoothing over the payment year;
- Inflation rebates;
- Part D redesign, including adjusting manufacturer and insurer incentives to encourage lower drug prices, as well as changes that would hold annual premium growth to current levels;
- Makes all vaccines free for Medicare beneficiaries;
- Fixes a loophole in the BBBA that would have permitted the HHS Secretary to refuse to negotiate the maximum number of negotiable drugs;
- Increases the low-income subsidy (LIS) benefit to Part D beneficiaries earning less than 150 percent of the federal poverty level (FPL) – full benefit LIS status is currently available to those earning less than 135 percent of FPL;
- Increases in negotiations for drug manufacturers that block new generics from coming to the market.

Whether savings generated from these reforms would be used towards temporarily extending the enhancements to advance premium tax credits (APTCs), provided by the American Rescue Plan Act of 2021 (P.L. 117-2) and expire at the end of the calendar year, or other health-related provisions remains an

open question. Democratic governors and congressional Democrats in swing districts have been urging congressional leaders to permanently expand the APTC enhancements.

Mental Health

The inclusion of some provisions from the Senate Finance Committee's youth mental health and telemental proposals (full summaries here and here) in the gun safety bill signed into law has raised some questions on the timing of Senate floor action on a more comprehensive mental health package. Discussion drafts from the 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.

The House passed the **Restoring Hope for Mental Health and Well-Being Act of 2022 (H.R. 7666)** by a vote of 402-20. The bipartisan bill would reauthorize over 30 programs related to mental health and substance use disorder within the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA) for FY 2023 through 2027 (WHG Summary). A similar reauthorization bill in the Senate, the **Mental Health Reform Reauthorization Act of 2022 (S. 4170),** has not yet been marked up by the Senate Committee on Health, Education, Labor and Pensions (HELP) (WHG summary).

COVID-19 and Public Health

The Biden Administration appears to have lost the support of Sen. Mitt Romney (R-UT) in securing additional funding for the federal COVID-19 response. Sen. Romney had brokered the bipartisan $10 billion COVID-19 emergency supplemental package, which included funding to purchase vaccines and therapeutics, maintain testing capacity, and research and develop vaccines for emerging variants. At a recent Senate HELP Committee hearing, Sen. Romney expressed feeling misled about the administration's funding needs and criticized the White House for diverting $10 billion from funding that Congress allocated for testing and medical supplies to purchase treatments and vaccines (WHG summary). The administration used a portion of that reallocated funding to purchase 105 million doses of Pfizer's COVID-19 vaccine for a fall vaccination campaign. Notably, Food and Drug Administration (FDA) recently advised pharmaceutical manufacturers to add an omicron component to the COVID-19 booster vaccine. Without any new investments from Congress, the administration will likely be required to make additional tradeoffs.

As for legislation addressing broader public health capacity, the Senate HELP Committee advanced the **Prepare for and Response to Existing Viruses, Emerging New Threats, and Pandemics (PREVENT Pandemics Act (S. 3799)**, introduced by Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) in March 2022. However, a floor vote has not yet been scheduled. The bipartisan bill legislation focuses on strengthening and modernizing federal public health and medical preparedness and response systems and programs and includes provisions from over 37 separate bills to strengthen the public health system. It includes initiatives to strengthen the supply chain, bolster the workforce, reform the CDC, support research, combat misinformation, and ensure health equity (WHG summary).

FDA User Fees

It appears likely that Congress will miss its self-imposed date of delivering the package to reauthorize the FDA user fee programs to President Biden by the beginning of August, resulting in potential furlough risks. The agency is required to issue layoff notices for employees supported by user fee revenue 60 days before the programs expire, placing this critical date on August 1.

The House passed its version of a bill – the bipartisan **Food and Drug Amendments of 2022 (H.R. 7667)** (WHG summary) in a largely bipartisan fashion. However, the diagnostic test, dietary supplement, and cosmetic provisions of the Senate version – the **Food and Drug Administration (FDA) Safety and Landmark Advancements (FDASLA) Act (S. 4348)** (WHG summary), are delaying quick passage of the

package. These provisions, which are not included in the House version, have failed to garner broad bipartisan support, and have resulted in additional negotiations.

Of note, the Senate bill also includes new provisions absent in the House version to strengthen the infant formula supply chain as well as provisions to address prescription drug pricing, including a proposal to allow the importation of drugs from Canada though Section 804 Importation Programs (SIPs) and personal importation and a proposal that would grant the FDA the authority to dismiss the citizen petitions if the primary reason of the petition is to delay a generic drug from entering the market.

FY 2023 Appropriations

The House Appropriations Committee has marked up all 12 of their FY 23 bills, with floor action expected this month. The Senate has not yet scheduled any markups. 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 stopgap measure would create a must-pass vehicle for other legislative priorities. With the Senate Appropriations Committee Chairman Pat Leahy (D-VT) and Ranking Member Richard Shelby (R-AL) both retiring, there will be great momentum to pass a final funding package before the end of the Congress.

Since lead appropriators in both chambers have not yet announced an agreement on topline numbers for FY 2023 government funding, bills marked up by the House Appropriations Committees serve as a starting point for negotiations later this year. Information on the FY 2023 Labor-HHS-Education appropriations bill is available here.

THIS WEEK IN HEALTH POLICY

Mon. (7/4)

- **Independence Day**

Wed. (7/6)

- **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.

Thurs. (7/7)

- **9:00am – NQF Meeting: Population Health** – NQF holds a meeting of the Prevention and Population Health Standing Committee to discuss measures related to prevention and population health. Details.

FEATURED WHG ANALYSIS

- *NEW* **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.
- **WHG Roundup of Recent Telehealth Policy** – In the Policy Hub Insight Bank here.
- **WHG 2022 Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank here.

CONGRESSIONAL LOOKBACK

Weds. (6/29)

- **The House E&C Subcommittee on Health** convened a hearing regarding public health legislation that would support patients, health workers, and biomedical research. Details.

Tues. (6/28)

- **The House E&C Subcommittee on Oversight and Investigations** convened a hearing on oversight of Medicare Advantage plans. Details.

REGULATORY LOOKBACK

Fri. (7/1)

- **CMS** released the latest enrollment data for Medicare, Medicaid and CHIP, and the Marketplace showing that 154.7 million people are enrolled in federal health care programs. Details.

Thurs. (6/30)

- **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). Comments are due August 29. Details.
- **CCIO** issued guidance on modified language that health insurance issuers could use to communicate the monthly premium for an individual market qualified health plan (QHP) in the 2023 benefit year**.** Details
- **CMS** issued updates to the guidance on minimum health and safety standards that long-term care (LTC) facilities must meet to participate in Medicare and Medicare. Details.
- **The FDA** issued two final guidance documents: 1) developing drugs and biologics for adjuvant treatment of renal cell carcinoma; and 2) developing drugs and biologics for adjuvant treatment of bladder cancer. Details.
- **The FDA** issued draft guidance entitled: Patient Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments (COAs). Comments are due September 29. Details.
- **The FDA** issued a request for nominations for voting and nonvoting consumer representatives to serve on advisory committees and panels. Nominations are due August 15. Details.

Tues. (6/28)

- **The FDA** issued a proposed rule to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). Comments are due October 26. Details.
- **CMS** released a data brief on Medicaid and CHIP enrollment and the COVID-19 public health emergency. Details.

Mon. (6/27)

- **CMMI** announced a new demonstration model aimed at improving oncology care. Applications are due September 30. Details.
- **The GAO** released a report finding that HHS needs to improve communications for breach reporting. Details.
- **CMS** released a Toolkit on the strategies available to support Medicaid and CHIP operations and beneficiaries during public health emergencies. Details.
- **HHS OIG** released a report on the level of COVID-19 vaccination in nursing homes. Details.

COMMENT & APPLICATION DEADLINES

- **July 5:** AHRQ released a notice of request for nominations for members of the National Advisory Council for Healthcare Research and Quality. Details.
- **July 7:** The FDA issued draft guidance on cybersecurity in medical devices and quality system considerations. Details.
- **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 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 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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