

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

With less than two weeks until the next recess, Congress continues to tackle a slate of priorities, including mental health, ARPA-H, LGBTQI+ data inclusion, and FY 2023 government funding. COVID-19 vaccines for children under five are now [authorized](#) and [recommended](#) by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC). The Biden Administration has begun distributing pediatric vaccinations, which will be available at pediatric practices, pharmacies, Federally Qualified Health Centers, local health departments, clinics, and other locations this week, announced CDC. The Calendar Year (CY) 2023 Medicare payment updates move closer to release.

*Mental Health*

The House is further along in the process on mental health legislation than the Senate. Later this week, the House is scheduled to vote on a pair of mental health bills. Later today, the House Rules Committee will meet to consider amendments to the legislation.

- **Restoring Hope for Mental Health and Well-being Act of 2022 ([H.R. 7666](#))**, introduced by House Energy and Commerce (E&C) Committee Chair Frank Pallone, Jr. (D-NJ) and Ranking Member Cathy McMorris Rogers, 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) (WHG summary). E&C unanimously approved the bill earlier this month. The manager's amendment includes provisions to increase transparency of pharmacy benefit managers (PBMs) in insurance plans by requiring them to submit reports on usage of rebates, copayment assistance, covered drugs, and other data.
- **Enhancing Mental Health and Suicide Prevention Through Campus Planning Act ([H.R. 5407](#))**, introduced by Reps. Susan Wild (D-PA) and Fred Keller (R-PA), would require the Department of Education to encourage institutions of higher education to develop and implement comprehensive campus mental health and suicide prevention plans. The House Education and Labor Committee unanimously approved the bill last month.

Meanwhile, the bipartisan group led by Sen. Chris Murphy (D-CT) is transforming the [bipartisan framework](#) into legislative text. The package includes provisions to expand the [Certified Community Behavioral Health Clinic model](#); increase investments in mental health and suicide prevention programs, including school-based mental health and supportive services; and provide funding to increase access to mental and behavioral health services for youth and families in crisis via telehealth.

The Senate Committee on Health, Education, Labor and Pensions is expected to soon mark up the Mental Health Reform Reauthorization Act of 2022 ([S. 4170](#)), which has several similar provisions to H.R. 7666 ([WHG summary](#)). So far, the Senate Finance Committee has released discussion drafts on telemental

health ([WHG summary](#)) and youth mental health ([WHG summary](#)). Discussion drafts from the three remaining workgroups – workforce, parity, and care integration – are expected in the coming weeks.

#### Other House Votes: ARPA-H, LGBTQI+ Data

The House is also scheduled to vote on the following bills:

- **Advanced Research Projects Agency-Health Act (H.R. 5585)**, introduced by House E&C Health Subcommittee Chair Anna Eshoo (D-CA), would require the Department of Health and Human Services (HHS) to move ARPA-H to an independent division within HHS no later than 180 days after enactment. E&C approved the bill by a vote of 53-3. The Biden Administration [established](#) ARPA-H “as an independent entity within the National Institute of Health.”
- **LGBTQI+ Data Inclusion Act (H.R. 4176)**, introduced by Rep. Raúl Grijalva (D-AZ), would require federal surveys to collect voluntary information on sexual orientation, gender identity, and variations in sex characteristics. The House Oversight and Reform Committee approved the bill by a 23-16 vote earlier this month. Last Wednesday, President Biden signed an [executive order](#) that establishes a new federal coordinating committee to strengthen the federal collection of sexual orientation and gender identity (SOGI) data ([WHG summary](#)).

#### Appropriations

With the goal of floor votes before the August recess, the House Appropriations Committee will continue to mark up FY 2023 appropriations bills this week.

- **Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill** full committee markup is on June 23;
- **Labor, Health and Human Services, Education, and Related Agencies bill** subcommittee markup is on June 23, and full committee markup is on June 30; and
- **Transportation, and Housing and Urban Development, and Related Agencies bill** subcommittee markup is on June 23, and full committee markup is on June 30.

Top appropriators continue to negotiate topline numbers for FY 2023 government funding. A continuing resolution, level-funding the government possibly through the end of the calendar year, remains a possibility. The stopgap measure could provide a must-pass vehicle for bipartisan legislative priorities.

#### Regulatory Update

Last week, the Centers for Medicare & Medicaid Services (CMS) issued its proposed payment update for the Medicare Home Health Prospective Payment System (HH PPS). Notably, the proposal included a negative 7.69 percent payment adjustment for the 30-day payment rate to home health agencies in 2023. Our full summary of the proposed rule is available [here](#).

The release of this rule marks the first Medicare payment proposal for the calendar year (CY) 2023 update cycle. An additional proposed update for Medicare’s end stage renal disease (ESRD) PPS [cleared review](#) by the Office of Management and Budget (OMB) late last week and is expected for release imminently. The remaining CY 2023 payment proposals – the Hospital Outpatient PPS; Physician Fee Schedule – currently remain under review by OMB.

#### **THIS WEEK IN HEALTH POLICY**

##### **Mon. (6/20)**

- **WHG closed in observance of Juneteenth**

### Tue. (6/21)

- **11:00am – BPC and Commonwealth Fund Event: Public Health System** – The Bipartisan Policy Center (BPC) and the Commonwealth Fund Commission hold an event on the national public health system. [Details.](#)

### Wed. (6/22)

- **10:00am – Hearing: Farm Bill** – The House Agriculture Committee holds a hearing titled, “A 2022 Review of the Farm Bill: Dairy Provisions.” [Details.](#)

### Thurs. (6/23)

- **8:30am – CMS Meeting: Outreach and Education** – The Centers for Medicare and Medicaid Services (CMS) holds a meeting of the Advisory Panel on Outreach and Education to provide recommendations on effective implementation of CMS programs. [Details.](#)
- **9:00am – CMS Meeting: CLFS** – The Centers for Medicare and Medicaid Services (CMS) hold a meeting to discuss the appropriate basis for establishing payment amounts for Healthcare Common Procedure Coding System (HCPCS) codes under the Clinical Laboratory Fee Schedule (CLFS). [Details.](#)
- **10:15am – Hearing: FNS** – The House Education & Labor Committee Civil Rights and Human Services Subcommittee holds a hearing titled, “Examining the Policies and Priorities of the US Department of Agriculture’s Food and Nutrition Service (FNS).” [Details.](#)
- **12:00pm – NIH Meeting: HIV/AIDS** – The National Institutes of Health (NIH) holds a meeting of the Office of AIDS Research Advisory Council to hear the Director’s report and other updates. [Details.](#)

### Fri. (6/24)

- **11:00am – AHP Event: Medicare Sustainability** – The Alliance for Health Policy (AHP) holds an event titled, “Perspectives on Medicare Sustainability with Former CMS Administrators DeParle and McClellan.” [Details.](#)

### Additional Multi-Day Events

- **June 21-June 22 – 10:00am – CDC Meeting: Tuberculosis** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Advisory Council for the Elimination of Tuberculosis to discuss program updates. [Details.](#)
- **June 22-June 23 – 10:00am – CDC Meeting: Immunization** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Advisory Committee on Immunization Practices to discuss the influenza vaccine; pneumococcal vaccine; human papillomavirus vaccine; measles, mumps, rubella vaccine; respiratory syncytial virus vaccine; rotavirus vaccine; and Chikungunya vaccine. [Details.](#)

### **FEATURED WHG ANALYSIS**

- **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**

#### Thurs. (6/16)

- **MedPAC released** its June 2022 Report to Congress. [Details.](#)
- **MACPAC released** its June 2022 Report to Congress. [Details.](#)

- **The Senate HELP Committee** [questioned](#) senior Biden Administration officials about the ongoing federal response to COVID-19. [Details](#).

#### **Weds. (6/15)**

- **The SFC** [released](#) a discussion draft of legislation that would address youth mental health. [Details](#).

#### **Tues. (6/14)**

- **The Senate HELP Committee** [convened](#) a mark up to examine several health-related bills, including the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act ([S. 4348](#)). [Details](#).
- **The House Ag Committee** [held](#) the latest in a series of hearings on the Farm Bill, this time on non-SNAP nutrition programs. [Details](#).

### **REGULATORY LOOKBACK**

#### **Fri. (6/17)**

- **CMS** [issued](#) the cycle year (CY) 2023 home health prospective payment system and rate update proposed rule. Comments are due August 16. [Details](#).
- **The FDA** [announced](#) the launch of pilot program for sponsors of CBER premarket notification (510(k)) submissions that wish to use the voluntary Electronic Submission Template and Resource. [Details](#).

#### **Thurs. (6/16)**

- **CMS** [approved](#) state plan amendments (SPAs) in Maine, Minnesota, New Mexico, and Washington, D.C. to extend Medicaid coverage to 12 months postpartum. [Details](#).
- **The FDA** [published](#) an updated to the list of off-patent, off-exclusivity (OPOE) drugs without an approved generic. [Details](#).
- **HRSA** [released](#) a request for information to inform the Early Hearing Detection and Intervention (EHDI) program. [Details](#).
- **The FDA** [issued](#) final guidance entitled “Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions.” [Details](#).

#### **Weds. (6/15)**

- **President Biden** signed an [Executive Order](#) on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex (LGBTQI+) Individuals. [Details](#).
- **The SCOTUS** [ruled](#) that CMS did not have the authority to reduce the \$1.6 billion in Medicare payments for outpatient drugs. [Details](#).
- **HHS OIG** [released](#) a report finding that inaccuracies in Medicare’s race and ethnicity data hinder the ability to assess health disparities. [Details](#).

#### **Tues. (6/14)**

- **HHS and USDA** [announced](#) the intention to establish the 2025 Dietary Guidelines Advisory Committee and solicit nominations for membership. Nominations are due July 15. [Details](#).
- **HHS OCR** issued new [guidance](#) on how health care providers and plans can use remote communication technologies to furnish audio-only telehealth services in a HIPPA-compliant way. [Details](#).
- **MACPAC** [released](#) a response to CMS’s RFI on revising the requirements for long-term care facilities to establish minimum mandatory staffing levels. [Details](#).

#### **Mon (6/13)**

- **CMMI** [announced](#) it is adding a [third track](#) to its Maryland Primary Care Program. [Details](#).
- **HHS OIG** [released](#) an audit finding that Medicare and beneficiaries paid more to provider-based facilities than they paid to freestanding facilities for the same type of services. [Details](#).

## COMMENT & APPLICATION DEADLINES

- **June 24:** HHS is [seeking nominations](#) for members on the [National Vaccine Advisory Committee](#). Nominations are due June 24. [Details](#).
- **June 24:** The CDC released a solicitation of nominations for appointment of individuals to serve as members of the Community Preventive Services Task Force (CPSTF). [Details](#).
- **June 27:** FNS [announced](#) \$5 million in grant funding for Process and Technology Improvement Grants in SNAP. [Details](#).
- **June 27:** SAMHSA [announced](#) \$55 million in grant funding for Tribal Opioid Response Grants. [Details](#).
- **July 1:** CMS [announced](#) the nomination period is now open for Wave 5 of the MACRA clinician expert workgroups. [Details](#).
- **July 3:** The FDA [released](#) proposed rules to prohibit menthol in cigarettes and characterizing flavors in cigars. [Details](#).
- **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 16:** CMS [issued](#) the cycle year (CY) 2023 home health prospective payment system and rate update proposed rule. [Details](#).
- **September 17:** The CDC [issued](#) a request for nominations for members to serve on the Healthcare Infection Control Practices Advisory Committee (HIPAC). [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](#).

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