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

## Wynne Health Group Weekly



#### FRAMING THE WEEK

Both sides of the Capitol are in session this week as attention remains focused on how to address the looming debt ceiling. President Biden hosted Democratic leaders at the White House last week and is expected to meet with Speaker of the House, Republican Kevin McCarthy, on Wednesday. Democrats largely remain unified that they will not negotiate on the debt ceiling and that Congress must pass a "clean" limit increase. Senator Majority leader Chuck Schumer reportedly left the White House meeting stating that House Republicans need to "put a plan on the table." Senate Republican leader Mitch McConnell is largely staying out of the discussion at this time, leaving it to House Republicans to come up with a strategy.

Most agree that the issue will not be resolved any time soon. Notably, House Republicans are reportedly contemplating a clean short-term suspension to delay dealing with the matter until the end of September to align with the end of the fiscal year.

Last week, Senate Democrats made progress in organizing themselves for the 118<sup>th</sup> Congress by assigning full committee memberships. Senate Republicans are taking longer, which is preventing the Senate from passing an organizing resolution and starting official business.

The House is also making progress with Democrats announcing key Committee <u>assignments</u> and Republicans starting to name Subcommittee Chairs. Rep. Vern Buchanan (R-FL) was officially named as the Chairman of the Ways and Means Health Subcommittee and Congressman Brett Guthrie (R-KY) was officially named the Chairman of the Energy and Commerce Subcommittee on Health. Both served as the Ranking Members in the last Congress. Chairman Guthrie recently discussed with the press what his priorities for the year would be, including plans to focus on price transparency, oversight of the CDC, and keeping expanded telehealth flexibilities "sustainable." Addressing the fentanyl crisis will be another priority. The full Committee held a Roundtable last Wednesday where Energy and Commerce Committee Republicans accused social media and technology firms of facilitating the deadly trafficking of fentanyl and not doing enough to prevent sales of the drug on their platforms. The issue will assuredly come up at the Subcommittee's first legislative hearing of the year on Wednesday. The <u>hearing</u> will focus on legislation introduced to address the fentanyl crisis, the cybersecurity breach of suicide lifelines, and Quality Adjusted Life Year (QALY) measures.

#### Regulatory Update

Two regulations cleared review by the Office of Management and Budget (OMB) last week and are likely poised for release this week. The first is a <u>proposed rule</u> pertaining the coverage of certain preventive services under the Affordable Care Act (ACA). Under such requirements, most private health insurance

plans must cover recommended preventive services without cost-sharing. The rule would specifically propose changes to previously finalized regulations regarding religious and moral exemptions and accommodations regarding coverage of certain preventive services. Notably, this rulemaking is occurring at the same time as ongoing litigation against the ACA's preventive services requirements, specifically concerning the existing requirement for health insurers to cover preexposure prophylaxis (PrEP) – a medication used to prevent HIV.

In addition, OMB concluded its review of a <u>final rule</u> related to the calendar year 2020 policy and technical changes to Medicare Advantage (MA) and Part D. The final rule appears to address the unfinalized provisions related to the MA Risk Adjustment Data Validation (RADV) program and the use of extrapolation for audit recovery findings in calculating improper payments. Details on this provision – originally proposed in 2018 – are available <u>here</u>. The Centers for Medicare & Medicaid Services (CMS) chose not to finalize the proposed changes and instead extended the comment period for these particular provisions until August 2019 (<u>details</u>). The statutory deadline for finalizing these changes is February 1, 2023 (i.e., this Wednesday).

# THIS WEEK IN HEALTH POLICY

## <u>Mon. (1/30)</u>

- 10:00am NIH Meeting: New Methodologies in Biological Research The National Institutes of Health (NIH) holds a meeting of the Interagency Coordinating Committee on the Validation of Alternative Methods to discuss emerging approaches for anchoring biological relevance of new approach methodologies. <u>Details</u>.
- 10:30am NIH Meeting: Allergy/Infectious Diseases Research NIH holds a meeting of the National Institute of Allergy and Infectious Diseases to hear a report from the acting director. <u>Details</u>.
- **1:00pm HITAC Meeting: Annual Report Workgroup –** The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Annual Report Workgroup to discuss program updates. <u>Details</u>.

## Tue. (1/31)

- 11:00am NIH Meeting: Firearm Injury Prevention NIH holds a meeting of the National Institute of Nursing Research to discuss research supporting firearm injury and mortality prevention. <u>Details</u>.
- 1:00pm BPC Discussion: Agriculture The Bipartisan Policy Center holds a discussion the processes and priorities around the 2023 Farm Bill, and new recommendations aimed at strengthening food and security through the Supplemental Nutrition Assistance Program (SNAP). Details.

## Wed. (2/1)

- **10:00am Hearing: Farm Bill –** The Senate Committee on Agriculture, Nutrition, and Forestry holds a hearing focusing on the trade and horticulture titles of the Farm Bill. <u>Details</u>.
- **10:00am Hearing: Fentanyl Crisis –** The House Energy and Commerce Health Subcommittee holds a hearing to discuss the fentanyl crisis and addressing discrimination against those with disabilities. <u>Details</u>.
- 10:30am HITAC Meeting: Interoperability Standards Workgroup The Health Information Technology Advisory Committee (HITAC) holds a meeting of the Interoperability Standards Workgroup to discuss program updates. <u>Details</u>.
- **1:00pm NIH Meeting: Neurological Disorders –** NIH holds a meeting of the National Institute of Neurological Disorders and Stroke (NINDS) to hear a report by the NINDS director. <u>Details</u>.

# Additional Multi-Day Events

- January 30-January 31 HHS Meeting: Alzheimer's Research The Department of Health and Human Services (HHS) holds a meeting of the Advisory Council on Alzheimer's Research, Care, and Services to hear presentations on issues related to clinical practice, plans for advanced care planning, and to review the impact of new drug approvals. <u>Details</u>.
- February 1-February 2 CMS Meeting: Discarded Drug Refund Policy The Centers for Medicare and Medicaid Services (CMS) hold a town hall discussion on important aspects of the discarded drug refund policy and the adopted requirements in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) final rule. <u>Details</u>.
- February 2-February 3 HRSA Meeting: Nurse Education The Health Resources and Services Administration holds a meeting of the National Advisory Council on Nurse Education and Practice (NACNEP) to discuss draft recommendations and nursing essentials. <u>Details</u>.

## FEATURED WHG ANALYSIS

- WHG Roundup of Surprise Bilking and Transparency Updates- In the Policy Hub Insight Bank <u>here.</u>
- WHG Maternal Health Policy Update: November December 2022 In the Policy Hub Insight Bank <u>here.</u>
- Blog on Which Issues Warrant Consideration in a Year-End Spending Package On Commonwealth Fund's To the Point <u>here</u>.
- Blog on What Recent State Elections Mean for Health Care On Health Affairs Forefront here.

## **CONGRESSIONAL LOOKBACK**

## <u>Fri. (1/27)</u>

 MACPAC <u>convened</u> virtually for Day Two of its January 2023 public meeting and held sessions on potential responses to HHS rulemaking and a state update on unwinding the PHE. All WHG session summaries are available on Policy Hub <u>here</u>.

## Thurs. (1/26)

• **MACPAC** <u>convened</u> virtually for Day One of its January 2023 public meeting and held sessions on race and ethnicity data collection, nursing facility payments, Medicaid coverage of drugs with NCDs, HCBS, and managed care. All WHG session summaries are available on Policy Hub <u>here</u>.

## **REGULATORY LOOKBACK**

## Fri. (1/27)

- **CMS** <u>issued</u> guidance outlining new requirements for state Medicaid and CHIP programs regarding the unwinding of continuous coverage requirements. <u>Details</u>.
- The FDA <u>issued</u> draft guidance on recommendations for evaluating donor eligibility using individual risk-based questions to reduce the risk of HIV by blood and blood products. Comments are due March 31. <u>Details</u>.

## <u>Thurs. (1/26)</u>

 The OMB <u>requests</u> comments on initial proposals to improve the quality and usefulness of race and ethnicity data collected and reported across federal agencies. Comments are due April 12. <u>Details</u>.

## Tues. (1/24)

• The FDA <u>issued</u> immediately in effect final guidance on compounding certain ibuprofen oral suspension products in outsourcing facilities for administration in hospitals and health systems. <u>Details</u>.

Mon. (1/23)

- **President Biden** <u>issued</u> a Presidential Memorandum on Further Efforts to Protect Access to Reproductive Healthcare Services. <u>Details</u>.
- **CMS** <u>issued</u> guidance on how the IRA inflation rebates and maximum fair price impact Medicaid AMP and Bes Price. <u>Details</u>.
- **HHS OIG** <u>released</u> a report on COVID-19 infection rates in nursing homes. <u>Details</u>.

#### COMMENT & APPLICATION DEADLINES

- January 30: CMS issued an RFI seeking feedback on issues related to the Essential Health Benefits. <u>Details</u>.
- **February 3: HRSA** <u>released</u> an RFI seeking perspectives regarding the design, implementation, and evaluation of the Healthy Start Program. <u>Details</u>.
- February 4: CMS <u>released</u> the 2024 HHS Notice of Benefit Payment Parameters proposed rule.
  <u>Details</u>
- **February 9:** The CDC <u>released</u> a grant opportunity for research programs to assess the effectiveness of programs, policies, or practices that affect SDOH. <u>Details</u>.
- **February 12:** CMS <u>issued</u> a request for nominations to fill vacancies on the Advisory Panel on Hospital Outpatient Payment. <u>Details</u>.
- February 13: CMS <u>released</u> the CY 2024 policy and technical changes to the MA and Part D programs. <u>Details</u>.
- **February 13:** HHS <u>issued</u> a request for public comment on new indicator targets for the National Action Plan to Prevent Health Care-Associated Infections. Details. <u>Details</u>.
- **February 23:** The GAO issued a request for nominations for appointments to MedPAC. Details.
- March 6: FNS <u>announced</u> \$60.58 million in funding for round two Reach and Resiliency grants in The Emergency Food Assistance Program (TEFAP). <u>Details</u>.
- **March 9:** The FDA <u>issued</u> a proposed rule to establish a new annual reporting requirement for investigational new drug applications. <u>Details</u>.
- **March 9:** The FDA <u>issued</u> draft guidance on content of human factors information in medical device marketing submissions. <u>Details</u>.
- March 13: CMS <u>released</u> a proposed rule to improve the electronic exchange of health care data and streamline prior authorization. <u>Details</u>.
- March 14: HHS and other agencies jointly <u>issued</u> a proposed rule to restore protections against religious discrimination for beneficiaries and prospective beneficiaries of federally funded services and programs. <u>Details</u>.
- March 15: The USPSTF <u>issued</u> a request for nominations to serve as members of the Task Force. <u>Details</u>.
- **March 19:** The FDA <u>issued</u> draft guidance on optimizing the dosage of human prescription drugs and biological products for the treatment of oncologic diseases. <u>Details.</u>
- March 31: The FDA issued draft guidance on recommendations for evaluating donor eligibility using individual risk-based questions to reduce the risk of HIV by blood and blood products. Details.
- April 12: The OMB <u>requests</u> comments on initial proposals to improve the quality and usefulness of race and ethnicity data collected and reported across federal agencies. <u>Details</u>.

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