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

# Wynne Health Group Weekly



#### FRAMING THE WEEK

Ahead of the two-week congressional recess, the Senate will have a busy week continuing to negotiate a bipartisan COVID-19 supplemental package and advancing the nomination of Ketanji Brown Jackson to the U.S. Supreme Court. Tomorrow, former President Barack Obama will return to the White House for an event celebrating the Affordable Care Act (ACA). President Biden is also expected to announce additional measures to strengthen the ACA – a key priority of the Administration especially as efforts to extend enhancements to ACA premium tax credits beyond 2022 stall in Congress.

Meanwhile, key congressional committees will convene hearings on top priorities, including the fiscal year (FY) 2023 budget for the Department of Health and Human Services (HHS), mental health legislation, and Food and Drug Administration (FDA) user fees. The Centers for Medicare & Medicaid Services (CMS) is expected to release its calendar year (CY) 2023 final Rate Announcement for Medicare Advantage (MA) and Part D plans. The Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) will meet later this week.

# <u>ACA</u>

Among what President Biden may announce includes a proposed rule to **fix the "family glitch,"** which has recently <u>cleared review</u> by the Office of Management and Budget (OMB). As a reminder, the family glitch is based on a 2015 Department of Treasury interpretation of the ACA tax credits such that family members were blocked from accessing tax credits if a worker had an employer offer of affordable self-only coverage and was offered a family plan, even if the family's coverage expenses were to exceed 9.5 percent of income. The Congressional Progressive Caucus recently <u>issued recommendations</u> for Executive Action that included a push to fix the family glitch. <u>Estimates</u> from last year from the Kaiser Family Foundation found that fixing the family glitch would lead to coverage gains of approximately 5.1 million people.

# COVID-19

The COVID-19 spending bill being negotiated between congressional Democrats and Republicans appears to be **around \$10 billion to procure therapeutics and vaccines for the U.S. and develop vaccines against variants.** "We're already seeing the consequences of congressional inaction," <u>said</u> President Biden last week. Without additional funding, monoclonal antibodies will run out by the end of May and testing capacity will drop after June, noted Biden. While the U.S. has enough supply to provide second boosters to <u>eligible individuals</u>, additional funding is needed to ensure second boosters are available to all Americans in the fall, he added. Tomorrow, the Health Resources and Services Administration (HRSA) will stop processing vaccination claims through the <u>COVID-19 Uninsured Program</u> and <u>Coverage Assistance Fund</u>. On March 22, the COVID-19 Uninsured Program stopped accepting claims for testing and treatment.

#### FY 2023 Budget

Tomorrow, Health and Human Services (HHS) Secretary Xavier Becerra will continue to field questions about the **President's FY 2023 budget** (WHG summary). He will appear in back-to-back hearings before

the <u>Senate Finance Committee</u> and <u>House Ways and Means Committee</u>. The President's budget requests \$20.8 billion, a \$4.9 billion increase in discretionary funding for behavioral health programs; \$470 million in funding across to reduce maternal mortality and morbidity; \$45 million for telehealth; \$81.7 billion over five years for future pandemic preparedness; and \$850 million to end HIV/AIDS, among an array of other requests to largely increase funding for HHS agencies.

Beginning today, <u>Community Project Funding requests</u> (i.e., earmarks) for FY 2023 can be submitted to the House Appropriations Committee. Like last year, Community Project Funding is limited to no more than one percent of discretionary spending. The <u>process</u> for submitting requests is mostly the same as last year. However, Members will now be able to submit up to 15 requests across all Subcommittees, up from a total of 10 requests last year. The deadline for Labor-HHS-Education Subcommittee is April 27. The deadline for the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies is April 28.

## Mental Health Legislation

Like key Senate committees, the House Energy and Commerce (E&C) Subcommittee on Health is also crafting legislation to address the nation's mental health crisis. Tomorrow, the Health Subcommittee will examine 19 mental health bills; most are bipartisan and few have Senate companions. In general, the bills align with priority issues for the Senate Finance Committee and Senate Health, Education, Labor and Pensions Committee – including, behavioral health workforce; children, adolescents, and young adults; access, integration, and coordination; telehealth; and federal programs at Substance Abuse and Mental Health Services Administration (SAMHSA) and HRSA.

# FDA User Fees

Tomorrow, the Senate HELP Committee will hold a <a href="hearing">hearing</a> on FDA user fee agreements. Because user fees make up <a href="nearly half">nearly half</a> of FDA's budget, their reauthorization is considered "must-pass" and could serve as a vehicle for changes to FDA's regulatory processes as well as other legislative priorities. The user fee programs for prescription drugs (PDUFA), generic drugs (GDUFA), and biosimilars, (BsUFA), and medical devices (MDUFA) will need to be reauthorized before their expiration on September 30, 2022. So far, the House E&C Health Subcommittee has convened two hearings on the topic (<a href="February 3 hearing memo">February 3 hearing memo</a>; March 30 hearing memo).

# MA and Part D

CMS is expected to release its **final CY 2023 Rate Announcement** for MA and Part D plans today. The Advance Notice included an estimated 7.98 percent increase to MA plans and solicited comments from stakeholders on ways to increase health equity via the MA and Part D programs (WHG <u>summary</u>). In these solicitations, CMS revealed it is contemplating potential health equity-related changes to its Star Ratings measures and risk adjustment methodologies.

#### MedPAC

Later this week, MedPAC will <u>convene</u> several sessions focused on addressing prescription drug prices under Medicare Part B and Part D. Commissioners will also discuss approaches to harmonizing Medicare's portfolio of alternative payment models, payment reforms for ambulatory settings, and policies to address social determinants of health.

# **MACPAC**

MACPAC will also meet to vote on recommendations regarding access monitoring, vaccine access for adults, managed care direct payments, and health IT adoption in behavioral health for the June Report. With the COVID-19 Public Health Emergency possibly ending this year and triggering Medicaid redeterminations, Commissioners will also review analyses of churn and coverage transitions and discuss the Biden Administration's request for information on access to care and coverage for people enrolled in Medicaid and CHIP. Comments are due April 18, 2022.

#### THIS WEEK IN HEALTH POLICY

# Tue. (4/5)

- 10:00am Hearing: HHS FY 2023 Budget The Senate Finance Committee holds a hearing titled, "The President's Fiscal Year 2023 Health and Human Services (HHS) Budget Request."
   Details.
- 10:00am Hearing: FDA User Fee Agreements The Senate Committee on Health, Education, Labor and Pensions (HELP) holds a hearing titled, "FDA User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients." Details.
- 10:15am Hearing: Mental Health The House Committee on Energy and Commerce Subcommittee on Health holds a hearing titled, "Communities in Need: Legislation to Support Mental Health and Well-Being." Details.
- 10:30am ONC Meeting: Interoperability The Office of the National Coordinator for Health Information Technology (ONC) holds a meeting of the Interoperability Standards Workgroup to discuss how to improve interoperability. Details.

# Wed. (4/6)

- 8:30am FDA Meeting: COVID-19 Vaccines The Food and Drug Administration (FDA) holds a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss COVID-19 booster doses and the process for COVID-19 vaccine strain selection. Details.
- 9:00am Hearing: HHS Priorities The House Education and Labor Committee holds a hearing titled, "Examining the Policies and Priorities of the U.S. Department of Health and Human Services." Details.
- 1:00pm ASPR Meeting: Seniors and Individuals with Disabilities and Disasters The
  Assistant Secretary for Preparedness and Response (ASPR) holds a joint meeting of the National
  Advisory Committee on Seniors and Disasters and the National Advisory Committee on
  Individuals with Disabilities and Disasters to discuss the needs of and priorities for older adults
  and people with disabilities in disasters. <a href="Details">Details</a>.
- 2:00pm Hearing: HHS FY 2023 Budget The House Ways and Means Committee holds a hearing titled, "Proposed Fiscal Year 2023 Budget with Health and Human Services Secretary Becerra." Details.
- 2:30pm Hearing: HHS FY 2023 Budget The House Committee on the Budget holds a hearing titled, "Department of Health and Human Services FY 2023 Budget." <u>Details</u>.
- 2:30pm Brookings Event: Mental Health The USC-Brookings Schaeffer Initiative for Health Policy holds a discussion titled, "Addressing the National Mental Health Crisis: Opportunities and Challenges." <u>Details</u>.

## Thurs. (4/7)

- 12:00pm 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 discuss opportunities to enhance consumer education strategies. <u>Details</u>.
- 12:00pm NIH Meeting: Sleep The National Institutes of Health (NIH) National Heart, Lung, and Blood Institute holds a meeting of the Sleep Disorders Research Advisory Board to provide program updates. <a href="Details">Details</a>.
- **3:00pm NQF Meeting: Clinical Quality Measures** The National Quality Forum (NQF) holds a meeting of the Clinical Quality Measures Collaborative (CQMC) Health Equity Workgroup to discuss how to improve equity with clinical quality measures. <a href="Details">Details</a>.

# **Additional Multi-Day Events**

- April 7-April 8 Meeting: MACPAC The Medicaid and CHIP Payment and Access
  Commission (MACPAC) holds a public meeting to discuss Medicaid and CHIP payment and
  policy issues. <u>Details</u>.
- April 7-April 8 Meeting: MedPAC The Medicare Payment Advisory Commission meets to discuss Medicare issues and policy questions. <u>Details</u>.

#### **FEATURED WHG ANALYSIS**

- 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.
- WHG Issue Brief on Health Equity Implications of Potential Telehealth Reform Under Medicare In the Policy Hub Insight Bank here.

#### **CONGRESSIONAL LOOKBACK**

## Weds. (3/30)

• The Senate Finance Committee <u>convened</u> a hearing to discuss parity and integration between behavioral health care and physical health care. <u>Details</u>.

# Tues. (3/29)

- The Senate Finance Committee <u>released</u> its bipartisan report on the case for federal action on mental health care in the United States. Details.
- The House Committee on Oversight and Reform <u>convened</u> a hearing to examine pathways to universal health coverage. Details.

# Mon. (3/28)

The White House released it's \$5.8 trillion plan to fund the government for FY 2023. <u>Details</u>.

#### **REGULATORY LOOKBACK**

#### Fri. (4/1)

- The GAO <u>released</u> a report on the impact of telehealth on the quality of care in Medicaid. <u>Details</u>.
- **CMS** hosted a listening session to help inform the agency's development of an alternative coverage pathway to provide transitional coverage for emerging technologies. <u>Details</u>.
- The GAO is <u>accepting</u> nominations for the Board of Governors of the Patient-Centered Outcomes Research Institute. Details.
- **HHS OIG** <u>released</u> a report finding that Medicare Part D and beneficiaries could realize spending reductions with increased biosimilar use. <u>Details</u>.

#### Thurs. (3/31)

- **CMS** <u>released</u> the FY 2023 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule. Comments are due May 31. <u>Details</u>.
- **CMS** <u>released</u> the FY 2023 inpatient psychiatric facility (IPF) prospective payment system (PPS) proposed rule. Comments are due May 31. <u>Details</u>.
- **CMS** <u>announced</u> that it will provide \$110 million through the Money Follows the Person (MFP) program to expand access to home and community-based services (HCBS). <u>Details</u>.
- MACPAC <u>published</u> an issue brief on the availability of race and ethnicity data for Medicaid beneficiaries. <u>Details</u>.
- **ASPE** <u>published</u> an issue brief summarizing an expert roundtable discussion on identifying and supporting individuals with SUD. Details.

## Weds. (3/30)

 CMS <u>released</u> the FY 2023 hospice payment rate update proposed rule. Comments are due May 31. Details.

## Mon. (3/28)

• **CMS** <u>released</u> the latest enrollment figures for Medicare, Medicaid and CHIP from November and December 2021. Details.

 AHRQ posted a request for supplemental data and evidence on postpartum home blood pressure monitoring and postpartum treatment of hypertensive disorders. Submissions are due April 28.
 Details.

# **COMMENT & APPLICATION DEADLINES**

- **April 4:** SAMHSA released a NOFO that will make \$10 million available for the Services Grant Program for Residential Treatment for Pregnant and Postpartum Women. <u>Details</u>
- **April 11:** The CDC <u>announced</u> it is requesting comments on the proposed clinical practice guideline, "CDC Clinical Practice Guideline for Prescribing Opioids." <u>Details</u>.
- April 12: The NIH <u>issued</u> an RFI to gather public input on developing the NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA). Comments are due April 12. <u>Details</u>.
- **April 16:** HRSA released a NOFO to support long term improvements in early developmental health through the Transforming Pediatrics for Early Childhood program. <u>Details</u>.
- April 18: CMS <u>released</u> an RFI on access to care and coverage for Medicaid and CHIP enrollees. Comments are due April 18. Details.
- April 19: HHS <u>announced</u> the availability of \$13 million to support increased access to behavioral health care services, including treatment for substance use disorder, in rural communities. <u>Details</u>.
- **April 19:** AHRQ <u>released</u> an RFI from the public on its proposed strategic framework for its Patient-Centered Outcomes Research Trust Fund (PCORTF) investments. Details.
- April 22: The NIH <u>announced</u> a \$1 million prize competition for innovative diagnostics technologies to help improve maternal health. <u>Details</u>.
- April 25: The FTC <u>issued</u> a request for public comments on the ways that <u>pharmacy</u> benefit managers (PBMs) affect drug affordability and access. <u>Details</u>.
- **April 28:** AHRQ posted a request for supplemental data and evidence on postpartum home blood pressure monitoring and postpartum treatment of hypertensive disorders. <u>Details</u>.
- May 2: The HHS Office of the Surgeon General is <u>seeking</u> input on the impact and prevalence of health misinformation in the digital information environment during the COVID-19 pandemic. <u>Details</u>.
- May 9: The NIH <u>released</u> a notice of proposed rulemaking to update the NIH Loan Repayment Programs (LRP) to reflect changes made by the 21<sup>st</sup> Century Cures Act. <u>Details</u>.
- May 17: SAMHSA posted three grant opportunities related to mental health. Details.
- May 17: SAMHSA <u>posted</u> a notice of funding opportunity for the Infant and Early Childhood Mental Health Grant Program. <u>Details</u>.
- May 24: The FDA issued a proposed rule to amend the device CGMP requirements. Details.
- May 31: CMS <u>released</u> the FY 2023 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule. Comments are due May 31. <u>Details</u>.
- May 31: CMS <u>released</u> the FY 2023 inpatient psychiatric facility (IPF) prospective payment system (PPS) proposed rule. Comments are due May 31. Details.
- May 31: CMS released the FY 2023 hospice payment rate update proposed rule. Details.
- **June 7:** The FDA <u>issued</u> a request for comments on changes to the agency's previously proposed quality metrics (QM) reporting program. Details.

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