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

Wynne Health Group Weekly



FRAMING THE WEEK

This week, the House may vote on legislation to delay several Medicare payment cuts that would take effect on January 1, 2022. The bill may include:

- Extending the temporary 3.75 percent increase to the physician fee schedule;
- Delaying cuts as large as 15 percent to clinical laboratory tests; and
- Extending the moratorium on 2 percent Medicare sequester.

The House is also scheduled to vote on the fiscal year (FY) 2022 National Defense Authorization Act (NDAA) and separate legislation to address the looming debt limit. Treasury Secretary Janet Yellen estimates the U.S. could reach its debt limit on December 15. Senate Majority Leader Chuck Schumer (D-NY) and Senate Minority Leader Mitch McConnell (R-KY) are considering adding language to raise the debt limit to NDAA, though it faces an uphill battle in the House. Whether enough Senate Republicans will support the approach is unclear.

The House is also scheduled to vote on a slew of mostly bipartisan health-related bills:

- Accelerating Access to Critical Therapies for ALS Act (H.R. 3537)
- SHINE for Autumn Act of 2021 (H.R. 5487)
- Early Hearing Detection and Intervention Act of 2021 (H.R. 5561)
- Improving the Health of Children Act (H.R. 5551)
- Cardiovascular Advances in Research and Opportunities Legacy Act (H.R. 1193)
- Dr. Lorna Breen Health Care Provider Protection Act (H.R. 1667)
- Allied Health Workforce Diversity Act of 2021 (<u>H.R. 3320</u>)
- Oral Health Literacy and Awareness Act of 2021 (H.R. 4555)
- Opioid Prescription Verification Act of 2021 (H.R. 2355), Republican support only
- Synthetic Opioid Danger Awareness Act (H.R. 2364), Democratic support only
- Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act (H.R. 3743), *Democratic support only*
- CARING for Social Determinants Act of 2021 (H.R. 3894)

Build Back Better Act

As for the Build Back Better Act (BBBA, <u>H.R. 5376</u>, <u>WHG summary</u>), the Senate parliamentarian will examine the health-related provisions this week – including prescription drug pricing, ACA premium tax credits, and Medicare and Medicaid coverage expansions. President Biden will deliver remarks at 2:00pm EST on how BBBA would lower the cost of prescription drugs. Collectively, BBBA includes measures that would:

- Authorize the Department of Health and Human Services (HHS) to negotiate the cost of singlesource Part B and Par D drugs without competition directly with drug manufacturers;
- Impose penalties on drug manufacturers if they increase prices faster than the rate of inflation;
- Redesign the Medicare Part D benefit to lower out-of-pocket costs for beneficiaries and offset greater financial liability onto insurers and manufacturers; and
- Repeal the Trump Administration's "rebate rule."

The legislation also addresses cost-sharing for certain insulin products and would increase oversight over pharmacy benefit manager (PBM) services.

Continuing Resolution

Last Friday, President Biden signed another continuing resolution (P.L. 117-70) into law, extending FY 2021 funding levels through February 18, 2022. The stopgap measure also included nutrition-related provisions:

- Allows the Food and Nutrition Service to continue providing a larger cash value for fruits and vegetables in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Food package through the second quarter of FY 2022.
- Extends waiver authority that allows residents in Supportive Living Facilities to receive Supplemental Nutrition Assistance Program (SNAP) benefits.

<u>MACPAC</u>

Later this week, the Medicaid and CHIP Payment and Access Commission (MACPAC) will <u>convene</u> to discuss various topics, including:

- **Transparency and oversight of state directed payment arrangements**, which may include value-based purchasing models, multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives, or fee schedule requirements for provider reimbursement;
- Policy options for Money Follows the Person (MFP) qualified residence criteria (MFP increase the use of home and community-based services (HCBS) and reduces the use of institutionally-based services. The program is currently authorized through September 30, 2023 and BBBA would make it permanent.);
- How to monitor access to care among Medicaid beneficiaries. A panel of experts, including Karen Llanos, Director, Medicaid Innovation Accelerator Program, Centers for Medicare & Medicaid Services will provide recommendations;
- Options to strengthen integration of behavioral health services through health information technology;
- Applying a health equity lens to Medicaid; and
- Addressing nursing facility staffing issues with state policy levers.

<u>MedPAC</u>

The Medicare Payment Advisory Commission (MedPAC) will also meet later this week to <u>discuss</u> payment adequacy and updates for the **Medicare fee-for-service (FFS) payment systems**.

THIS WEEK IN HEALTH POLICY

Tue. (12/7)

• **2:00pm – NQF Meeting: Leadership Consortium** – The National Quality Forum Leadership Consortium holds a meeting to highlight opportunities to address healthcare challenges including data collection, clinician and care team well-being, and measurement of person-centered care. <u>Details</u>.

<u>Wed. (12/8)</u>

- 10:00am Hearing: Nutrition Programs The House Agriculture Committee Nutrition, Oversight, and Department Operations Subcommittee holds a hearing titled, "Review of USDA Nutrition Distribution Programs." <u>Details</u>.
- **10:30am Hearing: Biomedicine** The House Committee on Energy & Commerce Subcommittee on Health holds a rescheduled hearing titled, "The Future of Biomedicine: Translating Biomedical Research into Personalized Health Care." <u>Details</u>.
- 12:00pm KFF Briefing: Drug Pricing in the Build Back Better Act The Kaiser Family Foundation (KFF) holds a briefing titled, "Unpacking the Prescription Drug Provisions of the Build Back Better Act." <u>Details</u>.
- 1:30pm CMS Webinar: CMMI Health Equity Strategy The Centers for Medicare and Medicaid Services (CMS) holds a roundtable to discuss how the CMS Innovation Center (CMMI) can execute its strategic objective to Advance Health Equity. <u>Details</u>.

Thurs. (12/9)

 1:00pm – HHS Meeting: Substance Use Disorder – The Department of Health and Human Services (HHS) holds a meeting of the Interdepartmental Substance Use Disorders Coordinating Committee to discuss federal advances to address challenges in substance use disorders. Details.

Fri. (12/10)

 9:00am – FDA Meeting: Neurological Devices – The Food and Drug Administration (FDA) Medical Devices Advisory Committee holds a meeting of the Neurological Devices panel to provide advice and recommendations on regulatory issues. <u>Details</u>.

Additional Multi-Day Events

- December 6-December 7 10:00am NIH Meeting: Child Medical Rehabilitation The National Institutes of Health (NIH) Eunice Kennedy Shriver National Institute of Child Health and Human Development holds a meeting of the National Advisory Board on Medical Rehabilitation Research to hear the Director's report. <u>Details</u>.
- December 7-December 8 8;30am HRSA Meeting: Nurse Education and Practice The Health Resources and Services Administration (HRSA) holds a meeting of the National Advisory Council on Nurse Education and Practice to discuss program updates. <u>Details</u>.
- December 9-December 10 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>.
- December 9-December 10 Meeting: MedPAC The Medicare Payment Advisory Commission meets to discuss Medicare issues and policy questions. <u>Details</u>.

FEATURED WHG ANALYSIS

- WHG Issue Brief on Health Equity Implications of Potential Telehealth Reform Under Medicare In the Policy Hub Insight Bank <u>here</u>.
- WHG Side-by-Side of Live Drug Pricing Proposals Under Consideration for Reconciliation – In the Policy Hub Insight Bank <u>here</u>.
- WHG Side-by-Side of Medicaid Expansion Gap Bills In the Policy Hub Insight Bank here.

- WHG Side-by-Side of Health Technology Assessment Models In the Policy Hub Insight Bank <u>here</u>.
- WHG Updated 2021 Legislative and Regulatory Outlook In the Policy Hub Insight Bank here.
- WHG Chart Key Federal Public Option Bills in the 117th Congress; Side-by-Side Comparison – In the Policy Hub Insight Bank <u>here</u>.

CONGRESSIONAL LOOKBACK

Mon. (11/29)

 MACPAC released two issue briefs analyzing <u>children's</u> and <u>adults'</u> experiences in accessing medical care. <u>Details</u>.

REGULATORY LOOKBACK

Fri (12/3)

- **CMS** released a <u>data snapshot</u> of Medicare telemedicine claims and encounter data (received by September 9, 2021) from March 1, 2020 through February 28, 2021. <u>Details</u>.
- CMS <u>announced</u> it is ending the streamlined process for ambulatory surgical centers (ASCs) and independent freestanding emergency departments (IFEDs) to temporarily enroll in Medicare as hospitals. <u>Details</u>.
- **CMS** <u>issued</u> a memorandum saying that the Agency will not enforce the new vaccine requirement for health care workers while there are court-ordered injunctions in place. <u>Details</u>

Thurs. (12/2)

- **CMS** <u>announced</u> that they are requiring states to cover COVID-19 vaccine counseling visits for children and youth through Medicaid.
- **The BPC** held a briefing and two panel discussions about a <u>report</u> from the bipartisan Public Health Forward Task Force that establishes a 5-year vision for public health. <u>Details</u>.

Wed. (12/1)

• **HRSA** seeks <u>nominations</u> for appointees to the National Advisory Council on Migrant Health (NACMH). <u>Details</u>.

<u>Mon. (11/29)</u>

- **CMS** <u>seeks</u> nominations for appointees to the Advisory Committee on Ground Ambulance and Patient Billing (GAPB Advisory Committee), which is newly established as required by the No Surprises Act. The deadline for nominations is December 13. <u>Details</u>.
- **APSE** published a <u>report</u> on the surprise billing provisions in the No Surprises Act that will go into effect on January 1, 2022. <u>Details</u>.
- **CMS** released an <u>informational bulletin</u> guiding state Medicaid and CHIP agencies on updates to processes for certain state submissions to CMS. <u>Details</u>.
- CMS released two tool (<u>here</u> and <u>here</u>) to guide states as they return to normal operations for eligibility and enrollment. <u>Details</u>.
- ASPE published a report on network adequacy standards for behavioral health. Details.

COMMENT & APPLICATION DEADLINES

- **December 6:** HHS, DOL, and Treasury issued an <u>interim final rule with comment period</u> (IFC) on Part II of its implementation of the No Surprises Act's surprise billing policies. <u>Details</u>.
- **December 6:** The USDA FNS <u>issued</u> an RFI to support state and local Special Nutrition Program for Women, Infants, and Children (WIC) agencies in improving the WIC application and certification process. <u>Details</u>.
- **December 7:** The FDA announced the launch of the <u>Novel Excipient Review Pilot Program</u> as a new pathway for manufacturers to obtain agency review of certain novel excipients. <u>Details</u>.

- **December 8:** HHS <u>seeks</u> public comment and nominations to inform the development of the Physical Activity Guidelines (PAG) Midcourse Report on older adults. <u>Details</u>.
- December 13: AHRQ released a request for information (RFI) on <u>climate change</u>. <u>Details</u>.
- **December 13: CMS** <u>seeks</u> nominations for appointees to the Advisory Committee on Ground Ambulance and Patient Billing (GAPB Advisory Committee), which is newly established as required by the No Surprises Act. <u>Details</u>.
- January 11: HHS <u>announced</u> it is making available up to \$256 million in grant funding to support equitable, affordable, and high-quality access to family planning services through the Title X family planning program. <u>Details</u>.
- **December 28:** HHS issued a <u>proposed rule</u> to withdraw or repeal the "Securing Updated and Necessary Statutory Evaluations Timely" SUNSET final rule. <u>Details</u>.
- January 18: The FDA issued a proposed rule and <u>draft guidance</u> to improve access to hearing aids through the establishment of an over-the-counter (OTC) hearing aid category. <u>Details</u>.
- January 21: The FDA issued draft guidance on data standards for drug and biological product submissions containing real-world data (RWD. <u>Details</u>.
- January 24: HHS, DOL, the Treasury, and OPM issued an IFC to implement the health insurance plan reporting requirements on prescription drug and health care spending. <u>Details</u>.
- January 25: NIOSH published a <u>notice</u> extending the public comment period for the previously announced request for information (RFI) on interventions to support health worker mental health. <u>Details</u>.
- **February 2:** The FDA <u>issued</u> draft guidance on content of premarket submissions for device software functions. <u>Details</u>.
- **February 22:** The USDA <u>announced</u> \$1.15 billion in grant funding for rural broadband access. <u>Details</u>.

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