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

Wynne Health Group Weekly



FRAMING THE WEEK

Infrastructure

With Congress back in session after a two-week recess, negotiations over the multi-trillion **American Jobs Plan** (i.e., traditional infrastructure) will intensify over the coming six weeks. Today, likely as part of President Joe Biden's push for bipartisanship, the White House <u>released</u> individual fact sheets that highlight the **infrastructure needs of each state** and the national investments proposed in the plan. Biden is scheduled to meet with a bipartisan group of lawmakers to discuss his infrastructure proposal later today. Despite the Biden Administration's bipartisan pitch, we anticipate Democrats will ultimately resort to budget reconciliation, as they cannot afford to risk losing the support of progressive Democrats in order to appeal to enough Republicans to clear the 60-vote threshold in the Senate. On this point, it is notable that Senate Minority Leader Mitch McConnell has already expressed his caucus's opposition to the plan.

If budget reconciliation is pursued, congressional Democrats will either have to amend the FY 2021 budget resolution (an unprecedented move recently authorized by the Senate parliamentarian) or adopt an FY 2022 resolution, either of which would provide reconciliation instructions to individual committees (i.e., report date, dollar amount of budgetary change). House Speaker Nancy Pelosi (D-CA) recently said that Democrats' push for infrastructure will likely be split into two bills – traditional infrastructure in the American Jobs Plan and human infrastructure in Biden's forthcoming American Family Plan (i.e., health care and child care reforms). Whether the two House bills are combined into a single reconciliation package or approved separately remains to be seen.

Based on Democratic leaders' statements thus far, we foresee the following tentative timeline under which they will pursue their infrastructure goals:

- April-May House Democrats will work to modify their \$1.5 trillion Moving Forward Act (<u>H.R.</u> 2, 116th) to align with the American Jobs Plan. The <u>deadline</u> for Members to submit requests for highway and transit projects to the House Committee on Transportation and Infrastructure is April 23.
- Mid-April Biden is expected to unveil his American Family Plan focused on human infrastructure. With regard to the health care components, House Democrats will likely build on existing legislation, including the Patient Protection and Affordable Care Enhancement Act (<u>H.R.</u> 1425, 116th), Elijah E. Cummings Lower Drug Costs Now Act (<u>H.R. 3</u>, 116th), and several bills introduced by House Energy and Commerce Democrats that expand upon the Affordable Care Act.
- May House Transportation and Infrastructure Committee Chair Peter DeFazio (D-OR) said he expects his committee will complete its markup of the American Jobs Plan legislation in May,

possibly the week of May 24 when the House is scheduled to conduct committee work and before the one-week Memorial Day recess scheduled for May (May 31-June 4).

- July-August Speaker Pelosi intends to pass the American Jobs Plan by July 4 but signaled floor action in the House on both the American Jobs Plan and American Family Plan could slip to after that and potentially conclude closer to the August Recess.
- August-September As noted, Congress is scheduled to adjourn in early August, but the infrastructure work could delay or cut short the recess. The Senate will likely vote on the two infrastructure packages in late summer/early fall. Any amendments to the expected House-passed packages would have to be approved in the House.

FY 2022 Budget

On top of the infrastructure talks, **appropriations season** is in full swing. Biden's <u>FY 2022 budget</u> requests approximately \$1.52 trillion in discretionary spending, including \$769 billion in non-defense discretionary funding, a 16 percent increase from the FY 2021 enacted level, and \$753 billion for national defense programs, a 1.7 percent increase.

Several House Appropriations Subcommittees have <u>begun</u> accepting **public witness testimony** regarding FY 2022 spending, with deadlines as soon as April 16. Through public witness testimony, members of the public can submit funding requests for federal programs. The Subcommittees on Labor, Health and Human Services (HHS), Education, and Related Agencies and Agriculture, Rural Development, Food and Drug Administration, and Related Agencies have not yet announced submission instructions for public witness testimony.

On Thursday (April 15), the House Appropriations HHS-Labor-Education Subcommittee will <u>question</u> **HHS Secretary Xavier Becerra** on HHS' FY 2022 budget request. The Biden Administration has requested \$131.7 billion for HHS, 23.5 percent above the FY 2021 enacted levels. Much of the new funding would go to the Centers for Disease Control and Prevention (CDC) for public health modernization and the National Institutes of Health to focus on conditions such as cancer, Alzheimer's disease, and diabetes. The budget also includes significant funding increases for mental health, the opioid epidemic, HIV/AIDs, gun violence, and health equity-related initiatives such as social determinants and maternal mortality.

House Floor Activity

Tomorrow, April 13, the House will vote on, and likely pass, the Senate-approved amendment to <u>H.R. 1868</u> that would extend the **moratorium on the two percent Medicare sequester** from March 31, 2021 to December 31, 2021. To pay for the change, sequestration would expire at the end of FY 2031 instead of FY 2030. The bill would make several technical corrections to rural health clinic payments and disproportionate share hospital payment policies affecting California.

Additionally, the House will vote on, and likely pass, the **Workplace Violence Prevention for Health Care and Social Service Workers Act** (<u>H.R. 1195</u>), a bill that would direct the Department of Labor to issue an occupational safety and health standard that requires certain employers within the health care and social service sectors to develop and implement a comprehensive workplace violence prevention plan.

The House is also scheduled to vote on (and expected to pass) a slate of health-related bills, including two bills passed by unanimous consent in the Senate that aim to increase competition and lower prescription drug prices:

- Advancing Education on Biosimilars Act of 2021(<u>S.164</u>) Requires the Department of Health and Human Services to create and maintain a public website to educate providers and patients about biosimilar drug products.
- Ensuring Innovation Act (<u>S. 415</u>) Seeks to clarify the meaning of "new chemical entity," which is used by the Food and Drug Administration (FDA) to determine whether to grant a drug product five years of market exclusivity.

In addition, the House will vote on:

- **FASTER Act of 2021** (<u>S. 578</u>) Requires food allergen labels to include sesame and a report describing ongoing federal activities aimed to improve the health and safety of individuals living with food allergies and related disorders.
- **TRANSPLANT Act of 2021** (<u>**H.R. 941**</u>) Reauthorizes the <u>**C.W. Bill Young Cell Transplantation**</u> <u>**Program** and the <u>National Coord Blood Inventory</u>.</u>
- John Lewis NIMHD Research Endowment Revitalization Act of 2021 (H.R. 189) Facilitates research on minority health disparities through research endowments at current or former centers of excellence

<u>COVID-19</u>

As noted in our calendar below, committees in both chambers will <u>examine</u> the federal government's COVID-19 response. On Thursday (April 15), key members of Biden's COVID-19 task force will appear before the House Select Subcommittee on the Coronavirus Crisis. Additionally, the House <u>Energy and</u> <u>Commerce</u> and <u>Education and Labor</u> and Committees will discuss the impact of COVID-19 on **mental** health and substance use disorder.

HHS and CMS Nominations

After a significant delay, the Senate Finance Committee (SFC) will convene a <u>hearing</u> to consider the nominations of Andrea Joan Palm to be **Deputy Secretary of Health and Human Services (HHS)** and Chiquita Brooks-LaSure to be **Administrator of the Centers for Medicare and Medicaid Services (CMS)** on Thursday (April 15). Palm and Brooks-LaSure are expected to be confirmed. We anticipate that Senate Democrats will move relatively quickly to fill these key leadership positions at HHS. SFC could vote as early as next week on these nominations, paving the way for a confirmation vote before the Senate adjourns for a one-week recess that begins May.

THIS WEEK IN HEALTH POLICY

Tue. (4/13)

- **10:00am Hearing: Housing** The Senate Banking, Housing, and Urban Affairs Committee convenes a hearing titled, "Separate and Unequal: The Legacy of Racial Discrimination in Housing." <u>Details</u>.
- **10:00am Hearing: FY 2022 Budget** The Senate Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies convenes a hearing on the National Science Foundation's FY 2022 budget request. <u>Details</u>.

• **1:00pm-2:00pm ET – CHCS Discussion: Nutrition** – The Center for Health Care Strategies (CHCS) hosts a discussion titled, "Addressing Food Insecurity Among Young Children During the Pandemic: Innovations from Vermont and Washington State. <u>Details</u>.

Wed. (4/14)

- **10:00am Hearing: COVID-19** The Senate Homeland Security and Government Affairs Committee convenes a hearing titled, "Preparedness for COVID-19: The Initial Pandemic Response and Lessons Learned." <u>Details</u>.
- **10:00am Hearing: USDA** The House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies convenes a hearing titled, "The U.S. Department of Agriculture The Year Ahead." <u>Details</u>.
- **10:00am Hearing: FY 2022 NSF Budget** The House Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies convenes a hearing on the National Science Foundation's (NSF) FY 2022 budget request. <u>Details</u>.
- 10:30am Hearing: Substance Use Disorder The House Energy and Commerce Subcommittee on Health convenes a hearing titled, "An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America." <u>Details</u>.
- **11:00am Webinar: Telehealth Grants** The Department of Agriculture (USDA) convenes a webinar to discuss the Distance Learning and Telemedicine (DLT) program grants, which are due by June 4. (Note that a second webinar is planned on April 20). <u>Details</u>.
- **2:00pm Hearing: COVID-19** The Senate Appropriations Subcommittee on Homeland Security convenes a hearing to examine FEMA's response to COVID-19 and other challenges. <u>Details</u>.
- 2:30pm Hearing: COVID-19 The Senate Joint Economic Committee convenes a hearing titled, "Vaccinations and the Economic Recovery." <u>Details</u>.
- 2:30pm Hearing: COVID-19 The Senate Committee on Indian Affairs convenes an oversight hearing titled, "Examining the COVID-19 Response in Native Communities: Native Health Systems One Year Later." <u>Details</u>.

Thurs. (4/15)

- 9:30am Hearing: CMS and HHS Nominees The Senate Finance Committee convenes a hearing to consider the nominations of Andrea Joan Palm to be Deputy Secretary of Health and Human Services and Chiquita Brooks-LaSure to be Administrator of the Centers for Medicare and Medicaid Services. <u>Details</u>.
- 9:30am-2:30pm ONC Meeting: Health IT The Office of the National Coordinator for Health Information Technology (ONC) convenes a meeting of the Health IT Advisory Committee. <u>Details</u>.
- **10:00am Hearing: COVID-19** The House Select Subcommittee on the Coronavirus Crisis convenes a hearing titled, "Reaching the Light at the End of the Tunnel: A Science-Driven Approach to Swiftly and Safely Ending the Pandemic." <u>Details</u>.
- 10:00am Hearing: FY 2022 HHS Budget The House Appropriations Subcommittee on the Departments of Labor, Health and Human Services, Education, and Related Agencies convenes a hearing on the FY 2022 budget request for HHS. <u>Details</u>.
- **10:00am Hearing: FY 2022 VA Budget** The House Appropriations Subcommittee on Military Construction, Veteran Affairs, and Related Agencies convenes a hearing on the Department of Veterans' Affairs FY 2022 budget. <u>Details</u>.
- 10:00am-11:15am BPC Discussion: Housing The Bipartisan Policy Center (BPC) hosts a discussion titled, "Building a Bipartisan Housing Agenda This Congress." <u>Details</u>.

• 10:15am – Hearing: Behavioral and Mental Health – The House Education and Labor Subcommittee on Health, Employment, Labor, and Pensions Subcommittee convenes a hearing titled, "Meeting the Moment: Improving Access to Behavioral and Mental Health Care." <u>Details</u>.

Additional Multi-Day Events

- April 14-April 15 CDC Meeting: CLIAC CDC convenes a meeting of the Clinical Laboratory Improvement Advisory Committee to discuss COVID-19 testing. <u>Details</u>.
- April 14-April 15 HRSA Meeting: GME HRSA convenes a meeting of the Council on Graduate Medical Education (GME) to confirm the recommendations for their third and final Issue Brief focused on rural health and discuss the development of their final summary report. Details.

FEATURED WHG ANALYSIS

- Summary of Recent Federal Actions on Maternal Health & Gender Equity In the Policy Hub Insight Bank <u>here</u>.
- WHG Catalogue of COVID-19 Government Response March Edition In the Policy Hub Insight Bank <u>here</u>.
- **Prospects for Drug Pricing Reform Under a Biden-Harris Administration** Featured on The Commonwealth Fund's *To the Point* <u>here</u>.
- Support for States' COVID-19 Response Efforts in the American Rescue Plan Featured on The Commonwealth Fund's *To the Point* <u>here</u>.
- WHG Summary of Biden-Harris Executive Actions Related to Health Equity and Racial Justice In the Policy Hub Insight Bank <u>here</u>.

CONGRESSIONAL LOOKBACK

<u>Fri. (4/9)</u>

• MACPAC <u>convened</u> virtually for Day Two of its April 2021 public meeting and held sessions on behavioral health services, the skilled nursing facility value-based purchasing program, high-cost specialty drugs, and COVID-19 vaccine coverage. All WHG session summaries are available on Policy Hub <u>here</u>.

Thurs. (4/8)

• MACPAC <u>convened</u> virtually for Day One of its March 2021 public meeting and held sessions on behavioral health services, the skilled nursing facility value-based purchasing program, highcost specialty drugs, and COVID-19 vaccine coverage. All WHG session summaries are available on Policy Hub <u>here</u>.

REGULATORY LOOKBACK

Thurs. (4/8)

- **CMS** released its <u>proposed rule</u> for the fiscal year (FY) 2022 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) (<u>fact sheet</u>). Comments are due June 7. <u>Details</u>.
- **CMS** released its FY 2022 Hospice Wage Index <u>proposed rule</u> (<u>fact sheet</u>). Comments are due June 7. <u>Details</u>.

Wed. (4/7)

• **CMS** <u>released</u> the fiscal year (FY) 2022 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule (<u>press release</u>). Comments are due June 7. <u>Details</u>.

- **CMS** <u>released</u> its proposed rule for the fiscal year (FY) 2022 Inpatient Psychiatric Facility (IPF) Prospective Payment System (PPS) (<u>fact sheet</u>). Comments are due June 7. <u>Details</u>.
- **CMS** announced (<u>press release</u>; <u>fact sheet</u>) more than 528,000 new enrollees have signed up for health insurance plans since the Coronavirus-related Special Enrollment Period (SEP) opened on February 15. <u>Details</u>.
- **EBSA** <u>released</u> Frequently Asked Questions (FAQs) regarding implementation of COBRA premium assistance made available by the American Rescue Plan Act of 2021 (ARP) (<u>P.L. 117-</u><u>2</u>). <u>Details</u>.

Tues. (4/6)

• USDA <u>announced</u> that it is accepting applications for Distance Learning and Telemedicine (DLT) program grants to help provide educational and medical services in rural areas. Applications are due June 4. <u>Details</u>.

Mon. (4/5)

• The White House ONDCP <u>released</u> its plan on addressing drug policy priorities under the current Administration. <u>Details</u>.

COMMENT & APPLICATION DEADLINES

- April 12: CMS issued a Calendar Year (CY) 2022 <u>Request for Applications</u> (RFA) and released an <u>application</u> for Part D sponsors. <u>Details</u>.
- April 16: CMS issued an updated <u>CY 2022 PDM Model RFA</u>. <u>Details</u>.
- April 12: USPSTF <u>issued</u> a draft recommendation statement in favor of screening for prediabetes and type 2 diabetes in adults ages 35 to 70 years who are overweight or obese. . <u>Details</u>.
- April 12: FDA <u>announced</u> the reopening of the comment period on listing patent information in the Orange Book. <u>Details</u>.
- April 19: HRSA <u>announced</u> a maternal and child health-focused Notice of Funding Opportunity (NOFO) Sickle Cell Disease Newborn Screening Follow-up Program. <u>Details</u>.
- April 20: The HHS OMH <u>announced</u> a \$250 million to fund the Advancing Health Literacy to Enhance Equitable Community Responses to COVID-19 initiative. <u>Details</u>.
- April 24: The FDA <u>announced</u> a request for nominees to serve as voting or nonvoting consumer representatives on several agency advisory committees. <u>Details</u>.
- April 30: Practice application deadline for the <u>Primary Care First Model</u>. <u>Details</u>.
- **May 6:** The OCR <u>announced</u> a 45-day extension of the public comment period for a <u>proposed</u> <u>rule</u> that would modify HIPAA <u>privacy</u> standards for individually identifiable health information. <u>Details</u>.
- **May 11:** CMS <u>released</u> a notice of funding opportunity (NOFO) to accompany the ambulance payment component of the Emergency Triage, Treat, and Transport (ET3) Model that began January 1, 2021. <u>Details</u>.
- May 24: The FDA issued draft and revised draft product-specific guidances. Details.
- May 28: Payer application deadline for the <u>Primary Care First Model</u>. <u>Details</u>.
- June 4: USDA <u>announced</u> that it is accepting applications for Distance Learning and Telemedicine (DLT) program grants to help provide educational and medical services in rural areas. <u>Details</u>.
- June 7: CMS <u>released</u> its proposed rule for the fiscal year (FY) 2022 Inpatient Psychiatric Facility (IPF) Prospective Payment System (PPS) (<u>fact sheet</u>). <u>Details</u>.
- June 7: CMS <u>released</u> the fiscal year (FY) 2022 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule (<u>press release</u>). <u>Details</u>.

- June 7: CMS released its <u>proposed rule</u> for the fiscal year (FY) 2022 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) (<u>fact sheet</u>). <u>Details</u>.
- June 7: CMS released its FY 2022 Hospice Wage Index proposed rule (fact sheet). Details.
- June 11: CMS <u>issued</u> a notice of funding opportunity for its Minority Research Grant Program. <u>Details</u>.
- **September 17:** The CDC <u>announced</u> it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee. <u>Details</u>.

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