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

Wynne Health Group Weekly



FRAMING THE WEEK

<u>Infrastructure</u>

President Joe Biden is slated to lay out the first part of his \$3 trillion "Build Back Better" economic recovery plan, focusing on rebuilding the nation's infrastructure, on Wednesday (March 30). The second part of Biden's plan will focus on health care and child care reforms and will be released in the coming weeks, according to White House press secretary Jen Psaki. Democrats are expected to push for prescription drug pricing reforms included in the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3, 116th), such as requiring the Department of Health and Human Services (HHS) to negotiate prices for selected drugs, to fund the infrastructure package.

Biden's infrastructure plan may resemble the \$1.5 trillion Moving Forward Act (H.R. 2, 116th) passed by House Democrats last Congress. The package would provide \$30 billion for **health care infrastructure**, including \$10 billion set aside for the construction and modernization of hospitals and medical facilities. In addition, the package would provide over \$100 billion to fund **broadband-related programs**. Biden's plan may also include investments in **public health infrastructure** at the federal, state, and local levels, a new priority included in the \$312 billion Leading Infrastructure for Tomorrow's (LIFT) America Act (H.R. 1848), introduced by all House Energy and Commerce Democrats earlier this month. On health care and broadband, the LIFT America Act largely mirrors provisions in the Moving Forward Act.

President's Budget

On Thursday (April 1), Biden is expected to unveil his **fiscal year (FY) 2022 "skinny" budget**, which will contain topline discretionary spending priorities, followed by the full budget in early May. Notably, under current law, discretionary spending beginning FY 2022 is not subject to statutory spending caps. The President's budget is likely to shed light on Biden's fiscal policy and spending priorities for his presidency.

Regulatory Update

The final rule for the **2022 Notice of Benefit and Payment Parameters** remains under review at the Office of Management and Budget (OMB) and its release is expected imminently. The rule would serve to finalize the set of provisions left unfinalized by the Trump Administration in its partial final rule earlier this year, wherein a subset of the most controversial provisions was finalized. Provisions that were not finalized then – and which could be finalized in this iteration – include policies on risk adjustment, medical loss ratio, and pharmacy benefit manager transparency.

MedPAC

Later this week (April 1 and 2), Medicare Payment Advisory Commission (MedPAC) will convene to **vote on draft recommendations** for its June Report to Congress regarding the following:

- Replacing the value-based purchasing program for skilled nursing facilities with an alternative value incentive program;
- <u>Streamlining</u> alternative payment models at the Centers for Medicare and Medicaid Services (CMS);
- Rebalancing Medicare Advantage program payments;
- Revising Medicare's indirect medical education payments;
- Changing Medicare vaccine coverage and payment; and
- <u>Updating</u> requirements for separately payable drugs.

MedPAC will also discuss the <u>role of private equity</u> and Medicare for a report requested by House Ways and Means Committee Chair Richard Neal (D-MA). Additionally, MedPAC will examine CMS' recent changes to <u>Medicare's clinical laboratory fee schedule payment rates</u> for a congressionally-mandated report.

THIS WEEK IN HEALTH POLICY

Thurs. (4/1)

• 11:15am-4:30pm – MedPAC: Day 1 – The Medicare Payment Advisory Committee (MedPAC) convenes a virtual public meeting to discuss Medicare payment and policy issues. Details.

Fri. (4/2)

• 9:30am-12:30pm – MedPAC: Day 2 – MedPAC convenes a virtual public meeting to discuss Medicare payment and policy issues. Details.

FEATURED WHG ANALYSIS

- *New* Prospects for Drug Pricing Reform Under a Biden-Harris Administration Featured on The Commonwealth Fund's *To the Point* here.
- *New* Support for States' COVID-19 Response Efforts in the American Rescue Plan Featured on The Commonwealth Fund's *To the Point* here.
- WHG Summary of Biden-Harris Executive Actions Related to Health Equity and Racial Justice In the Policy Hub Insight Bank here.
- WHG Catalogue of COVID-19 Government Response February Edition In the Policy Hub Insight Bank here.
- WHG Issue Brief: No Surprises Act Implementation In the Policy Hub Insight Bank here.
- WHG: Implementation Timeline of the Omnibus Package In the Policy Hub Insight Bank here.
- WHG Legislative and Regulatory Outlook for 2021 In the Policy Hub Insight Bank here.
- WHG: Regulatory Freeze: Key Policies and Dates In the Policy Hub Insight Bank here.

CONGRESSIONAL LOOKBACK

Tues. (3/23)

- The Senate HELP Subcommittee on Primary Health and Retirement Security <u>convened</u> a hearing to explore the drivers of high drug costs in the U.S. and continue sketching possible solutions. Details
- The House E&C Subcommittee on Health convened a <u>hearing</u>, on the 11th anniversary of the Affordable Care Act (ACA), to discuss legislation to build on the ACA. <u>Details</u>.

REGULATORY LOOKBACK

Thurs. (3/25)

- **ASPE** <u>released</u> several issue briefs that discuss health disparities. <u>Details.</u>
- The White House <u>announced</u> it is distributing \$10 billion to expand access to COVID-19 vaccines, with a focus on improving vaccine confidence in high-risk communities. <u>Details</u>.

Wed. (3/24)

- **CMS** <u>released</u> an updated data snapshot detailing the impact of COVID-19 on Medicare beneficiaries. Details.
- The FDA <u>announced</u> a request for nominees to serve as voting or nonvoting consumer representatives on several agency advisory committees. Nominations are due April 24. <u>Details</u>.
- **The FDA** <u>issued</u> draft and revised draft product-specific guidances. Comments are due May 24. <u>Details</u>.

Tues. (3/23)

- **CMS** <u>announced</u> it is extending the ongoing special enrollment period (SEP) for an additional three months (i.e., until August 15, 2021). <u>Details</u>.
- **The FDA** <u>convened</u> virtual workshop on the Roadmap to 2030 for New Drug Evaluation in Older Adults. Details.
- **CMS** <u>issued</u> a notice of funding opportunity for its Minority Research Grant Program. Applications are due June 11. <u>Details</u>.
- The CMS From Coverage to Care (C2C) program released a set of resources to aid providers and patients as telehealth systems continue to be implemented in response to the COVID-19 pandemic. Details.

COMMENT & APPLICATION DEADLINES

- **April 1:** The AHRQ <u>announced</u> it is seeking scientific information from stakeholders to inform its work on improving rural health through telehealth-guided, provider-to-provider communication. Details.
- **April 9:** The NIH <u>issued</u> a request for information (RFI) on how the agency can advance research to eliminate or lessen health disparities and inequities. <u>Details</u>.
- **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 CY 2022 PDM Model RFA. Details.
- **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. . Details.
- **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. Details.
- 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 11:** CMS <u>issued</u> a notice of funding opportunity for its Minority Research Grant Program. Details.
- **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>.

WHG Contacts for Inquiries

Alyssa Llamas: alyssa@wynnehealth.com; (562) 207-8807 Billy Wynne: billy@wynnehealth.com; (202) 309-0796 Erin Slifer: erin@wynnehealth.com; (410) 984-4552

