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Health Policy Update – October 19, 2021

Negotiations on Infrastructure and Reconciliation Bills Continue, Bill Authorizing ARPA-H Introduced in the House

Earlier this month, President Biden told House Democrats that he would like the reconciliation and infrastructure packages to be voted on together, a key concession to progressives but a disappointment for centrist Democrats. The new self-imposed deadline to reach an agreement on the two packages is the end of October.

As negotiators on Capitol Hill work to find agreement on the details of the reconciliation package, Senator Joe Manchin (D-WV) said he would not support a bill costing more than $1.5 trillion over 10 years—far less than the $3.5 trillion sought by the White House and House progressives. On October 6, President Biden conceded that the reconciliation package would likely shrink to be within the $1.9 trillion to $2.3 trillion range. With lawmakers and lobbyists scrambling to ensure their priorities are included, there is anxiety across Capitol Hill about what programs will be funded, how much will they receive, and for how long. On October 11, House Speaker Nancy Pelosi (D-CA) said lawmakers overwhelmingly told her that they would prefer robust funding for fewer priorities, but one day later, she reversed herself and said that the reconciliation bill will likely include many of the policies preferred by Democrats but funded for a shorter period of time.

The politics of reconciliation also cast doubt on Democrats' drug pricing proposals. On October 13, Speaker Pelosi said she doesn't expect H.R. 3 – Democrats' signature legislation that would allow Medicare to negotiate prices for hundreds of drugs – to be included in the final reconciliation package in its current form. To win support from House and Senate moderates, the drug pricing proposals from H.R. 3 will likely be reduced in scope. Negotiation changes being considered include shifting from an international to a domestic price benchmark, limiting negotiations to Medicare (not extending to the commercial market), reducing the number of drugs subject to negotiation, and exempting small pharmaceutical companies.

It has also been reported that language authorizing the creation of and funding for President Biden's proposed Advanced Research Projects Agency for Health (ARPA-H) was stripped from the reconciliation package. Supporters of the proposed agency said the funding was stripped due to technical reconciliation rules in the Senate. Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) quickly announced that their Cures 2.0 bill, which is expected to be introduced in the coming weeks, would include the necessary authorizing language to establish the agency. Rep. Anna Eshoo (D-CA), chair of the House Energy and Commerce Health Subcommittee, also filed legislation to authorize ARPA-H in a standalone bill, which she introduced on October 15.

To read more about Rep. Eshoo's bill to authorize ARPA-H, CLICK HERE.

President Biden Considering Robert Califf as FDA Administrator as Francis Collins Steps Down as NIH Chief

On October 14, The Washington Post and POLITCO reported that President Joe Biden is likely to nominate former Food and Drug Administration (FDA) Commissioner Robert Califf to once again lead the agency. While inside sources say the decision is not final, Califf is viewed as a leading candidate for the post. Since President Biden came to office in January, the FDA has been led by Acting Commissioner Janet Woodcock, but President Biden has been criticized for not yet nominating a permanent head to the agency, which plays a critical role in the nation's pandemic response. Under federal law, President Biden has until mid-November to make a leadership change as Woodcock's acting status is time-limited.

Califf previously served as FDA Commissioner under President Obama when he was confirmed on a 89-4 vote in February 2016. He stepped down in January 2017 upon the inauguration of President Trump and returned to cardiology at the Duke Clinical Research Institute. He also works as Head of Clinical Policy & Strategy for Verily and Google Health.

In related news, the National Institutes of Health (NIH) Director Francis Collins announced that he would step down from the agency by the end of 2021 after leading it for 12 years. As the longest-serving NIH Director in American history, Collins played a major role in shaping the agency and helped increase the NIH's budget by 38%, from $30 billion in 2009 to $41.3 billion in 2021. He played a major role in helping America address the COVID-19 pandemic and also presided over ambitious initiatives to improve treatment of chronic diseases, including cancer. While he will no longer head the NIH, he will continue to lead his research laboratory at the National Human Genome Research Institute. President Biden has yet to name a replacement for Collins.

To read President Biden's statement on Collins stepping down, CLICK HERE.

Bipartisan Group of Lawmakers Urge Action to Avert Looming "Medicare Cliff"

On October 14, 245 Members of Congress submitted a letter to House Leadership calling on Speaker Nancy Pelosi (D-CA) and Minority Leader Kevin McCarthy (R-CA) to work quickly to address the impending payment cuts facing healthcare providers. Spearheaded by Reps. Ami Bera (D-CA) and Larry Bucshon (R-IN), the bipartisan letter urged Congress to take up long-term payment reform and avert Medicare cuts to physicians that are scheduled to go into effect on January 1, 2022.

Specifically, the lawmakers highlighted the need to extend the temporary 3.75% conversion factor increase that Congress passed in last year's Consolidated Appropriations Act. The one-year increase, sought to mitigate the effects of a shift in E/M coding and the COVID-19 pandemic, is set to expire at the end of the calendar year.

On October 6, the American Hospital Association (AHA) submitted a letter of its own to both House and Senate leadership urging Congress to prevent scheduled Medicare cuts from going into effect

in 2022. Its letter urged Congress to extend the moratorium on sequester cuts and prevent a Statutory Pay-As-You-Go Act (S-PAYGO) sequester from taking effect. Without intervention, Medicare sequestration relief will expire at the end of the calendar year, and a second S-PAYGO sequestration of 4% may be triggered.

To read the letter spearheaded by Reps. Bera and Bucshon, CLICK HERE.

To read the text of the AHA's letter, CLICK HERE.

CMMI Director Fowler Discusses Future of Value-Based Care Models

At a press-only briefing hosted by the Alliance for Health Policy, Center for Medicare and Medicaid Innovation (CMMI) Director Liz Fowler made several remarks concerning the future of value-based care - reiterating that the agency is committed to developing fewer and more streamlined, but also more mandatory, payment models in the coming years.

"In my mind, I think we should look down the mandatory model line … but we need to move away from having a model for every episode and specialty group," she told reporters.

She also complemented the agency's plans to move forward with the Radiation Oncology Model, which has been strongly criticized by oncology stakeholders, including The Network.

"On the [Radiation Oncology] model, I know there's still a lot of concerns. I feel like in some ways we're hearing from those who feel like they have - they stand to lose, and I appreciate and understand those concerns….in some cases, they may see an increase, but that's not who we're necessarily hearing from. But I also understand - and I have done many meetings on that issue and I understand where they're coming from and their concerns - but I also think that the model is a solid one and hopefully will lead to positive results for patients," Fowler said.

Fowler also noted in her remarks that CMMI won't be designing models to control drug costs until after Congress decides what it's going to do on drug pricing. Likewise, she said her agency can't design demonstration products for Aduhelm - the Alzheimer's treatment whose approval by the FDA in June has attracted significant controversy - until after CMS issues a national coverage determination for the drug.

Medicare Advisors Consider Options for Addressing High Drug Costs

On October 7, the Medicare Payment Advisory Commission (MedPAC) discussed potential drug pricing control policies, including changes within the existing Medicare program, such as modifying the ASP-based payment formula, and ways to better align clinical value for coverage and/or payment. While the discussions mostly focused on Part B, commissioners also noted that some policies might work in Part D as well.

The commissioners discussed value-based pricing for first-in-class drugs, which would set payment based on cost-effectiveness analyses and applying coverage with evidence development (CED).

They emphasized that they would only be interested in value-based pricing for drugs without any competition as it could lead to price increases otherwise.

The discussions covered varied approaches to reference pricing, including domestic and international reference pricing, which would set a maximum payment rate for a group of drugs with similar health effects. MedPAC is also examining the reimbursement formula for physicians. Its options for modifying the ASP +6% formula include reducing the percentage add-on, converting the add-on to a fixed fee, and placing a dollar cap on the percentage add-on.

MedPAC noted that Medicare spending in Part B was $39 billion in 2019 and is rising roughly 10% each year, with drug prices serving as the largest driver of spending growth. While unclear if the reconciliation bill will include any of the referenced drug pricing reform options, commissioners are expected to return to the issue at its spring meeting.

To view the MedPAC brief and presentation, CLICK HERE.

With COVID-19 Endangering Cancer Patients, Lawmakers Call for More Early Cancer Detection

A group of bipartisan lawmakers recently called for more support of emerging research for early cancer detection. While there have been advances in treatments, the lawmakers seek to remove barriers for patients trying to receive early diagnostic testing necessary to identify cancer.

Sen. Roy Blunt (R-MO), a cancer survivor himself, discussed a bill he introduced with Sen. Jeanne Shaheen (D-NH) that would eliminate out-of-pocket expenses for breast cancer diagnostic tests. Rep. Bonnie Watson Coleman (D-NJ), also a cancer survivor said Congress must ensure access to healthcare and create a healthcare system that will enable more patients to receive early cancer monitoring.

This comes at a time when doctors say people in lower-income communities, particularly people of color, are showing up with advanced-stage cancers due to diagnosis and treatment delays during the pandemic. Last year alone, millions of cancer screenings and diagnostic tests were canceled, and surgeries were delayed. Researchers fear this will lead to increased health care disparities and increased cancer deaths in the coming years.

To hear Sen. Blunt's comments on early cancer detection, CLICK HERE.

To read more about the Blunt-Shaheen bill, CLICK HERE.